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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.
The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 536

Grade and Pay Retention

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management is adopting an interim rule as a final rule to provide for entitlement to pay retention when a Federal prevailing rate (wage) schedule is reduced as the result of the findings of a wage survey. This change addresses certain anomalies in the statutory wage and survey process for Federal wage employee by providing that wage employees will not have their pay reduced solely because of changes in the local private sector economy over which they have no control.

EFFECTIVE DATE: This final rule becomes effective on January 11, 1990.

FOR FURTHER INFORMATION CONTACT: Jan B. Karicher (202) 632-5056.

SUPPLEMENTARY INFORMATION: On December 8, 1988, the Office of Personnel Management (OPM) published an interim rule (53 FR 49545) to provide pay retention for prevailing rate (wage) employees when a wage schedule is reduced as the result of a wage survey, providing that interested persons could file comments through February 6, 1989. One management association commented favorably on OPM's interim regulations, stating that the interim rule "represents an appropriate measure for reducing the impact of survey anomalies."

E.O. 12291, Federal Regulation

I have determined that this is not a major rule as defined under section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because it will affect only Federal employees and agencies.

List of Subjects in 5 CFR Part 536

Administrative practice and procedure, Government employees, Wages.

U.S. Office of Personnel Management.
Constance B. Newman,
Director.

PART 536—GRADE AND PAY RETENTION

Accordingly, OPM is adopting the interim rule amending 5 CFR part 536 published in the **Federal Register** on December 8, 1988 (53 FR 49545), as a final rule without change.

[FR Doc. 89-28973 Filed 12-11-89; 8:45 am]
BILING CODE 6325-01-M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 89-207]

Citrus Canker Regulations; Change in Status of Pinellas County, Florida

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are removing the remainder of Pinellas County, Florida, from the list of areas under special restriction because of citrus canker caused by the Asiatic strains. This action is warranted because no infestation caused by an Asiatic strain of canker has been found anywhere in Pinellas County since the last infested plant in the county was destroyed on July 15, 1987. Further, Pinellas County is separated by a large body of water from the only neighboring county where there has been an infestation within the past 2 years. This action relieves some restrictions on the interstate movement of citrus fruit and calamondin and kumquat plants from the portion of Pinellas County previously under special restriction because of citrus canker caused by the Asiatic strains.

EFFECTIVE DATE: December 6, 1989.

FOR FURTHER INFORMATION CONTACT: Eddie W. Elder, Chief Operations Officer, Domestic and Emergency Operations, PPQ, APHIS, USDA, Room 661, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 436-6365.

SUPPLEMENTARY INFORMATION:

Background

Citrus canker is a plant disease caused by strains of the bacterium *Xanthomonas campestris* pv. *citri* (Hasse) Dye. The disease is known to affect plants and plant parts, including fruit, of citrus and citrus relatives (Family Rutaceae). It can cause defoliation and other serious damage to the leaves and twigs of susceptible plants. It may also make the fruit of infected plants unmarketable by causing lesions on the fruit. Infected fruit may also drop from trees before reaching maturity. Aggressive strains of *Xanthomonas campestris* pv. *citri* can infect susceptible plants rapidly and lead to extensive economic losses in commercial citrus-producing areas.

In the United States, Florida is the only State where citrus canker exists. Regulations to prevent the interstate spread of citrus canker from Florida are contained in 7 CFR 301.75 through 301.75-16, "Subpart—Citrus Canker." These regulations recognize two types of citrus canker: one type caused by the Florida nursery strains, and a more severe type caused by Asiatic strains of *Xanthomonas campestris* pv. *citri*. Citrus fruit and plants from areas of Florida affected by the Asiatic strains are subject to more stringent restrictions on interstate movement than citrus fruit and plants from other areas of the State.

In a document published in the **Federal Register** on October 26, 1989 (54 FR 43585-43586, Docket Number 89-181), we proposed to relieve some restrictions on the interstate movement of citrus fruit and calamondin and kumquat plants from areas of Pinellas County, Florida, under special restriction because of the Asiatic strains.

Comments on the proposed rule were required to be received on or before November 13, 1989. We did not receive any comments. Based on the rationale set forth in the proposal and in this document, we are adopting the

provisions of the proposal as a final rule without change.

As a result of this action, under conditions specified in the regulations, regulated fruit from groves of 10 or more trees is now eligible for interstate movement to commercial citrus-producing areas of the United States, and own-root-only calamondin and kumquat plants are eligible for interstate movement to all areas of the United States except commercial citrus-producing areas.

Effective Date

This is a substantive rule which relieves restrictions, and, pursuant to the provisions of 5 U.S.C. 553, may be made effective less than 30 days after publication in the **Federal Register**. Immediate implementation of this rule is necessary to provide relief to those persons who are adversely affected by restrictions we no longer find warranted. Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this rule should be effective upon signature.

Executive Order 12291 and the Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

For this action, the Office of Management and Budget has waived its review process required by Executive Order 12291.

As a result of this rule, no portion of Pinellas County, Florida, remains under special restriction because of citrus canker caused by the Asiatic strains. The entire State of Florida, however, remains a quarantined area for citrus canker.

We anticipate that adoption of this rule will have the most impact on private individuals who want to send fruit from their dooryard plantings (groves of fewer than 10 trees) to relatives and friends. Before publication of this document, the regulations allowed individuals to ship the fruit with a limited permit; however few have been doing so because of the cost and inconvenience of having the fruit treated.

The changes pertaining to groves of 10 or more regulated trees will affect two owners of commercial citrus groves, one of three acres and the other of nine acres, which are harvested for fresh fruit. We estimate that the owners could save an estimated $20 per acre per year by no longer having to disinfect personnel, vehicles, and equipment. It does not appear that any of the other changes will result in substantial savings or gain for the owners. The cost of chemically treating fruit appears to be a very small part of the overall costs associated with packing house operations, and there is little difference in price between fruit sold for interstate movement to commercial citrus-producing areas and fruit sold for interstate movement to other areas or for intrastate movement.

We do not know of any nurseries in Pinellas County that raise calamondin or kumquat plants for interstate movement.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S. 3501 *et seq.*).

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

List of Subjects in 7 CFR Part 301

Agricultural commodities, Citrus canker, Plants (Agriculture), Plant diseases, Plant pests, Quarantine, Transportation.

PART 301—DOMESTIC QUARANTINE NOTICES

Accordingly, 7 CFR part 301 is amended as follows:

1. The authority citation for part 301 continues to read as follows:

Authority: 7 U.S.C. 150bb, 150dd, 150ee, 150ff, 161, 162, and 164–167; 7 CFR 2.17, 2.51, and 371.2(c).

§ 301.75–7 [Amended]

2. Section 301.75–7 is amended by removing paragraph (b)(3)(ii), and by redesignating paragraphs (b)(3)(iii) and (b)(3)(iv) as (b)(3)(ii) and (b)(3)(iii), respectively.

Done in Washington, DC, this 6th day of December, 1989.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 89–28885 Filed 12–11–89; 8:45 am]

BILLING CODE 3410–34–M

FEDERAL RESERVE SYSTEM

12 CFR Part 204

[Regulation D; Docket No. R–0678]

Reserve Requirements of Depository Institutions; Reserve Requirement Ratios

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board is amending 12 CFR part 204 (Regulation D—Reserve Requirements of Depository Institutions) to decrease the amount of transaction accounts subject to a reserve requirement ratio of three percent, as required by section 19(b)(2)(C) of the Federal Reserve Act (12 U.S.C. 461(b)(2)(C)), from $41.5 million to $40.4 million of net transaction accounts (known as the low reserve tranche adjustment). The Board has left at $3.4 million the amount of reservable liabilities of each depository institution that is subject to a reserve requirement of zero percent (known as the reservable liabilities exemption adjustment), as required by section 19(b)(11)(B) of the Federal Reserve Act (12 U.S.C. 461(b)(11)(B)). The Board has also increased from $42.1 million to $43.4 million the deposit cutoff level that is used in conjunction with the reservable liabilities exemption amount to determine the frequency of deposit reporting.

DATES: *Effective date:* This final rule is effective December 12, 1989. *With compliance as follows:* For depository institutions that report weekly, the low reserve tranche adjustment will be effective starting with the reserve computation period beginning Tuesday, December 26, 1989, and with the corresponding reserve maintenance periods beginning Thursday, December 28, 1989, for net transaction accounts, and Thursday, January 25, 1990, for other reservable liabilities. For

institutions that report quarterly, the low reserve tranche adjustment will be effective with the computation period beginning Tuesday, December 19, 1989, and with the reserve maintenance period beginning Thursday, January 18, 1990. For all depository institutions, the increase in the deposit cutoff level will be used to screen institutions in the second quarter of 1990 to determine reporting frequency beginning September 1990.

FOR FURTHER INFORMATION CONTACT: Patrick J. McDivitt, Attorney (202/452-3818), Legal Division, or June O'Brien, Economist (202/452-3790), Division of Monetary Affairs; for users of the Telecommunications Device for the Deaf (TDD), Earnestine Hill or Dorothea Thompson (202/452-3544); Board of Governors of the Federal Reserve System, Washington, DC 20551.

SUPPLEMENTARY INFORMATION: Section 19(b)(2) of the Federal Reserve Act requires each depository institution to maintain with the Federal Reserve System reserves against its transaction accounts and nonpersonal time deposits, as prescribed by Board regulations. The initial reserve requirements imposed under section 19(b)(2) were set at three percent for total transaction accounts of $25 million or less and at 12 percent on total transaction accounts above $25 million for each depository institution. Section 19(b)(2) further provides that, before December 31 of each year, the Board shall issue a regulation adjusting for the next calendar year the total dollar amount of the transaction account tranche against which reserves must be maintained at a ratio of three percent. The adjustment in the tranche is to be 80 percent of the percentage change in total transaction accounts for all depository institutions determined as of June 30 of each year, and the statute requires an adjustment resulting from decreases as well as increases in total transaction accounts.

Currently, the low reserve tranche on transaction accounts is $41.5 million. The decline in the total of net transaction accounts of all depository institutions from June 30, 1988, to June 30, 1989, was 3.4 percent (from $604.3 billion to $584.0 billion). In accordance with section 19(b)(2), the Board is amending Regulation D to decrease the low reserve tranche for transaction accounts for 1990 by $1.1 million to $40.4 million.

Section 19(b)(11)(A) of the Federal Reserve Act provides that $2 million of reservable liabilities [1] of each depository institution shall be subject to a zero percent reserve requirement. Section 19(b)(11)(A) permits each depository institution, in accordance with the rules and regulations of the Board, to designate the reservable liabilities to which this reserve requirement exemption is to apply. However, if transaction accounts are designated, only those that would otherwise be subject to a three percent reserve requirement (*i.e.*, transaction accounts within the low reserve requirement tranche) may be so designated.

Section 19(b)(11)(B) of the Federal Reserve Act provides that, before December 31 of each year, the Board shall issue a regulation adjusting for the next calendar year the dollar amount of reservable liabilities exempt from reserve requirements. Unlike the adjustment for transaction accounts, which adjustment can result in a decrease as well as an increase, the change in the exemption amount is to be made only if the total reservable liabilities held at all depository institutions increases from one year to the next. Total reservable liabilities of all depository institutions from June 30, 1988, to June 30, 1989, declined by 0.5 percent (from $1,263.5 billion to $1,256.7 billion). Under section 19(b)(11), the Board's Regulation D will not be changed. Consequently, the reserve requirement exemption for 1990 will remain at the 1989 level of $3.4 million.

The effect of the application section 19(b) of the Federal Reserve Act is to reduce the low reserve tranche to $40.4 million and to continue to apply a zero percent reserve requirement on the first $3.4 million of transaction accounts and to apply a three percent reserve requirement on the remainder of the low reserve tranche. Any portion of this zero percent reserve requirement tranche remaining after the tranche is applied to transaction accounts will be applied to nonpersonal time deposits with maturities of less than 1½ years or to Eurocurrency liabilities, both of which are subject to a reserve requirement ratio of three percent.

The tranche adjustment for weekly reporting institutions will be effective starting with the reserve computation period beginning Tuesday, December 26, 1989, and with the corresponding reserve maintenance periods beginning Thursday, December 28, 1989, for net transaction accounts, and Thursday, January 25, 1990, for other reservable liabilities. For institutions that report quarterly, the tranche adjustment will be effective with the computation period beginning Tuesday, December 19, 1989, and with the reserve maintenance period beginning Thursday, January 18, 1990. In addition, all entities currently submitting Form FR 2900 will continue to submit reports to the Federal Reserve under current reporting procedures.

In order to reduce the reporting burden for small institutions, the Board established a deposit reporting cutoff level to determine deposit reporting frequency. Institutions are screened during the second quarter of each year to determine reporting frequency beginning the following September. In March of 1985, the Board decided to index this reporting cutoff level in an amount equal to 80 percent of the annual rate of increase of total deposits.[2] In July of 1988, in conjunction with approval of the extension of the deposit reporting system, the Board increased the cutoff to $40 million, effective in September 1988, from the $30 million cutoff that would have become effective in September 1988.

From June 30, 1988, to June 30, 1989, total deposits grew 4.0 percent, from $3,513.6 billion to $3,654.6 billion. This results in an increase of $1.3 million in the deposit cutoff level that determines the frequency of reporting from the current $42.1 million to $43.4 million. Based on the indexation of the reserve requirement exemption, the cutoff level for total deposits above which reports of deposits must be filed will remain at $3.4 million. Institutions with total deposits below $3.4 million are excused from reporting if their deposits can be estimated from other sources. The $43.4 million cutoff level for weekly versus quarterly FR 2900 reporting and for quarterly FR 2910q versus annual FR 2910a reporting, and the $3.4 million level threshold for reporting will be used in the second quarter 1990 deposits report screening process, and the adjustments will be made when the new deposit reporting panels are implemented in September 1990.

All U.S. branches and agencies of foreign banks and all Edge and Agreement Corporations, regardless of size, and all other institutions with reservable liabilities in excess of the exemption level amount prescribed by section 19(b)(11) of the Federal Reserve Act (known as "nonexempt institutions") and with total deposits at

[1] Reservable liabilities include transaction accounts, nonpersonal time deposits, and Eurocurrency liabilities as defined in section 19(b)(5) of the Federal Reserve Act.

[2] In November of 1985, the Board amended the definition of "total deposits" as used in determining the cutoff level to include not only gross transaction deposits, savings accounts, and time deposits but also reservable obligations of affiliates, ineligible acceptance liabilities, and net Eurocurrency liabilities.

least equal to the deposit cutoff level are required to file weekly the Report of Transaction Accounts, Other Deposits and Vault Cash (FR 2900). Depository institutions that have reservable liabilities in excess of the exemption level, but have total deposits less than the deposit cutoff level, may file the FR 2900 quarterly for the twelve month period starting each September. Institutions that obtain funds from non-U.S. sources or that have foreign branches or international banking facilities are required to file the Report of Certain Eurocurrency Transactions (FR 2950/2951) on the same frequency as they file the FR 2900. The deposit cutoff is also used to determine whether an institution with reservable liabilities at or below the exemption level (known as an "exempt institution") must file one of two reduced deposits reports—the Quarterly Report of Selected Deposits, Vault Cash, and Reservable Liabilities (FR 2910q) or the Annual Report of Total Deposits and Reservable Liabilities (FR 2910a). Exempt institutions (that is, institutions with total deposits less than the exemption amount) are not required to file a deposits report if their deposits can be estimated from other sources.

Finally, the Board may require a depository institution to report on a weekly basis, regardless of the cutoff level, if the institution manipulates its total deposits and other reservable liabilities in order to qualify for quarterly reporting. Similarly, any depository institution that reports quarterly may be required to report weekly and to maintain appropriate reserve balances with its Reserve Bank if, during its computation period, it understates its usual reservable liabilities or it overstates the deductions allowed in computing required reserve balances.

Notice and public participation. The provisions of 5 U.S.C. 553(b) relating to notice and public participation have not been followed in connection with the adoption of these amendments because the amendments involve adjustments prescribed by statute and by an interpretative statement reaffirming the Board's policy concerning reporting practices. The amendments also reduce regulatory burdens on depository institutions. Accordingly, the Board finds that notice and public participation is unnecessary and contrary to the public interest.

Regulatory Flexibility Act analysis. Pursuant to section 605(b) of the Regulatory Flexibility Act (Pub. L. No. 96-354, 5 U.S.C. 601 *et seq.*), the Board certifies that the proposed amendments will not have a significant economic impact on a substantial number of small entities. The proposed amendments reduce certain regulatory burdens for all depository institutions, reduce certain burdens for small depository institutions, and have no particular effect on other small entities.

List of Subjects in 12 CFR Part 204

Banks, banking; Currency; Federal Reserve System; Penalties and Reporting and recordkeeping requirements.

Pursuant to the Board's authority under section 19 of the Federal Reserve Act, 12 U.S.C. 461 *et seq.*, the Board is amending 12 CFR part 204 as follows:

PART 204—RESERVE REQUIREMENTS OF DEPOSITORY INSTITUTIONS

1. The authority citation for 12 CFR part 204 continues to read as follows:

Authority: Sections 11(a), 11(c), 19, 25, 25(a) of the Federal Reserve Act (12 U.S.C. 248(a), 248(c), 371a, 371b, 461, 601, 611); section 7 of the International Banking Act of 1978 (12 U.S.C. 3105); and section 411 of the Garn St-Germain Depository Institutions Act of 1982 (12 U.S.C. 461).

2. In § 204.9 paragraph (a)(1) is revised to read as follows:

§ 204.9 Reserve requirement ratios.

(a)(1) *Reserve percentages.* The following reserve ratios are prescribed for all depository institutions, Edge and Agreement Corporations, and United States branches and agencies of foreign banks:

Category	Reserve requirement
Net transaction accounts [1]	
$0 to $40.4 million	3 percent of amount.
Over $40.4 million	$1,212,000 plus 12 percent of amount over $40.4 million.
Nonpersonal time deposits by original maturity (or notice period):	
Less that 1½ years.	3 percent.
1½ years or more	0 percent
Eurocurrency liabilities	3 percent.

[1] Dollar amounts do not reflect the adjustment to be made by the next paragraph.

* * * * *

By order of the Board of Governors of the Federal Reserve System, December 6, 1989.

William W. Wiles,

Secretary of the Board.

[FR Doc. 89-28944 Filed 12-11-89; 8:45 am]

BILLING CODE 6210-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 337

RIN 3064-AB00

Unsafe and Unsound Banking Practices

AGENCY: Federal Deposit Insurance Corporation ("FDIC").

ACTION: Interim rule and request for comments.

SUMMARY: Section 224 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 ("FIRREA") added a new section 29 to the Federal Deposit Insurance Act ("FDIA"). This new section prohibits the acceptance or renewal of brokered deposits by any undercapitalized insured depository institution (bank or thrift) after December 7, 1989 except on specific application to and waiver of the prohibition by the FDIC. The interim rule, new § 337.6 of FDIC regulations, provides guidance and further detail on when an institution is considered undercapitalized, when certain deposits are considered "brokered" for purposes of the prohibition, and the circumstances under which a waiver from the prohibition may be granted. The FDIC is soliciting comment on this interim rule with a view towards possible revision or modification at a later date. The interim rule will "sunset" or terminate automatically in six months unless modified or replaced by a final rule prior to that time.

EFFECTIVE DATE: The interim rule is effective December 12, 1989. Comments must be submitted by February 12, 1990. The interim rule will remain in effect for a period of six months following its publication in the **Federal Register** or until expressly rescinded, amended, modified or replaced by the FDIC following the public comment period, whichever occurs first.

ADDRESSS: Send comments to: Hoyle L. Robinson, Executive Secretary, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429. Comments may be hand delivered to Room 6097 on business days between 8:30 a.m. and 5:00 p.m. Comments may also be inspected in Room 6097 between 8:30 a.m. and 5:00 p.m. on business days.

FOR FURTHER INFORMATION CONTACT: William G. Hrindac, Examination Specialist, Division of Supervision, (202) 898-6892, or Valerie Best, Senior Attorney, Legal Division, (202) 898-3812, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act. The collection of information contained in this notice of rulemaking, which is entitled "Application for Waiver of Prohibition on Acceptance of Brokered Deposits by Undercapitalized Insured Depository Institutions," has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). Comments on the collection of information should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, Attention: Desk Officer for the FDIC, with copies to the Assistant Executive Secretary (Administration), Room 6096, Federal Deposit Insurance Corporation, Washington, DC 20429.

The information will be collected from undercapitalized insured depository institutions applying for a waiver from the prohibition on the acceptance or renewal of brokered deposits contained in section 29 of the Federal Deposit Insurance Act (12 U.S.C. 1831f).

The estimated annual reporting burden for the collection of information in this regulation is summarized as follows:

Number of Respondents: 370.

Number of Responses Per Respondent: 1.

Total Annual Responses: 370.

Hours per Response: 6.

Total Annual Burden Hours: 2220.

Regulatory Flexibility Act. The FDIC's Board of Directors hereby certifies that the interim rule will not have a significant economic impact on a substantial number of small entities because it largely tracks and clarifies strictures previously established by statute and affords a means by which undercapitalized insured depository institutions may avoid the application of those strictures by applying to the FDIC for a waiver. Moreover, it is anticipated that relatively few small entities will be impacted by the regulation since most insured depository institutions are adequately capitalized or, if undercapitalized, do not utilize brokered deposits. Consequently, the provisions of the Regulatory Flexibility Act relating to an initial and final regulatory flexibility analysis (5 U.S.C. 603 & 604) are not applicable.

Reasons for Interim Rule. The provisions of this rule are designed to give insured depository institutions guidance as to how the FDIC intends to interpret and apply the new statutory prohibition on acceptance or renewal of bokered deposits, how the FDIC will determine whether an institution is "troubled" (undercapitalized) and therefore subject to the prohibition, how such an institution may apply for a waiver of the prohibition, and the circumstances under which the FDIC would consider granting a waiver. Because the statutory prohibition applies to brokered deposits accepted or renewed after December 7, 1989, it is imperative that the FDIC formalize its position on these important matters immediately and that rules and procedures be established to allow the orderly processing of waiver applications.

For these reasons, the FDIC Board of Directors has determined that the notice and public participation that are ordinarily required by the Administrative Procedure Act (5 U.S.C. 553) before a regulation may take effect would, in this case, be impracticable and contrary to the public interest and that good cause exists for waiving the customary 30-day delayed effective date. Therefore, the Board has adopted a temporary rule that is effective immediately and will remain in effect for six months in order to permit the Board the opportunity to review public comment before adoption of a final rule on this subject. Interested persons are invited to submit comments on the interim rule during a 60-day comment period. In adopting a final regulation, the Board will make such revisions in the interim rule as may be appropriate based on the comments received.

Discussion. The new regulation closely tracks the statute and is believed to be largely self-explanatory. It does, however, provide additional guidance on when an institution is considered undercapitalized, when certain deposits should be considered "brokered," and the circumstances under which a waiver may be granted. In general, the regulation takes a broad view of when an institution is considered undercapitalized and a narrow view of when a waiver may be granted with the objective and expectation that undercapitalized institutions normally will not have access to brokered deposits.

Three issues, however, warrant special attention. The first is the relationship between the new capital requirements established by the FIRREA for savings associations and the prohibition on the acceptance of brokered deposits by all undercapitalized institutions. More specifically, the issue posed is whether the existence of a capital plan or approval of that plan by the Office of Thrift Supervision ("OTS") in any way impacts the ability of an institution to accept or renew brokered deposits. The interim rule takes the position that these are separate issues. Consequently, an undercapitalized savings association may not accept or renew brokered deposits without a waiver from the FDIC so long as it remains undercapitalized whether or not it has a capital plan or its plan has been approved by the OTS. The same principle will apply to any plan or forebearance approved by a banking regulator for an insured bank.

For purposes of applying for a waiver, an undercapitalized insured savings association may submit to the FDIC the same documentation regarding its capital plans that it submits to the OTS. The FDIC will make its own judgment as to sufficiency of any plan and its prospects for success in the context of deciding a particular waiver application. In this regard, the FDIC notes that the OTS's capital regulations do not call for submission of capital plans until early next year. If sufficient other information (including tentative capital considerations) is available and safety and soundness concerns are satisfied, the FDIC's Division of Supervision expects to consider granting short-term waivers until the full capital plan can be submitted to both the OTS and the FDIC.

The second issue relates to the definition of brokered deposits in the law. In addition to deposits obtained through the mediation of third-party brokers, the definition of brokered deposits includes deposits on which an institution offers or has agreed to pay rates of interest that are "significantly" higher than the prevailing rates of interest offered by other depository institutions with the same type of charter in its normal market area. The law makes no distinction between deposits obtained locally or out-of-territory through the operation of a so-called "money desk." The interim rule takes the view that more than 50 basis points is "significant" for this purpose and thus establishes what is believed to be a reasonable compromise between the need to permit even undercapitalized institutions to compete on a reasonable basis in their local market and yet prevent such institutions from bidding excessively for an increasing share of local deposits or paying excessive rates to fund themselves through the operation of a "money desk" soliciting deposits throughout the country.

Finally, the interim rule excludes from coverage under the brokered deposits prohibition any insured depository institution for which the FDIC or the Resolution Trust Corporation ("RTC") has been appointed conservator or receiver. Section 29(d) of the Federal

Deposit Insurance Act, as added by section 224 of the FIRREA, authorizes the FDIC to grant a limited exception from the prohibition for such institutions if it determines that the acceptance of brokered deposits by such institutions "(1) is not an unsafe or unsound practice, and (2) either (A) is necessary to enable the institution to meet the demands of its depositors or pay its obligations in the ordinary course of business; or (B) is consistent with the conservator's fiduciary duty to minimize the losses of the institution." The FDIC Board of Directors is able to make these findings with respect to all insured depository institutions under FDIC or RTC conservatorship or receivership because such institutions are essentially under FDIC or RTC control and management and therefore pose no risk to the deposit insurance funds beyond the FDIC's control, and because the FDIC, in its own capacity and as exclusive manager for the RTC, intends to direct and monitor the brokered deposit activities of the various institutions under FDIC or RTC conservatorship or receivership to ensure that such deposits are used only as necessary to meet essential liquidity needs or to minimize losses to the institution. Accordingly, the FDIC Board has made the requisite findings and has determined to exclude from coverage under the brokered deposits prohibition any insured depository institution for which the FDIC or the RTC has been appointed conservator or receiver. As a result, no such institution will need to apply for a waiver of the prohibition.

In the interest of orderly administration, the FDIC has also provided for a 60-day transition period during which an undercapitalized institution will be permitted to continue to accept brokered deposits provided it does not significantly increase the average maturity and volume of its brokered deposits or, if it does increase its volume of brokered deposits to replace a run-off of other types of existing funding, it promptly notifies the FDIC regional office and files a waiver application within ten days thereafter. In the event an application is filed during this period and denied, the institution will no longer be permitted to accept brokered deposits.

Comment is solicited on the issues mentioned in particular as well as all other aspects of the interim rules.

Accordingly, notice is hereby given that the FDIC Board of Directors has adopted the following interim rule on the acceptance or renewal of brokered deposits after December 7, 1989 by undercapitalized insured depository institutions. The interim rule remains effective for six months following publication in the **Federal Register** or until further action is taken by the Board after the expiration of the official comment period, whichever is first.

List of Subjects in 12 CFR Part 337

Banks, banking; Savings and loan associations, savings associations.

For the reasons set forth in the preamble, the FDIC hereby amends part 337 of title 12 Code of Federal Regulations as follows:

PART 337—UNSAFE AND UNSOUND BANKING PRACTICES

1. The authority citation for part 337 is revised to read as follows:

Authority: 12 U.S.C. 1816, 1818(a), 1818(b), 1819, 1828(j)(2), 1821(f); Pub. L. No. 101–73, § 224, 103 Stat. 183, 273–75 (1989) (to be codified at 12 U.S.C. 1831f).

2. A new section 337.6 is added to read as follows:

§ 337.6 Brokered deposits in undercapitalized depository institutions.

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Brokered deposit.* The term "brokered deposit" means any deposit, as that term is defined in section 3(1) of the Federal Deposit Insurance Act (18 U.S.C. 1813(1)), that is obtained from or through the mediation or assistance of a deposit broker or by offering a rate of interest (with respect to such deposit) which is significantly higher than the prevailing rate of interest on a deposit with similar terms and conditions, including maturity, offered by other insured depository institutions having the same type of charter (bank or thrift) in the institution's normal market area. For this purpose, a rate of interest is deemed "significantly higher" if, when including any fees paid directly or indirectly to any third-party, it is more than 50 basis points higher than the prevailing rate offered or agreed to at the time for deposits of comparable amount, maturity and other terms by other insured depository institutions with the same type of charter (bank or thrift) in the institution's market area. A rate of interest on a deposit with an odd maturity is "significantly higher" if it is more than 50 basis points higher than the rate interpolated between the prevailing rates offered or paid by other depository institutions with the same charter on deposits of the next longer and shorter maturities offered in the market.

(2) *Deposit broker.* (i) The term "deposit broker" means:

(A) Any person engaged in the business of placing deposits, or facilitating the placement of deposits, of third parties with insured depository institutions or the business of placing deposits with insured depository institutions for the purpose of selling interests in those deposits to third parties; and

(B) An agent or trustee who establishes a deposit account to facilitate a business arrangement with an insured depository institution to use the proceeds of the account to fund a prearranged loan.

(ii) The term does not include:

(A) An insured depository institution, with respect to funds placed with that depository institution;

(B) An employee of an insured depository institution, with respect to funds placed with the employing depository institution;

(C) A trust department of an insured depository institution, if the trust in question has not been established for the primary purpose of placing funds with insured depository institutions;

(D) The trustee of a pension or other employee benefit plan, with respect to funds of the plan;

(E) A person acting as a plan administrator or an investment adviser in connection with a pension plan or other employee benefit plan provided that that person is performing managerial functions with respect to the plan;

(F) The trustee of a testamentary account;

(G) The trustee of an irrevocable trust (other than one described in paragraph (a)(2)(i)(B) of this section, as long as the trust in question has not been established for the primary purpose of placing funds with insured depository institutions;

(H) A trustee or custodian of a pension or profit-sharing plan qualified under section 401(d) or 403(a) of the Internal Revenue Code of 1986; or

(I) An agent or nominee whose primary purpose is not the placement of funds with depository institutions.

(3) *Employee.* The term "employee" means any employee:

(i) Who is employed exclusively by the insured depository institution;

(ii) Whose compensation is primarily in the form of a salary;

(iii) Who does not share such employee's compensation with a deposit broker; and

(iv) Whose office space or place of business is used exclusively for the benefit of the insured depository institution which employs such individual.

(4) *Insured depository institution.* The term "insured depository institution"

means any bank or savings association insured under the provisions of the Federal Deposit Insurance Act (12 U.S.C. 1811 *et seq.*).

(5) *Undercapitalized insured depository institution.* The term "undercapitalized insured depository institution" means any insured depository institution that fails to meet the minimum capital requirements applicable to it at the time and includes any insured depository institution which—

(i) After giving effect to any charge-offs or other capital reductions directed by its principal federal or state regulator, fails to meet any applicable capital standard (e.g., tangible, core, primary, total, risk-based, or leverage) established by law or regulation promulgated by its principal federal or state regulator, as applicable; or

(ii) Has been directed by a formal administrative order or advised in writing by its principal federal or state regulator as part of the supervisory process to achieve a higher level of capital, for example, to margin additional risk inherent in its activities and assets, balance sheet structure, or off-balance sheet liabilities, and has failed to meet that higher capital level.

For purposes of this section, the determination of whether an insured depository institution is undercapitalized shall be made without regard to whether it has been granted any forbearance or other relief from any statutory, regulatory, or other capital requirements by any federal or state regulator, whether the institution has submitted to any such regulator a plan to meet applicable capital requirements or standards over time, or whether any such capital plan has been approved by a federal or state regulator.

(b) *Prohibition.* No undercapitalized insured depository institution may accept, renew or rollover, whether on the same or differing terms and conditions, any brokered deposit unless it has applied for and been granted a waiver of this prohibition by the FDIC in accordance with the provisions of this section.

(c) *Waiver.* The FDIC may, on a case-by-case basis and upon application by an undercapitalized insured depository institution, waive the prohibition on the acceptance, renewal or rollover of brokered deposits upon a finding that such acceptance, renewal or rollover does not constitute an unsafe or unsound practice with respect to the particular institution. The FDIC may conclude that it is not unsafe and unsound and may grant a waiver when the acceptance, renewal or rollover of brokered deposits is necessary to maintain the institution's short-term liquidity or to facilitate a restructuring of its liabilities to reduce costs with no significant increase in total assets. A waiver will not be granted to permit an institution to grow in size.

(d) *Application.* An undercapitalized insured depository institution wishing to accept, renew or rollover brokered deposits may apply to the appropriate FDIC regional director for supervision for the region in which the head office of the institution is located. The application may be in letter form and shall be accompanied by a resolution of the board of directors or trustees of the institution authorizing the filing of the application. A copy of the application should be submitted to the institution's primary federal regulator and any state regulator, as appropriate. Any application filed shall address the following elements:

(1) The institution's plans to meet applicable capital requirements within a reasonable time period;

(2) The volume, rates and maturities on brokered deposits currently held;

(3) The scope of the waiver sought in terms of the volume and cost of brokered deposits to be obtained or retained and the time period for which a waiver may be needed;

(4) Alternative funding sources available to the institution; and

(5) Reasons the institution believes the acceptance, renewal or rollover of brokered deposits does not constitute an unsafe or unsound practice in its particular circumstances. In this regard, the institution should seek to demonstrate that its acceptance, renewal or rollover of brokered deposits would not likely increase materially the credit, interest-rate or operating risk of the institution.

(e) *Decision.* The FDIC Director, Division of Supervision, and when confirmed in writing by the Director, an associate director or the appropriate regional director or deputy regional director shall have the authority to approve or deny any waiver application properly filed. An application is properly filed when complete and accurate information addressing each of the elements listed in paragraph (d) of this section has been provided to the appropriate regional director. Any waiver granted will be for a fixed period, generally no longer than one year, but may be extended upon re-application.

(f) *Exclusion for institutions in FDIC or RTC conservatorship or receivership.* No insured depository institutions for which the FDIC or the Resolution Trust Corporation has been appointed conservator or receiver shall be subject to this § 337.6 or to section 29 of the Federal Deposit Insurance Act.

(g) *Sunset.* This § 337.6 shall remain in effect until June 12, 1990, unless sooner terminated, amended, modified, or replaced by the FDIC.

(h) *Sixty-day transition period.* Anything in this section to the contrary notwithstanding, an undercapitalized insured depository institution may accept, renew or rollover brokered deposits during the 60-day period commencing on December 8, 1989 and ending on February 5, 1990, provided that such insured undercapitalized depository institution:

(1) Does not extend the average maturity of its brokered deposits by more than three months; and

(2) Either does not significantly increase its total volume of brokered deposits, or If it does significantly increase its total volume of brokered deposits, it does so only to replace existing funding, provides prior notice to the appropriate FDIC regional director for supervision by telephone or letter and, within 10 days after such notification, files a waiver application in accordance with paragraph (d) of this section.

By order of the Board of Directors.

Dated at Washington, DC this 5th day of December, 1989.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 89-28906 Filed 12-11-89; 8:45 am]

BILLING CODE 6714-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 89-ANE-35; Amdt. 39-6411]

Airworthiness Directives; General Electric Company (GE) CF6-6 Series Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, request for comments.

SUMMARY: This amendment amends existing airworthiness directive (AD) 89-20-01 which established ultrasonic inspection requirements for certain Stage 1 fan disks on CF6-6 series turbofan engines installed in McDonnell Douglas DC10-10 aircraft. This amendment is needed to identify and remove from service additional CF6-6 Stage 1 fan disks which may have

metallurgical defects. Such defects can adversely affect the service life of the disk.

DATES: Effective—December 12, 1989.

Comments for inclusion in the docket must be received on or before January 12, 1990.

Compliance: As indicated in the body of the AD.

ADDRESSES: Comments on the amendment may be mailed in duplicate to Federal Aviation Administration, New England Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 89–ANE–35, 12 New England Executive Park, Burlington, Massachusetts 01803, or delivered in duplicate to Room 311, at the above address.

Comments must be marked: Docket No. 89–ANE–35.

Comments may be inspected at the above location in Room 311, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays.

The applicable General Electric Service Bulletin (CF6–6) 72–947, Revision 2, dated November 21, 1989, and General Electric Manufacturing and Field Quality Procedures Nos. 391, 384, 385, and 389 may be obtained from General Electric Company, Technical Publications Department, 1 Neumann Way, Cincinnati, Ohio 45215, or may be examined in the Regional Rules Docket.

FOR FURTHER INFORMATION CONTACT: John E. Golinski, Engine Certification Branch, ANE–142, Engine Certification Office, Engine and Propeller Directorate, Aircraft Certification Service, Federal Aviation Administration, 12 New England Executive Park, Burlington, Massachusetts 01803; telephone (617) 273–7097.

SUPPLEMENTARY INFORMATION: This amendment amends Amendment 39–6337 (54 FR 38814; September 21, 1989), AD 89–20–01, which currently requires that certain Stage 1 fan disks installed in GE CF6–6 series engines receive ultrasonic inspections to ensure that metallurgical defects are not present. After issuing Amendment 39–6337, the FAA has determined that 50 additional Stage 1 fan disks have been manufactured utilizing the same processes as that disk which failed during United Airlines Flight 232, at Sioux City, Iowa. Therefore, the FAA is amending Amendment 39–6337 by adding new disk serial numbers to Table 2 and Table 3 categories of the original AD. This amendment presents these serial numbers under new table designations (Tables 2A and 3A) to allow for different compliance schedules.

Since this condition is likely to exist or develop on other engines of the same type design, this AD is being issued to require a contact ultrasonic inspection and an immersion ultrasonic inspection of the Stage 1 fan disk.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable, and good cause exists for making this amendment effective in less than 30 days.

Although this action is in the form of a final rule which involves requirements affecting immediate flight safety and, thus, was not preceded by notice and public procedure, comments are invited on the rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket number and be submitted in duplicate to the address specified above.

All communications received on or before the closing date for comments will be considered by the FAA. This rule may be amended in light of comments received. Comments that provide a factual basis supporting the views and suggestions presented are particularly helpful in evaluating the effectiveness of the AD and determining whether additional rulemaking is needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available both before and after the closing date for comments in Room 311, at the Office of the Assistant Chief Counsel, 12 New England Executive Park, Burlington, Massachusetts, for examination by interested persons. A report summarizing each FAA-public contact, concerned with the substance of this AD, will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this amendment must submit a self-addressed, stamped postcard on which the following statement is made: Comments to Docket No. 89–ANE–35. The postcard will be date/time stamped and returned to the commenter.

The regulations adopted herein do not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation and that it is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Executive Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket (otherwise, an evaluation is not required). A copy of it, if filed, may be obtained from the Rules Docket.

List of Subjects in 14 CFR Part 39

Air Transportation, Aircraft, Aviation safety, and Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration (FAA) amends 14 CFR part 39 of the Federal Aviation Regulations (FAR) as follows:

PART 39 [AMENDED]

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 (Amended)

2. Section 39.13 is amended by amending Amendment 39–6337 (54 FR 38814; September 21, 1989), AD 89–20–01, by adding paragraphs (d) and (e), adding Tables (2A) and (3A), by reidentifying existing paragraphs, and by making other minor editorial changes as follows:

The AD is restated in its entirety for clarity.

General Electric Company: Applies to General Electric Company (GE) CF6–6 series turbofan engines installed in McDonnell Douglas DC10–10 aircraft.

Compliance is required as indicated, unless already accomplished.

To detect the existence of metallurgical imperfections in Stage 1 fan disks which could adversely affect Step 1 fan disk service life, ultrasonic inspect all Stage 1 fan disks in accordance with the Appendix to this AD, and the following schedule:

(a) All Stage 1 fan disks with those serial numbers listed in Table 3 of this AD,

immerson ultrasonic inspect no later than October 27, 1989.

(b) All Stage 1 fan disks identified by those serial numbers listed in Table 2 of this AD, as follows:

(1) Remove fan rotor spinner cone and contact ultrasonic inspect the installed fan disk no later than November 21, 1989.

(2) Immerson ultrasonic inspect within the next 500 cycles in service after accomplishing the contact ultrasonic inspection requirements of paragraph (b)(1) above, or at the next shop visit after October 7, 1989, or no later than April 1, 1990, whichever comes first.

(c) All Stage 1 fan disks identified by serial numbers listed in Table 3 of this AD, as follows:

(1) Remove fan rotor spinner cone and contact ultrasonic inspect the installed fan disk no later than February 4, 1990, and reinspect at intervals not to exceed 500 cycles since the last contact ultrasonic inspection until the immersion ultrasonic requirement of paragraph (c)(2) has been accomplished.

(2) Immerson ultrasonic inspect at the next shop visit after October 7, 1989, but no later than December 31, 1990.

(d) All Stage 1 fan disks identified by those serial numbers listed in Table 2A of this AD, as follows:

(1) Remove fan rotor spinner cone and contact ultrasonic inspect the installed fan disk no later than January 23, 1990.

(2) Immerson ultrasonic inspect within the next 500 cycles in service after accomplishing the contact ultrasonic inspection requirements of paragraph (d)(1) above, or at the next shop visit after December 12, 1989, or no later than June 5, 1990, whichever comes first.

(e) All Stage 1 fan disks identified by serial numbers listed in Table 3A of this AD, as follows:

(1) Remove fan rotor spinner cone and contact ultrasonic inspect the installed fan disk no later than April 10, 1990, and reinspect at intervals not to exceed 500 cycles since the last contact ultrasonic inspection until the immersion ultrasonic requirement of paragraph (e)(2) has been accomplished.

(2) Immerson ultrasonic inspect at the next shop visit after December 12, 1989, but no later than March 5, 1991.

Notes: (1) Disks which have been previously immersion ultrasonic inspected in accordance with GE Commercial Engine Memorandum No. 98, Rev. 2, dated October 5, 1989, are considered to be in compliance with the immersion ultrasonic inspection requirements of paragraphs (a), (b), (c), (d), and (e) above.

(2) For the purpose of this AD, "shop visit" is defined as the induction of the engine into the shop for any reason.

(3) Accomplishment of the immersion ultrasonic inspection requirements of paragraphs (b)(2), (c)(2), (d)(2), and (e)(2) above relieves the requirements for contact ultrasonic inspections of paragraphs (b)(1), (c)(1), (d)(1), and (e)(1) above.

(f) Remove from service, prior to further flight, fan disks inspected in accordance with paragraphs (a), (b), (c), (d), and (e) which do not meet the acceptance criteria of the Appendix to this AD and replace with a serviceable part. Report all inspection findings in writing within 10 days of the inspection to the Manager, Engine Certification Office, ANE-140, Engine and Propeller Directorate, Aircraft Certification Service, 12 New England Executive Park, Burlington, Massachusetts 01803; Telex No. 949301 FAANE BURL.

Information collection requirements contained in this regulation section 39.13) have been approved by the Office of Management and Budget under the provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96-511) and have been assigned OMB Control No. 2120-0056.

(g) Aircraft may be ferried in accordance with the provisions of FAR 21.197 and 21.199 to a base where the AD can be accomplished.

(h) Upon submission of substantiating data by an owner or operator through an FAA Airworthiness Inspector, an alternate method of compliance with the requirements of this AD or adjustments to the compliance schedules specified in this AD may be approved by the Manager, Engine Certification Office, Engine and Propeller Directorate, Aircraft Certification Service, Federal Aviation Administration, 12 New England Executive Park, Burlington, Massachusetts 01803.

TABLE 1

MPOO0382	MPOO0383	MPOO0384	MPOO0386	MPOO0387	MPOO0388

TABLE 2

MPOO0352	MPOO0363	MPOO0374	MPOO0390	MPOO0407	MPOA0117
MPOO0354	MPOO0364	MPOO0375	MPOO0393	MPOO0411	MPOA0133
MPOO0357	MPOO0365	MPOO0376	MPOO0395	MPOA0108	MPOA0136
MPOO0358	MPOO0368	MPOO0377	MPOO0397	MPOA0109	MPOA0140
MPOO0359	MPOO0370	MPOO0378	MPOO0398	MPOA0110	MPOA0141
MPOO0360	MPOO0371	MPOO0379	MPOO0399	MPOA0111	MPOA0142
MPOO0361	MPOO0372	MPOO0380	MPOO0402	MPOA0112	MPOA0143
MPOO0362	MPOO0373	MPOO0389	MPOO0404	MPOA0113	MPOA0145
				MPOA0115	

TABLE 2A

MPOA0135	MPOA0182

TABLE 3

MPOO0150	MPOO0188	MPOO0222	MPOO0251	MPOO0284	MPOO0319
MPOO0151	MPOO0189	MPOO0223	MPOO0253	MPOO0285	MPOO0320
MPOO0152	MPOO0190	MPOO0224	MPOO0254	MPOO0286	MPOO0321
MPOO0153	MPOO0191	MPOO0225	MPOO0255	MPOO0289	MPOO0322
MPOO0154	MPOO0193	MPOO0226	MPOO0257	MPOO0290	MPOO0323
MPOO0155	MPOO0194	MPOO0228	MPOO0258	MPOO0291	MPOO0325
MPOO0156	MPOO0195	MPOO0229	MPOO0260	MPOO0292	MPOO0326
MPOO0158	MPOO0196	MPOO0230	MPOO0263	MPOO0293	MPOO0331
MPOO0159	MPOO0197	MPOO0231	MPOO0264	MPOO0295	MPOO0334
MPOO0160	MPOO0198	MPOO0232	MPOO0265	MPOO0297	MPOO0336

TABLE 3—Continued

MPOO0161	MPOO0199	MPOO0233	MPOO0266	MPOO0298	MPOO0337
MPOO0162	MPOO0200	MPOO0234	MPOO0267	MPOO0299	MPOO0338
MPOO0163	MPOO0204	MPOO0235	MPOO0268	MPOO0300	MPOO0339
MPOO0168	MPOO0205	MPOO0236	MPOO0270	MPOO0302	MPOO0340
MPOO0171	MPOO0206	MPOO0237	MPOO0271	MPOO0303	MPOO0341
MPOO0172	MPOO0207	MPOO0238	MPOO0272	MPOO0304	MPOO0342
MPOO0173	MPOO0208	MPOO0240	MPOO0273	MPOO0305	MPOO0343
MPOO0175	MPOO0209	MPOO0241	MPOO0274	MPOO0308	MPOO0346
MPOO0176	MPOO0210	MPOO0242	MPOO0275	MPOO0309	MPOO0347
MPOO0177	MPOO0212	MPOO0243	MPOO0276	MPOO0311	MPOO0348
MPOO0178	MPOO0213	MPOO0244	MPOO0277	MPOO0312	MPOO0349
MPOO0179	MPOO0214	MPOO0245	MPOO0278	MPOO0313	MPOO0350
MPOO0180	MPOO0215	MPOO0246	MPOO0279	MPOO0314	MPOA0137
MPOO0181	MPOO0216	MPOO0247	MPOO0280	MPOO0315	MPOA0139
MPOO0182	MPOO0217	MPOO0248	MPOO0281	MPOO0316	MPOA0207
MPOO0184	MPOO0218	MPOO0249	MPOO0282	MPOO0317	MPOA0439
MPOO0185	MPOO0219	MPOO0250	MPOO0283	MPOO0318	
MPOO0186	MPOO0220				
MPOO0187	MPOO0221				

TABLE 3A

MPOO0618	MPOO0139	MPOO0103	MPOO0011	MPOC2744	MPOA0376
MPOO0436	MPOO0136	MPOO0102	MPOO0010	MPOC0321	MPOA0291
MPOO0353	MPOO0113	MPOO0078	MPOO0009	MPOA0880	MPOA0284
MPOO0351	MPOO0111	MPOO0016	MPOO0005	MPOA0810	MPOA0206
MPOO0294	MPOO0109	MPOO0015	MPOO0004	MPOA0801	MPOA0200
MPOO0174	MPOO0108	MPOO0014	MPOO0003	MPOA0736	MPOA0139
MPOO0149	MPOO0107	MPOO0013	MPOO0002	MPOA0662	MPOA0138
MPOO0141	MPOO0104	MPOO0012	MPOH3844	MPOA0481	MPOG2753

The ultrasonic inspections shall be done in accordance with the Appendix to this AD.

This amendment becomes effective on December 12, 1989.

This amendment amends Amendment 39-6337 (54 FR 38814; September 21, 1989), AD 89-20-01.

Issued in Burlington, Massachusetts, on November 24, 1989.

Jack A. Sain,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

Appendix

Note: This Appendix is not published in the **Federal Register.** It is available from General Electric or from the Federal Aviation Administration, New England Headquarters. See ADDRESSES section. This Appendix contains pertinent portions of GE Service Bulletin (CF6-6) S/B 72-947, Revision 2, dated November 21, 1989, and the following documents:

(A) General Electric Manufacturing and Field Quality Technology Procedure No. 391, issued September 15, 1989, Rev. 1, dated September 28, 1989.

(B) General Electric Manufacturing and Field Quality Technology Procedure No. 384, issued September 15, 1989, Rev. 2, dated October 5, 1989.

(C) General Electric Manufacturing and Field Quality Technology Procedure No. 385, issued September 14, 1989, Rev. 2, dated October 5, 1989.

(D) General Electric Manufacturing and Field Quality Technology Procedure No. 389, issued September 14, 1989, Rev. 2, dated October 3, 1989.

[FR Doc. 89-28933 Filed 12-11-89; 8:45 am]
BILLING CODE 4910-13-M

14 CFR Part 71

[Airspace Docket No. 89-AEA-03]

Establishment of Transition Area; Danville, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes a 700-foot transition area to accommodate a new Milton, PA, VHF Omnidirectional Range/Tactical Air Navigation (VORTAC) Copter VHF Omnidirectional Range/Distance Measuring Equipment (VOR/DME) 336 Standard Instrument Approach Procedure to the Geisinger Medical Center, Danville, Pennsylvania. The intended effect of this action is to ensure segregation of the aircraft using approach procedures in instrument conditions from other aircraft operating under visual weather conditions in controlled airspace.

EFFECTIVE DATE: 0901 u.t.c. January 14, 1990.

FOR FURTHER INFORMATION CONTACT: Mr. Curtis L. Brewington, Airspace Specialist, System Management Branch, AEA-530, Federal Aviation Administration, Fitzgerald Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430; telephone: (718) 917-0857.

SUPPLEMENTARY INFORMATION:

History

On July 7, 1989, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by establishing a 700-foot Transition Area at the Geisinger Hospital Helipad, Danville, PA (54 FR 31703). The proposed action would establish that airspace necessary to contain an Instrument Approach Procedure to the Helipad.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments on this proposal were received. Section 71.181 of part 71 of the Federal Aviation Regulations was republished in FAA Handbook 7400.6E, January 3, 1989.

The Rule

This amendment to part 71 of the Federal Aviation Regulations establishes a 700-foot Transition Area at Danville, PA. This airspace is required to contain helicopter operations operating to and from the Geisinger

Medical Center, Danville, PA under an instrument flight plan. Additionally, this action would separate these aircraft operating under instrument meterological conditions from those operating under visual weather conditions in controlled airspace.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Transition areas.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 71 of the Federal Aviation Regulations (14 CFR part 71) is amended as follows:

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; E.O. 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

§ 71.181 [Amended]

2. Section 71.181 is amended as follows:

Danville, PA [New]

That airspace extending upward from 700' above the surface within a 5-mile radius of the Geisinger Hospital Helipad (lat. 40°58'05" N., long. 76°36'25" W.); and within 4-miles each side of the 321°(T) 330°(M) bearing from the Geisinger Hospital Helipad to the 5-mile radius.

Issued in Jamaica, New York, on September 25, 1989.

John D. Canoles,

Manager, Air Traffic Division.

[FR Doc. 89-28935 Filed 12-11-89; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 97

[Docket No. 26073; Amdt. No. 1414]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occuring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

EFFECTIVE DATE: An effective date for each SIAP is specified in the amendatory provisions.

Incorporation by reference—approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

ADDRESS: Availability of matters incorporated by reference in the amendment is as follows:

For Examination—1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; 2. The FAA Regional Office of the region in which the affected airport is located; or 3. The Flight Inspection Field Office which originated the SIAP.

For Purchase—Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA-200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription—Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Paul J. Best, Flight procedures Standards Branch (AFS-420), Technical programs Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-8277.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs). The complete regulatory description of each SIAP is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation Regulations (FAR). The applicable FAA Forms are identified as FAA forms 8260-3, 8260-4, and 8260-5. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, space and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form document is unncessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

This amendment to part 97 is effective on the date of publication and contains separate SIAPs which have compliance dates stated as effective dates based on related changes in the National Airspace System or the application of new or revised criteria. Some SIAP amendments may have been previously issued by the FAA in a National Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPs). In developing these SIAPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs

is unnecessary, impracticable, and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only inolves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Approaches, Standard Instrument, Incorporation by reference.

Issued in Washington, DC on November 24, 1989.

Daniel C. Beaudette,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking standard Instrument Approach Procedures, effective at 0901 GMT on the dates specified, as follows:

PART 97—(AMENDED)

1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 1348, 1354(a), 1421, and 1510; 49 U.S.C. 106(g) (revised, Pub. L. 97-449, January 12, 1983; and 14 CFR 11.49(b)(2)).

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33 and 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS. MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

. . . Effective January 11, 1990

Auburn, AL—Auburn-Opelika Robert G. Pitts, VOR RWY 28, Amdt. 9
Fairbanks, AK—Fairbanks Intl, ILS RWY 1L, Amdt. 4
Corning, AR—Corning Muni, VOR/DME-A, Amdt. 1
Denver, CO—Stapleton Intl, ILS RWY 36, Amdt. 3
Peru, IL—Illinois Valley Rgnl-Walter A Duncan Field, LOC RWY 36, Orig.
Iron Mountain/Kingsford, MI—Ford, VOR RWY 1 Amdt. 11
Iron Mountain/Kingsford, MI—Ford, LOC/DME BC RWY 19, Amdt. 11
Iron Mountain/Kingsford, MI—Ford, ILS RWY 1, Amdt. 9
Pellston, MI—Pellston Regional Airport of Emmet County, VOR RWY 23, Amdt. 13
Pellston, MI—Pellston Regional Airport of Emmet County, VOR/DME RWY 5, Amdt. 8
Pellston, MI—Pellston Regional Airport of Emmet County, ILS RWY 32, Amdt. 8
St. Paul, MN—St. Paul Downtown Holman Fld, NDB RWY 30, Amdt. 7
St. Paul, MN—St. Paul Downtown Holman Fld, ILS RWY 32, Amdt. 2
Ocean Springs, MS—Gulfpark, VOR-B, Amdt. 1, CANCELLED
Chadron, NE—Chadron Muni, VOR RWY 20, Amdt. 6
Chadron, NE—Chadron Muni, VOR/DME RWY 02, Amdt. 1
Chadron, NE—Chadron Muni, NDB RWY 02, Amdt. 2
Chadron, NE—Chadron Muni, NDB RWY 20, Amdt. 11
Baytown, TX—Baytown, NDB RWY 31, Orig.
La Porte, TX—La Porte Muni, VOR-A, Amdt. 12
Wallops Island, VA—Wallops Flight Facility, VOR/DME or TACAN RWY 10, Amdt. 2

. . . Effective December 14, 1989

Gunnison, CO—Gunnison County, LOC RWY 6, Amdt. 2
Sanford, ME—Sanford Muni, LOC RWY 07, Orig.
West Point, MS—McCharen Field, VOR/DME-B, Amdt. 4
Nashville, TN—Nashville International, VOR/DME RWY 13, Amdt. 11
Nashville, TN—Nashville International, VOR/DME RWY 20C, Amdt. 3
Nashville, TN—Nashville International, VOR/DME RWY 20R, Amdt. 5
Nashville, TN—Nashville International, NDB RWY 20R, Amdt. 5
Fort Worth, TX—Bourland Field, VOR RWY 35, Amdt. 1, CANCELLED
Fort Worth, TX—Bourland Field, VOR-A, Orig.
Fort Worth, TX—Fort Worth Alliance, ILS RWY 16, Orig.
Junction, TX—Kimble County, VOR-A, Amdt. 11
Junction, TX—Kimble County, RNAV RWY 17, Amdt. 2
Victoria, TX—Victoria Regional, VOR RWY 12L, Amdt. 12
Victoria, TX—Victoria Regional, VOR/DME RWY 30R, Amdt. 4
Victoria, TX—Victoria Regional, ILS RWY 12L, Amdt. 7
Manassas, VA—Manassas Muni/Harry P. Davis Field, ILS RWY 16L, Amdt. 1

. . . Effective November 22, 1989

San Francisco, CA—San Francisco Intl, ILS RWY 28R, Amdt. 9

. . . Effective November 21, 1989

Scottsbluff, NE—William B. Heilig Field, RNAV RWY 12, Amdt. 3

. . . Effective November 20, 1989

Vacaville, CA—Nut Tree, RNAV RWY 20, Amdt. 1

[FR Doc. 89-28936 Filed 12-11-89; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 524

Animal Drugs, Feeds, and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from Stauffer Chemical Co. to Coopers Animal Health, Inc.

EFFECTIVE DATE: December 12, 1989.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1414.

SUPPLEMENTARY INFORMATION: Coopers Animal Health, Inc., 2000 South 11th St., Kansas City, KS 66103-1438, advised FDA of the change of sponsor of NADA 44-757 from Stauffer Chemical Co., Westport, CT (formerly 1200 South 47th St., Richmond, CA 94804). ICI Americas, Inc., Wilmington, DE 19897, in lieu of the sponsor of record and as the successor in interest, advised FDA of the change on behalf of Stauffer Chemical Co., the sponsor of record. As a result of this change of sponsor, Stauffer Chemical Co. is no longer the sponsor of any approved NADA. Therefore, FDA is amending 21 CFR 510.600(c) (1) and (2) to remove the sponsor entries for Stauffer Chemical Co. and 21 CFR 524.1742(b) to reflect the sponsor change.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner

of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 524 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376).

§ 510.600 [Amended]

2. Section 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications is amended in the table in paragraph (c)(1) by removing the entry for "Stauffer Chemical Co.," and in the table in paragraph (c)(2) by removing the entry for "017032".

PART 524—OPTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

3. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 524.1742 [Amended]

4. Section 524.1742 *N/(Mercaptomethyl) phthalimide S-(0,0-dimethyl phosphorodithioate) emulsifiable liquid* is amended in paragraph (b) by removing the number "017032" and inserting in its place "017220".

Dated: December 6, 1989.

Robert C. Livingston,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 89-28959 Filed 12-11-89; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

Animal Drugs, Feeds, and Related Products; Tylosin, Tylosin/Sulfamethazine, Hygromycin B

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove those portions of the regulations reflecting approval of three new animal drug applications (NADA's) held by Cadco, Inc. One NADA provides for use of a tylosin Type A article to make Type C swine, beef cattle, and chicken feeds, the second for use of a tylosin-sulfamethazine Type A article to make Type C swine feeds, and the third for use of a hygromycin B Type A article to make Type C swine feeds. In a notice published elsewhere in this issue of the Federal Register, FDA is withdrawing approval of the NADA's.

EFFECTIVE DATE: December 22, 1989.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4093.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the Federal Register, FDA is withdrawing approval of NADA's 91-783, 99-561, and 109-635 held by Cadco, Inc. NADA 91-783 provides for use of tylosin Type A medicated article for making Type C medicated swine, beef cattle, and chicken feeds. NADA 99-561 provides for use of tylosin-sulfamethazine Type A medicated article to make Type C medicated swine feeds. NADA 109-635 provides for use of hygromycin B Type A medicated article to make Type C medicated swine feeds. This document removes the firm's drug labeler code from 21 CFR 558.274 (a)(2) and (c)(1), 558.625(b)(4), and 558.630(b)(10) to reflect withdrawal of the approvals.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.274 [Amended]

2. Section 558.274 *Hygromycin B* is amended in paragraph (a)(2) and in the table in paragraph (c)(1) under the "Sponsor" column for entry (ii) by removing "011490,".

§ 558.625 [Amended]

3. Section 558.625 *Tylosin* is amended by removing paragraph (b)(4) and reserving it.

§ 558.630 [Amended]

4. Section 558.630 *Tylosin and sulfamethazine* is amended in paragraph (b)(10) by removing "011490,".

Dated: December 6, 1989.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 89-28957 Filed 12-11-89; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 31, and 602

[T.D. 8276]

RIN 1545-AN98

Employee Business Expenses—Reporting and Withholding on Employee Business Expense Reimbursements and Allowances

AGENCY: Internal Revenue Service, Treasury.

ACTION: Temporary and final regulations.

SUMMARY: This document contains temporary and final regulations concerning the taxation of and reporting and withholding on payments with respect to employee business expenses under a reimbursement or other expense allowance arrangement. These temporary regulations reflect changes to the law made by the Family Support Act of 1988. These temporary regulations will affect employees who receive payments and payors who make payments under reimbursement or other expense allowance arrangements. The text of the temporary regulations set forth in this document also serves as the text of the proposed regulations cross-referenced in the notice of proposed rulemaking in the Proposed Rules section of this issue of the Federal Register.

EFFECTIVE DATES: The provisions of these temporary regulations under § 1.62-1T are effective for expenses paid or incurred in taxable years beginning before January 1, 1989. The income tax provisions of these temporary regulations under § 1.62-2T are effective for taxable years beginning on or after January 1, 1989, with respect to expenses paid or incurred in taxable years beginning on or after January 1, 1989. The provisions of § 1.162-17(e)(3) of these regulations are effective for taxable years beginning on or after January 1, 1989. The provisions of § 1.274-5T(g) of these regulations are effective upon publication. The provisions of § 1.162-25T of these regulations are effective upon publication. The reporting provisions of these temporary regulations under

§ 1.6041–3(i) are effective for payments made under reimbursement or other expense allowance arrangements on or after January 1, 1989; however, a transition rule is provided under § 1.6041–3(i) effective for payments made prior to January 1, 1990. The amendments to §§ 31.3121(a)–1(h), 31.3231(e)–1, 31.3306(b)–1, and 31.3401(a)–(1)(b)(2) of these regulations are effective for amounts that are received by an employee on or after July 1, 1990, with respect to expenses paid or incurred on or after July 1, 1990. The provisions of these temporary regulations under §§ 31.3121(a)–2T, 31.3231(e)–3T, 31.3306(b)–2T, and 31.3401(a)–2T regarding withholding and payment of employment taxes are effective for payments made under reimbursement or other expense allowance arrangements on or after July 1, 1990.

FOR FURTHER INFORMATION CONTACT: Richard Pavel at 202–377–9372 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

This regulation is being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collection of information contained in this regulation has been reviewed and, pending receipt and evaluation of public comments, approved by the Office of Management and Budget (OMB) under control number 1545–1148. The estimated average annual burden per recordkeeper is 0.5 hour. This estimate is an approximation of the average time expected to be necessary for a collection of information. It is based on such information as is available to the Internal Revenue Service. Individual recordkeepers may require greater or less time, depending on their particular circumstances.

For further information concerning this collection of information, and where to submit comments on this collection of information and the accuracy of the estimated burden, and suggestions for reducing this burden, please refer to the preamble to the cross-referenced notice of proposed rulemaking published in the Proposed Rules section of this issue of the Federal Register.

Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) under sections 62, 162, 274 and 6041 of the Internal Revenue Code, and to the Employment Tax Regulations (26 CFR part 31) under sections 3121, 3231, 3306, and 3401 of the Code as a result of the Family Support Act of 1988, Public Law No. 100–485.

Need For Temporary and Final Regulations

Because of the need for immediate guidance regarding the reporting and withholding requirements of these regulations, it is impracticable and contrary to the public interest to issue these temporary and final regulations with notice and public procedure under section 553(b) of title 5 of the United States Code, or subject to the effective date limitation of section 553(d) of title 5.

Explanation of Provisions

Section 62(a) of the Internal Revenue Code generally defines "adjusted gross income" as gross income minus certain deductions. These "above-the-line" deductions are allowed without regard to whether a taxpayer itemizes deductions and are not subject to the two-percent floor of section 67. Among the above-the-line deductions, section 62(a)(2)(A) allows an employee a deduction for expenses (reimbursed employee business expenses) paid by the employee, in connection with the performance of services as an employee, under a reimbursement of other expense allowance arrangement with his or her employer. In addition, the above-the-line deduction is available for reimbursement or other expense allowance arrangements maintained by an agent of the employer or by a third party for whom the employee performs a service as an employee of the employer. Throughout these regulations, such employers, agents, and third parties are referred to as "payors."

As amended, section 62(c) provides that an arrangement will not be treated as a "reimbursement or other expense allowance arrangement" for purposes of section 62(a)(2)(A) unless—

(1) The arrangement requires the employee to substantiate the expenses covered by the arrangement to the payor, and

(2) The arrangement requires the empoyee to return any amount in excess of the substantiated expenses covered under the arrangement.

Reimbursement or Other Expense Allowance Arrangements

1. Defined

For purposes of the temporary regulations, a reimbursement or other expense allowance arrangement is an arrangement that meets three requirements: (1) Business connection, (2) substantiation, and (3) returning amounts in excess of expenses.

2. Business Connection Requirement

An arrangement meets the business connection requirement under the temporary regulations if it provides reimbursements, advances, or allowances (including per diem allowances, allowances for meals and incidental expenses, and mileage allowances) for business expenses that are allowable as deductions for expenses paid or incurred by an employee in connection with the performance of services as an employee. The business connection requirement therefore requires a nexus between an amount denominated an "advance" and the business expenses that it is anticipated the employee will incur. For example, if an employer provides an employee with an "advance" of $3000 at a time when it is not anticipated that the employee will incur travel or other expenses deductible in the trade or business of being an employee, the "advance" does not meet the business connection requirement and will not be treated as paid under an accountable plan.

3. Substantiation

In order to meet the substantiation requirement, the employee must be required to substantiate the expenses covered by the arrangement to the payor. For example, to the extent employee business expenses covered by such arrangements are governed by the substantiation rules of section 274(d), the employee must meet the substantiation requirements of that section, which, for example, with respect to a travel expense, generally require substantiation of the amount, time, place and business purpose of the expense.

Under section 274(d), the Commissioner has the authority to provide simplified methods of substantiation. The Service is publishing several such simplified methods of substantiation. Under these simplified methods, known as "deemed substantiation" methods, employees are deemed to have substantiated an amount of expenses equal to the lesser of the amount of the reimbursement or the amount specified by the Service.

The methods of deemed substantiation available to employers will include methods applicable to lodging, meal and/or incidental expenses, both within and outside the continental United States, and methods applicable to reimbursement of transportation expenses. Such methods

will include reimbursements paid under arrangements similar to the methods for reimbursing Federal employees. In addition, deemed substantiation methods will be available for reimbursements paid at a flat rate or under a stated schedule, such as reimbursements for lodging, meals and/or incidental expenses calculated on the basis of hours worked or miles driven.

The Service will, in a separate announcement, request suggestions from taxpayers concerning appropriate additional methods of deemed substantiation.

4. Returning Amounts in Excess of Expenses

In order to meet the requirement of returning amounts in excess of expenses, an arrangement must require the employee to return any amount in excess of the substantiated expenses covered under the arrangement. If an employee receives an advance for anticipated business expenses that exceeds the amount of such expenses actually incurred and substantiated by the employee, but the employee uses such excess to pay expenses incurred for other business expenses, the employee need not return such excess to the payor.

The temporary regulations grant the Commissioner the authority to prescribe rules under which an arrangement providing per diem allowances or mileage allowances will be treated as satisfying the requirement of returning amounts in excess of expenses, even though an employee is not required to return the portion of such an allowance that exceeds the amount of the employee's expenses which is deemed substantiated under rules prescribed under section 274(d), provided the allowance is reasonably calculated not to exceed the amount of the employee's expenses or anticipated expenses and the employee is required to return any portion of such an allowance which relates to days or miles of travel not substantiated. For example, assume a payor provides an employee an advance mileage allowance of $60, based on an anticipated 200 business miles at 30 cents-per-mile (at a time when the applicable standard mileage rate is 26 cents-per-mile), and the employee substantiates 120 business miles. Under these rules, the requirement to return excess amounts will be treated as satisfied if the employee is required to return the amount of the advance allowance that is attributable to the 80 unsubstantiated business miles ($24.00), even though the employee is not required to return the portion of the allowance ($4.80) that exceeds the amount of the employee's expenses deemed substantiated ($31.20) pursuant to rules prescribed under section 274(d).

5. Timeliness

Both the requirements of substantiation and the requirement that excess reimbursements be returned must be met within a reasonable period of time after an expense is paid or incurred. What constitutes a reasonable period of time depends on the facts and circumstances. Thus, for example, it is reasonable that an employee who is on an extended travel assignment would have a longer period to substantiate expenses and return excess amounts than an employee who undertakes a single overnight trip.

The regulations provide two safe harbor methods. Under the first, the requirements will be treated as met within a reasonable period of time if an advance is made within 30 days of when an expense is paid or incurred, an expense is substantiated within 60 days after it is paid or incurred, or an excess amount is returned to the payor within 120 days after the expense is paid or incurred. Under the second, the requirements will be treated as met within a reasonable period of time if an expense is substantiated or an amount is returned within 120 days after the payor provides a periodic statement (no less frequently than quarterly) of the amount paid under the arrangement that exceeds the expenses the employee has substantiated. Both methods are intended solely as safe harbors, and no adverse inference is intended with respect to amounts advanced, substantiated, or returned after such periods. However, for purposes of withholding, a payor may treat amounts substantiated or returned after such periods as not having been substantiated or returned within a reasonable period of time.

Reporting and Employment Taxes

The Conference Report on the Family Support Act of 1988 (H.R. Rep. No. 998, 100th Cong., 2d Sess. 202–206 (1988)) provides that the regulations and rulings regarding the reporting of employee business expense reimbursements and allowances generally are also to be revised to conform to the changes in section 62 and to subject amounts treated as paid pursuant to nonaccountable plans to income tax withholding. In addition, the legislative history provides authority to alter the relevant employment tax rules. Pursuant to the regulatory authority granted by Congress under the Family Support Act, these temporary regulations provide guidance regarding the circumstances under which travel and other expense allowance arrangements are subject to the Federal Insurance Contributions Act (FICA), the Federal Unemployment Tax Act (FUTA), the Railroad Retirement Tax Act (RRTA), the Railroad Unemployment Repayment Tax (RURT) and the Collection of Income Tax at Source on Wages ("employment taxes"). These regulations also provide guidance with regard to reporting of such amounts on Form W–2.

Delayed effective dates are provided for the changes in the employment tax regulations. The changes in the employment tax regulations are effective for payments made under reimbursement or other expense allowance arrangements that are received by an employee on or after July 1, 1990, with respect to expenses paid or incurred on or after July 1, 1990. For reimbursements or other expense allowance payments made before July 1, 1990, or made with respect to expenses paid or incurred before July 1, 1990, the rules in existing regulations will apply. Hence, for payments made under reimbursement or other expense allowance arrangements before July 1, 1990, no withholding or employment tax liability will attach with respect to amounts paid specifically—either as advances or reimbursements—for traveling or other bona fide ordinary and necessary expenses incurred or reasonably expected to be incurred in the business of the employer. Of course, as under existing regulations, such expenses must be identified either by making a separate payment or by specifically identifying the separate amounts if both wages and expense allowances are combined in a single payment.

A delayed effective date is not provided for the amendments to the reporting requirements under section 6041. The reporting requirements are effective for payments made under reimbursement or other expense allowance arrangements on or after January 1, 1989, with respect to expenses paid or incurred on or after January 1, 1989. However, for payments made before January 1, 1990, no reporting is required if the payor has made a reasonable, good faith effort to comply with the requirements of section 62(c). In general, compliance with the provisions of prior section 1.6041–3(i) of the Income Tax Regulations will indicate such reasonable good faith effort to comply with the requirements of section 62(c). Under those regulations, reporting on form W–2 was not required if the employee was required to account and did so account to the employer for

such expenses. See Rev. Rul. 60–62, 1960–1 C.B. 63, as modified, and Rev. Rul. 84–127, 1984–2 C.B. 246. A payor must, however, report payments made before January 1, 1990, if an arrangement (other than a per diem or mileage type arrangement) does not require the employee to substantiate expenses or to return excess amounts.

Payments Under Accountable Plans

If an arrangement meets all the requirements of the regulations, the amounts paid under the arrangement are excluded from the employee's gross income, are not required to be reported on the employee's Form W–2, and are exempt from withholding and payment of employment taxes (FICA, FUTA, RRTA, RURT, and income tax). If an arrangement meets the requirements of the regulations, but an employee fails to return amounts in excess of amounts substantiated, only the amounts not in excess of the substantiated, expenses are excluded from the employee's gross income, are not required to be reported on the employee's Form W–2, and are exempt from withholding and payment of employment taxes (FICA, FUTA, RRTA, RURT, and income tax).

Payments Under Nonaccountable Plans

If an arrangement does not meet one or more of the requirements of the regulations, all payments under the arrangement are included in the employee's gross income, are reported as wages on Form W–2, and are wages for purposes of withholding and payment of employment taxes. If an arrangements meets the requirements of the regulations, but an employee fails to return amounts in excess of amounts substantiated, such excess is included in the employee's gross income, is reported as wages on Form W–2, and is wages for purposes of withholding and payment of employment taxes. Employee business expenses that exceed the amount of the reimbursements that are excluded from the employee's gross income are not allowable as a deduction in computing adjusted gross income. Rather, such employee business expenses are deductible by the employee in computing taxable income only if the employee itemizes deductions, and only to the extent that the total of such expenses and other miscellaneous itemized deductions exceeds two percent of the taxpayer's adjusted gross income.

Special Analyses

It has been determined that these rules are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It has also been determined that section 553(b) of the Administrative Prodecure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and, therefore, a final Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking for the regulations was submitted to the Administrator of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these regulations is Richard Pavel, Office of the Assistant Chief Counsel (Employee Benefits and Exempt Organizations), Internal Revenue Service. However, personnel from other offices of the Service and Treasury Department participated in their development.

List of Subjects

26 CFR Part 1.61–1 through 1.281–4

Deductions, Exemptions, Income taxes, Taxable income.

26 CFR Part 31

Employment taxes, Income taxes, Lotteries, Railroad retirement, Social Security, Unemployment tax, Withholding.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 1, 31, and 602 are amended as follows:

PART 1—[AMENDED]

Paragraph 1. The authority for part 1 is amended by adding the following citations:

Authority: 26 U.S.C. 7805 * * * Secs. 1.62–1T and 1.62–2T also issued under 26 U.S.C. 62 * * * Sec. 1.6041–3 also issued under 26 U.S.C. 62.

Par. 2. Section 1.62–1T is amended by revising paragraph (c)(2) and by inserting a new sentence before the first sentence of paragraph (f), to read:

§ 1.62–1T Adjusted gross income (temporary).

* * * * *

(c) *Deductions allowable in computing adjusted gross income.* * * *

(2) Deductions allowable under part VI, subchapter B, chapter 1 of the Code, (section 161 and following) that consist of expenses paid or incurred by the taxpayer in connection with the performance of services as an employee under an express reimbursement or other expense allowance arrangement (as defined in paragraph (f) of this section or § 1.62–2T, whichever is applicable) with his or her employer;

* * * * *

(f) *Reimbursement or other expense allowance arrangement.* This paragraph (f) applies to expenses paid or incurred in taxable years beginning before January 1, 1989. * * *

* * * * *

Par. 3. Section 1.62–2T is added immediately following 1.62–1T to read as follows:

§ 1.62–2T Reimbursements and other expense allowance arrangements (Temporary).

(a) *Table of contents.* The contents of this section are as follows:

(a) Table of contents.
(b) Scope.
(c) Reimbursement or other expense allowance arrangement.
(1) Defined.
(2) Accountable plans.
(i) In general.
(ii) Special rule for failure to return excess.
(3) Nonaccountable plans.
(i) In general.
(ii) Special rule for failure to return excess.
(4) Treatment of payments under accountable plans.
(5) Teatment of payments under nonaccountable plans.
(d) Business connection.
(e) Substantiation.
(1) In general.
(2) Expenses governed by section 274(d).
(3) Expenses not governed by section 274(d).
(f) Returning amounts in excess of expenses.
(1) In general.
(2) Per diem or mileage allowances.
(g) Reasonable period.
(1) In general.
(2) Safe harbors.
(i) Fixed date method.
(ii) Periodic payment method.
(h) Timing of withholding.
(i) Application.
(j) Cross references.
(k) Effective date.

(b) *Scope.* For purposes of determining "adjusted gross income," section 62(a)(2)(A) allows an employee a deduction for expenses allowed by part VI (section 161 and following), subchapter B, chapter 1 of the Code, paid by the employee, in connection with the preformance of services as an employee, under a reimbursement or other expense allowance arrangement with a payor (the employer, its agent, or a third party). Section 62(c) provides that an arrangement will not be treated

as a reimbursement or other expense allowance arrangement for purposes of section 62(a)(2)(A) if—

(1) Such arrangement does not require the employee to substantiate the expenses covered by the arrangement to the payor, or (2) Such arrangement provides the employee the right to retain any amount in excess of the substantiated expenses covered under the arrangement.

This section prescribes rules relating to the requirements of section 62(c).

(c) *Reimbursement or to each expense allowance arrangement"*—(1) *Defined.* For purposes of §§ 1.62–1T and 1.62–2T, the phrase "reimbursement or other expense allowance arrangement" means an arrangement that meets the requirements of paragraphs (d) (business connection), (e) (substantiation), and (f) (returning amounts in excess of expenses) of this section. A payor may have more than one arrangement with respect to a particular employee, depending on the facts and circumstances.

(2) *Accountable plans*—(i) *In general.* Except as provided in paragraph (c)(2)(ii) of this section, if an arrangement meets the requirements of paragraphs (d), (e), and (f) of this section, all amounts paid under the arrangement are treated as paid under an "accountable plan."

(ii) *Special rule for failure to return excess.* If an arrangement meets the requirements of paragraphs (d), (e), and (f) of this section, but the employee fails to return, within a reasonable period of time, any amount in excess of the amount of the expenses substantiated in accordance with paragraph (e), only the amounts paid under the arrangement that are not in excess of the substantiated expenses are treated as paid under an accountable plan.

(3) *Nonaccountable plans*—(i) *In general.* If an arrangement does not satisfy one or more of the requirements of paragraph (d), (e), or (f) of this section, all amounts paid under the arrangement are treated as paid under a "nonaccountable plan."

(ii) *Special rule for failure to return excess.* If an arrangement meets the requirements of paragraphs (d), (e), and (f) of this section, but the employee fails to return, within a reasonable period of time, any amount in excess of the amount of the expenses substantiated in accordance with paragraph (e), the amounts paid under the arrangement that are in excess of the substantiated expenses are treated as paid under a nonaccountable plan.

(4) *Treatment of payments under accountable plans.* Amounts treated as paid under an accountable plan are excluded from the employee's gross income, are not required to be reported on the employee's Form W–2, and are exempt from the withholding and payment of employment taxes (Federal Insurance Contributions Act (FICA), Federal Unemployment Tax Act (FUTA), Railroad Retirement Tax Act (RRTA), Railroad Unemployment Repayment Tax (RURT), and income tax). See paragraph (j) of this § 1.62–2T for cross references.

(5) *Treatment of payments under nonaccountable plans.* Amounts treated as paid under a nonaccountable plan are included in the employee's gross income, must be reported to the employee on Form W–2, and are subject to withholding and payment of employment taxes (FICA, FUTA, RRTA, RURT, and income tax). Expenses attributable to amounts included in the employee's gross income may be deducted, provided the employee can substantiate the full amount of his or her expenses (i.e., the amount of the expenses, if any, the reimbursement for which is treated as paid under an accountable plan as well as those for which the employee is claiming the deduction) in accordance with § 1.274–5T or § 1.162–17, but only as a miscellaneous itemized deduction subject to the limitations applicable to such expenses (e.g., the 80-percent limitation on meal and entertainment expenses provided in section 274(n) and the 2-percent floor provided in section 67).

(d) *Business connection.* An arrangement meets the requirements of this paragraph (d) if it provides advances, allowances (including per diem allowances, allowances for meals and incidental expenses, and mileage allowances), or reimbursements for business expenses that are allowable as deductions by part VI (section 161 and the following), subchapter B, chapter 1 of the Code, and that are paid or incurred by the employee in connection with the performance of services as an employee. The payment may be actually received from the employer, its agent, or a third party for whom the employee performs a service as an employee of the employer and may include amounts charged directly or indirectly to the payor through credit card systems or otherwise. In addition, if both wages and the reimbursement or other expense allowance are combined in a single payment, the reimbursement or other expense allowance must be identified either by making a separate payment or by specifically identifying the amount of the reimbursement or other expense allowance.

(e) *Substantiation*—(1) *In general.* An arrangement meets the requirements of this paragraph (e) if it requires each business expense to be substantiated to the payor in accordance with paragraph (e)(2) or (e)(3) of this section, whichever is applicable, within a reasonable period of time. See § 1.274–5T or § 1.162–17.

(2) *Expenses governed by section 274(d).* An arrangement that reimburses travel, entertainment, use of a passenger automobile or other listed property, or other business expenses governed by section 274(d) meets the requirements of this paragraph (e)(2) if information sufficient to satisfy the substantiation requirements of section 274(d) and the regulations thereunder is submitted to the payor. See § 1.274–5T. Under section 274(d), information sufficient to substantiate the requisite elements of each expenditure or use must be submitted to the payor. For example, with respect to travel away from home, § 1.274–5T(b)(2) requires that information sufficient to substantiate the amount, time, place, and business purpose of the expense must be submitted to the payor. Similarly, with respect to use of a passenger automobile or other listed property, § 1.274–5T(b)(6) requires that information sufficient to substantiate the amount, time, use, and business purpose of the expense must be submitted to the payor. See § 1.274–5T(g), however, which grants the Commissioner authority to prescribe rules permitting the amount of certain expenses to be deemed substantiated to the payor (in lieu of substantiating the actual amount of such expenses) where an arrangement provides for a reimbursement, a per diem allowance, or a mileage allowance for travel away from home or transportation expenses. See also § 1.274–5T(j), which grants the Commissioner the authority to establish a method under which a taxpayer may elect to use a specified amount for meals while traveling away from home in lieu of substantiating the actual cost of meals. Substantiation of the amount of a business expense in accordance with rules prescribed pursuant to the authority granted by § 1.274–5T(g) or § 1.274–5T(j) will be treated as substantiation of the amount of such expense for purposes of this section.

(3) *Expenses not governed by section 274(d).* An arrangement that reimburses business expenses not governed by section 274(d) meets the requirements of this paragraph (e)(3) if information is submitted to the payor sufficient to enable the payor to identify the specific nature of each expense and to conclude that the expense is attributable to the payor's business activities. Therefore,

each of the elements of an expenditure or use must be substantiated to the payor. It is not sufficient if an employee merely aggregates expenses into broad categories (such as "travel") or reports individual expenses through the use of vague, nondescriptive terms (such as "miscellaneous business expenses"). See § 1.162–17(b).

(f) *Returning amounts in excess of expenses*—(1) *In general.* Except as provided in paragraph (f)(2) of this section, an arrangement meets the requirements of this paragraph (f) if it requires the employee to return to the payor within a reasonable period of time any amount paid under the arrangement in excess of the expenses substantiated in accordance with paragraph (e) of this section. The determination of whether an arrangement requires an employee to return amounts in excess of substantiated expenses will depend on the facts and circumstances. An arrangement whereby money is advanced to an employee to defray expenses will be treated as satisfying the requirements of this paragraph (f) only if the amount of money advanced is reasonably calculated not to exceed the amount of anticipated expenditures, the advance of money is made on a day within a reasonable period of the day that the anticipated expenditures are paid or incurred, and any amounts in excess of the expenses substantiated in accordance with paragraph (e) are required to be returned to the payor within a reasonable period of time after the advance is received.

(2) *Per diem or mileage allowances.* The Commissioner may, in his discretion, prescribe rules in pronouncements of general applicability under which a reimbursement or other expense allowance arrangement that provides per diem allowances providing for ordinary and necessary expenses of traveling away from home (exclusive of transportation costs to and from destination) or mileage allowances providing for ordinary and necessary expenses of local travel and transportation while traveling away from home will be treated as satisfying the requirements of this paragraph (f), even though the arrangement does not require the employee to return the portion of such an allowance that exceeds the amount of the employee's expenses deemed substantiated pursuant to rules prescribed under section 274(d), provided the allowance is reasonably calculated not to exceed the amount of the employee's expenses or anticipated expenses and the employee is required to return to the payor within a reasonable period of time any portion of such allowance which relates to days or miles of travel not substantiated in accordance with paragraph (e) of this section.

(g) *Reasonable period*—(1) *In general.* The determination of a reasonable period of time will depend on the facts and circumstances.

(2) *Safe harbors*—(i) *Fixed date method.* An advance made within 30 days of when an expense is paid or incurred, an expense substantiated to the payor within 60 days after it is paid or incurred, or an amount returned to the payor within 120 days after an expense is paid or incurred will be treated as having occurred within a reaonable period of time.

(ii) *Periodic statement method.* If a payor provides employees with periodic statements (no less frequently than quarterly) stating the amount, if any, paid under the arrangement in excess of the expenses the employee has substantiated in accordance with paragraph (e) of this section, and requesting the employee to substantiate any additional business expenses that have not yet been substantiated (whether or not such expenses related to the expenses with respect to which the original advance was paid) and/or to return any amounts remaining unsubstantiated within 120 days of the statement, an expense substantiated or an amount returned within that period will be treated as being substantiated or returned within a reasonable period of time.

(h) *Timing of withholding.* If the expenses covered under an arrangement are not substantiated to the payor in accordance with paragraph (e) of this section within a reasonable period of time or if any amounts in excess of the substantiated expenses are not returned to the payor in accordance with paragraph (f) of this section within a reasonable period of time, the amount which is treated as paid under a nonaccountable plan under paragraph (c)(3) of this section is subject to withholding and payment of employment taxes no later than the first payroll period following the end of the reasonable period. A payor may treat any amount not substantiated or returned within the periods specified in paragraph (g)(2) of this section as not substantiated or returned within a reasonable period of time. See paragraph (j) of this § 1.62–2T for cross references.

(i) *Application.* The requirements of paragraphs (d) (business connection), (e) (substantiation), and (f) (returning amounts in excess of expenses) of this section will be applied on an employee-by-employee basis. Thus, for example, the failure by one employee to substantiate expenses under an arrangement in accordance with paragraph (e) will not cause amounts paid to other employees to be treated as paid under a nonaccountable plan.

(j) *Cross references.* For employment tax regulations relating to reimbursement and expense allowance arrangements, see §§ 31.3121(a)–1(h), 31.3231(e)–1(a)(3)(iv), 31.3306(b)–1(h), and 31.3401(a)–(1)(b)(2), which apply to payments made under reimbursement or other expense allowance arrangements received by an employee on or after July 1, 1990 with respect to expenses paid or incurred on or after July 1, 1990. For reporting requirements, see § 1.6041–3(i), which generally applies to payments made under reimbursement or other expense allowance arrangements received by an employee on or after January 1, 1989 with respect to expenses paid or incurred on or after January 1, 1989.

(k) *Effective date.* This section applies to payments made under reimbursement or other expense allowance arrangements received by an employee in taxable years of the employee beginning on or after January 1, 1989, with respect to expenses paid or incurred in taxable years beginning on or after January 1, 1989.

Par. 4. In § 1.162–17, a new paragraph (e)(3) is added, to read as follows:

§ 1.162–17 Reporting and substantiation of certain business expenses of employees.

* * * * *

(e) *Applicability.* * * *

(3) For taxable years beginning on or after January 1, 1989, the provisions of this section are superseded by the regulations under section 62(c) to the extent this section is inconsistent with those regulations. *See* § 1.62–2T.

Par. 5. Paragraph (b) of § 1.162–25T is amended by removing the first sentence and adding in its place three new sentences to read as follows:

§ 1.162–25T Deductions with respect to noncash fringe benefits (temporary).

* * * * *

(b) *Employee.* If an employer provides the use of a vehicle (as defined in § 1.61–21(e)(2)) to an employee as a noncash fringe benefit and includes the entire value of the benefit in an employee's gross income without taking into account any exclusion for a working condition fringe allowable under section 132 and the regulations thereunder, the employee may deduct that value multiplied by the percentage

of the total use of the vehicle that is in connection with the employer's trade or business ("business value"). For taxable years beginning before January 1, 1990, the employee may deduct the business value from gross income in determining adjusted gross income. For taxable years beginning on or after January 1, 1990, the employee may deduct the business value only as a miscellaneous itemized deduction in determining taxable income, subject to the 2-percent floor provided in section 67. * * *

* * * * *

§ 1.274-5T [Amended]

Par. 6. Paragraph (g) of § 1.274-5T is amended by adding the words "in pronouncements of general applicability" immediately following the word "rules" in the first sentence, effective upon publication.

Par. 7. in § 1.6041-3, paragraph (i) is revised to read as follows:

§ 1.6041-3 Payments for which no return of information is required under section 6041.

* * * * *

(i)(1) *In general.* Payments made under reimbursement or other expense allowance arrangements that meet the requirements of section 62(c) of the Code and § 1.62-2T, that do not exceed the amount of the expenses substantiated (i.e., amounts which are treated as paid under an accountable plan), and that are received by an employee on or after January 1, 1989, with respect to expenses paid or incurred on or after January 1, 1989;

(2) *Transition rule.* Payments made under reimbursement or other expense allowance arrangements that are received by an employee on or after January 1, 1989, but prior to January 1, 1990, to the extent that the employee is required to account (within the meaning of the term "account" as set forth in § 1.162-17(b)(4) or § 1.274-5T(f)(4), whichever is applicable) and does so account to the payor for such expenses, provided the payor has made a reasonable, good faith effort to comply with the requirements of section 62(c). In general, compliance with the provisions of this section, as in effect for payments made under reimbursement or other expense allowance arrangements that were received by an employee before January 1, 1989, with respect to expenses paid or incurred before January 1, 1989, will constitute such reasonable good faith compliance. In no event, however, will reasonable good faith compliance exist if a payor fails to report payments made under an arrangement (other than a per diem or mileage allowance type arrangement) under which an employee is not required to substantiate expenses paid or incurred or is not required to return amounts in excess of the substantiated expenses;

* * * * *

PART 31—[AMENDED]

Par. 8. The authority for part 31 is amended by adding the following citation:

Authority: 26 U.S.C. 7805 * * * Secs. 31.3121(a)-1, 31.3231(e)-1, 31.3306(b)-1, and 31.3401(a)-1 also issued under 26 U.S.C. 62.

Par. 9. In § 31.3121(a)-1, paragraph (h) is amended by adding a sentence at the end to read as follows:

§ 31.3121(a)-1 Wages.

* * * * *

(h) * * * For amounts that are received by an employee on or after July 1, 1990, with respect to expenses paid or incurred on or after July 1, 1990, see § 31.3121(a)-2T.

* * * * *

Par. 10. Section 31.3121(a)-2T is added to read as follows:

§ 31.3121(a)-2T Reimbursement and other expense allowance amounts.

(a) *When excluded from wages.* If a reimbursement or other expense allowance arrangement meets the requirements of section 62(c) of the Code and § 1.62-2T and the expenses are substantiated within a reasonable period of time, payments made under the arrangement that do not exceed the substantiated expenses are treated as paid under an accountable plan and are not wages. In addition, if both wages and the reimbursement or other expense allowance are combined in a single payment, the reimbursement or other expense allowance must be identified either by making a separate payment or by specifically identifying the amount of the reimbursement or other expense allowance.

(b) *When included in wages.* If a reimbursement or other expense allowance arrangement does not satisfy the requirements of section 62(c) and § 1.62-2T (e.g., the arrangement does not require expenses to be substantiated or require amounts in excess of the substantiated expenses to be returned), all amounts paid under the arrangement are treated as paid under a nonaccountable plan, are included in wages, and are subject to withholding and payment of employment taxes when paid. If an arrangement satisfies the requirements of section 62(c) and § 1.62-2T, but the expenses are not substantiated within a reasonable period of time or amounts in excess of the substantiated expenses are not returned within a reasonable period of time, the amount paid under the arrangment in excess of the substantiated expenses is treated as paid under a nonaccountable plan, is included in wages, and is subject to withholding and payment of employment taxes no later then the first payroll period following the end of the reasonable period.

(c) *Effective date.* This section applies to payments made under reimbursement or other expense allowance arrangements received by an employee on or after July 1, 1990, with respect to expenses paid or incurred on or after July 1, 1990.

Par. 11. In § 31.3231(e)-1, paragraph (a)(3)(iv) is amended by adding a sentence at the end to read as follows:

§ 31.3231(e)-1 Compensation.

(a) * * *

(iv) * * * For amounts that are received by an employee on or after July 1, 1990, with respect to expenses paid or incurred on or after July 1, 1990, see § 31.3231(e)-3T.

Par. 12 Section 31.3231(e)-3T is added to read as follows:

§ 31.3231(e)-3T Reimbursement and other expense allowance amounts.

(a) *When excluded from compensation.* If a reimbursement or other expense allowance arrangement meets the requirements of section 62(c) of the Code and § 1.62-2T and the expenses are substantiated within a reasonable period of time, payments made under the arrangement that do not exceed the substantiated expenses are treated as paid under an accountable plan and are not compensation. In addition, if both wages and the reimbursement or other expense allowance are combined in a single payment, the reimbursement or other expense allowance must be identified either by making a separate payment or by specifically identifying the amount of the reimbursement or other expense allowance.

(b) *When included in compensation.* If a reimbursement or other expense allowance arrangement does not satisfy the requirements of section 62(c) and § 1.62-2T (e.g., the arrangement does not require expenses to be substantiated or require amounts in excess of the substantiated expenses to be returned), all amounts paid under the arrangement are treated as paid under a nonaccountable plan, are included in compensation, and are subject to withholding and payment of employment taxes when paid. If an

arrangement satisfies the requirements of section 62(c) and § 1.62–2T, but the expenses are not substantiated within a reasonable period of time or amounts in excess of the substantiated expenses are not returned within a reasonable period of time, the amount paid under the arrangement in excess of the substantiated expenses is treated as paid under a nonaccountable plan, is included in compensation, and is subject to withholding a payment of employment taxes no later than the first payroll period following the end of the reasonable period.

(c) *Effective date.* This section applies to payments made under reimbursement or other expense allowance arrangements received by an employee on or after July 1, 1990, with respect to expenses paid or incurred on or after July 1, 1990.

Par. 13. In § 31.3306(b)–1, paragraph (h) is amended by adding a sentence at the end to read as follows:

§ 31.3306(b)–1 Wages.

* * * * *

(h) * * * For amounts that are received by an employee on or after July 1, 1990, with respect to expenses paid or incurred on or after July 1, 1990, see § 31.3306(b)–2T.

* * * * *

Par. 14 Section 31.3306(b)–2T is added to read as follows:

§ 31.3306(b)–2T Reimbursement and other expense allowance amounts.

(a) *When excluded from wages.* If a reimbursement or other expense allowance arrangement meets the requirements of section 62(c) of the Code and § 1.62–2T and the expenses are substantiated within a reasonable period of time, payments made under the arrangement that do not exceed the substantiated expenses are treated as paid under an accountable plan and are not wages. In addition, if both wages and the reimbursement or other expense allowance are combined in a single payment, the reimbursement or other expense allowance must be identified either by making a separate payment or by specifically identifying the amount of the reimbursement or other expense allowance.

(b) *When included in wages.* If a reimbursement or other expense allowance arrangement does not satisfy the requirements of section 62(c) and § 1.62–2T (e.g., the arrangement does not require expenses to be substantiated or require amounts in excess of the substantiated expenses to be returned), all amounts paid under the arrangement are treated as paid under a nonaccountable plan, are included in wages, and are subject to withholding and payment of employment taxes when paid. If an arrangement satisfies the requirements of section 62(c) and § 1.62–2T, but the expenses are not substantiated within a reasonable period of time or amounts in excess of the substantiated expenses are not returned within a reasonable period of time, the amount paid under the arrangement in excess of the substantiated expenses is treated as paid under a nonaccountable plan, is included in wages, and is subject to withholding and payment of employment taxes no later than the first payroll period following the end of the reasonable period.

(c) *Effective date.* This section applies to payments made under reimbursement or other expense allowance arrangements received by an employee on or after July 1, 1990, with respect to expenses paid or incurred on or after July 1, 1990.

Par. 15. In § 31.3401(a)–1, paragraph (b)(2) is amended by adding a sentence at the end to read as follows:

§ 31.3401(a)–1 Wages.

(b) * * *

(2) *Traveling and other expenses.* * * * For amounts that are received by an employee on or after July 1, 1990, with respect to expenses paid or incurred on or after July 1, 1990, see § 31.3401(a)–2T.

* * * * *

Par. 16 Section 31.3401(a)–2T is added to read as follows:

§ 31.3121(a)–2T Reimbursements and other expense allowance amounts.

(a) *When excluded from wages.* If a reimbursement or other expense allowance arrangement meets the requirements of section 62(c) of the Code and § 1.62–2T and the expenses are substantiated within a reasonable period of time, payments made under the arrangement that do not exceed the substantiated expenses are treated as paid under an accountable plan and are not wages. In addition, if both wages and the reimbursement or other expense allowance are combined in a single payment, the reimbursement or other expense allowance must be identified either by making a separate payment or by specifically identifying the amount of the reimbursement or other expense allowance.

(b) *When included in wages.* If a reimbursement or other expense allowance arrangement does not satisfy the requirements of section 62(c) and § 1.62–2T (e.g., the arrangement does not require expenses to be substantiated or require amounts in excess of the substantiated expenses to be returned), all amounts paid under the arrangement are treated as paid under a nonaccountable plan, are included in wages, and are subject to withholding and payment of employment taxes when paid. If an arrangement satisfies the requirements of section 62(c) and § 1.62–2T, but the expenses are not substantiated within a reasonable period of time or amounts in excess of the substantiated expenses are not returned within a reasonable period of time, the amount paid under the arrangement in excess of the substantiated expenses is treated as paid under a nonaccountable plan, is included in wages, and is subject to withholding and payment of employment taxes no later than the first payroll period following the end of the reasonable period.

(c) *Withholding rate.* Employers may add any payments made under reimbursement or other expense allowance arrangements that are subject to income tax withholding to the employee's regular wages for a payroll period and compute withholding taxes on the total. Alternatively, the employer may withhold income tax from the reimbursement or other expense allowance at the flat 20-percent rate applicable to supplemental wages, provided the employer withholds income tax from the employee's regular wages and provided the reimbursement or allowance is paid separately (or separately identified if wages and reimbursement amounts are combined in a single payment). See § 31.3402(g)–1 regarding supplemental wage payments.

(d) *Effective date.* This section applies to payments made under reimbursement or other expense allowance arrangements received by an employee on or after July 1, 1990, with respect to expenses paid or incurred on or after July 1, 1990.

PART 602—[AMENDED]

Par. 17. The authority for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

§ 602.101(c) [Amended]

Par. 18. Section 602.101(c) is revised by inserting in the appropriate places in the table "1.62–2 . . . 1545–1148".

Dated: December 4, 1989.

Fred T. Goldberg,

Commissioner of Internal Revenue.

Approved:

Kenneth W. Gideon,

Assistant Secretary of the Treasury.

[FR Doc. 89–28941 Filed 12–7–89; 12:20 pm]

BILLING CODE 4830–01–M

DEPARTMENT OF EDUCATION

34 CFR Part 255

RIN 1810-AA53

Indian Education; Gifted and Talented Program

AGENCY: Department of Education.

ACTION: Final regulation.

SUMMARY: The Secretary amends 34 CFR part 255 to add an Office of Management and Budget (OMB) control number to a section of the regulations. The section contains information collection requirements approved by OMB. The Secretary takes this action to inform the public that these requirements have been approved.

EFFECTIVE DATE: Section 255.31 and this amendment are effective December 12, 1989.

FOR FURTHER INFORMATION CONTACT: Ms. Julia Lesceux, Indian Education Programs, Office of Elementary and Secondary Education, U.S. Department of Education, 400 Maryland Avenue, SW., Room 2177 (Mail Stop 6267), Washington, DC, 20202. Telephone: (202) 732-1938.

SUPPLEMENTARY INFORMATION: On May 11, 1989, final regulations governing the Gifted and Talented Program were published as the new 34 CFR part 255 (54 FR 20483). The effective date of § 255.31 was delayed until information collection requirements contained in that section were approved by OMB under the Paperwork Reduction Act of 1980, as amended. OMB has approved the information collection requirements, and § 255.31 is now effective.

Waiver of Proposed Rulemaking

In accordance with section 431(b)(2)(A) of the General Education Provisions Act (20 U.S.C. 1232(b)(2)(A)) and the Administrative Procedure Act (5 U.S.C. 553), it is the practice of the Secretary to offer interested parties the opportunity to comment on proposed regulations. However, the publication of OMB control numbers is purely technical and does not establish substantive policy. Therefore, the Secretary has determined, under 5 U.S.C. 553(b)(B), that proposed rulemaking is unnecessary and contrary to the public interest and that a delayed effective date is not required under 5 U.S.C. 553 (d)(3).

List of Subjects in 34 CFR Part 255

Education, Elementary and secondary education, Grant programs-education, Grant programs-Indians, Indians-education, Reporting and recordkeeping requirements.

Dated: December 6, 1989.

Lauro F. Cavazos,

Secretary of Education.

(Catalog of Federal Domestic Assistance No. 84.061, Indian Education—Special Program and Projects)

The Secretary amends part 255 of title 34 of the Code of Federal Regulations as follows:

PART 255—GIFTED AND TALENTED PROGRAM

1. The authority citation for part 255 continues to read as follows:

Authority: 25 U.S.C. 2624(c), unless otherwise noted.

§ 255.31 [Amended]

2. Section 255.31 is amended by adding "(Approved by the Office of Management and Budget under control number 1810-0021)" following the section.

[FR Doc. 89-28929 Filed 12-11-89; 8:45 am]

BILLING CODE 4000-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL-3695-4; TN-078]

Approval and Promulgation of Implementation Plans; Tennessee: PM_{10} Revisions for Nashville/Davidson County

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On December 14, 1988, the State of Tennessee submitted Board Orders 10-88, 88-11 and 88-15 as revisions to the Nashville/Davidson County portion of its State Implementation Plan (SIP) for particulate matter. The revisions became State-effective on June 8, 1988, and November 16, 1988. The revisions were adopted pursuant to the requirements of section 110 of the Clean Air Act to provide for the attainment of EPA's new particulate matter standards, known as "PM_{10}" standards. EPA proposed approval of these revisions on June 12, 1989 (54 FR 24913) and no comments were received.

DATES: This rule will become effective on January 11, 1990.

ADDRESSES: Copies of the State's submittal are available for review during normal business hours at the following locations:

Public Information Reference Unit, Library Systems Branch, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Environmental Protection Agency, Region IV, Air Programs Branch, 345 Courtland Street, NE., Atlanta, Georgia 30365.

Tennessee Department of Health and Environment, Division of Air Pollution Control, 4th Floor, Customs House, 701 Broadway, Nashville, Tennessee 37219-5403.

Metropolitan Health Department, Bureau of Pollution Control, 311-23rd Ave. North, Nashville, Tennessee 37203.

FOR FURTHER INFORMATION CONTACT: Ms. Rosalyn D. Hughes, Air Programs Branch, EPA Region IV, at the above address and telephone number (404) 347-2864.

SUPPLEMENTARY INFORMATION: Pursuant to the 1977 amendments to the Clean Air Act, EPA, on July 1, 1987 (52 FR 24634), promulgated revised primary and secondary National Ambient Air Quality Standards (NAAQS) for particulate matter by replacing the total suspended particulate matter standard with a standard that included only those particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers. The particles are referred to as PM_{10}.

The PM_{10} standards cover a size range of particles that is different than the range of particles covered by the former particulate standard for total suspended particulates (TSP). This means that states must develop and implement PM_{10} control programs. The process being used generally follows the basic approach used in the development and implementation of TSP control programs. First, EPA evaluated the probabilities of PM_{10} air quality levels predicted from actual TSP data and concluded that Nashville/Davidson County was a Group III area, which means that the existing particulate matter control strategy is believed to be largely adequate to attain and maintain the PM_{10} standards. However, the Nashville/Davidson County portion of the Tennessee SIP still needs to be revised to address the PM_{10} NAAQS in the following ways:

a. To include ambient air quality standards for PM_{10} at least as stringent as the NAAQS,

b. To trigger preconstruction review for new or modified sources which would emit significant amounts of either PM or PM_{10} emissions,

c. To invoke the emergency episode plan to prevent PM_{10} concentrations from reaching the significant harm level of 600 ug/m^3,

d. To meet ambient PM_{10} monitoring requirements of 40 CFR Part 58, and

e. To meet the requirements of 40 CFR 51.322 and 51.323 to report actual annual emissions of PM_{10} (beginning with emissions for 1988) for point sources emitting 100 tons per year or more.

In response to the above requirements, Nashville/Davidson County revised their regulations. The State of Tennessee adopted the Nashville/Davidson County regulations in Board Orders 10–88, 88–11, and 88–15 and submitted those Board Orders as revisions to the SIP. EPA proposed approval of these revisions on June 12, 1989 (54 FR 24913) and no comments were received. The definitions for "PM_{10}," "PM_{10} emissions," "particulate matter," and "total suspended particulates" have been added. The old definition for "particulate matter" has been deleted in its entirety and replaced with the federal definition.

In section 4–1–6, Incinerator Regulations, paragraph (f) was added. This paragraph exempts certain incinerators from 4–1–6 if they are covered by another regulation. This revision would allow Nashville to adopt additional regulations for specific classifications of incinerators.

In section 4–1–16, Registration and Permits, several housekeeping revisions have been made. No action will be taken on the deletion of subsection (c)(2) because it deals with operating permit regulations. Subsection (f)(3), has been revised to allow Nashville to adopt additional regulations for specific classifications of incinerators.

Regulation No. 3, New Source Review, has also been revised. Several definitions in section 3–1, Definitions, have been revised. Paragraph (dd), "Secondary Emissions," was revised so that it does not exclude vessel emissions which occur during loading/unloading at the facility or which are dockside emissions. In paragraph (ee), "Significant," subparagraph (1) was revised to add PM_{10} when referencing net emissions increase or a source's potential to emit. Subparagraph (2) limits the emissions impact on a nonattainment area. The limits for particulate matter and carbon monoxide were deleted and replaced with limits for sulfur dioxide, nitrogen dioxide, carbon monoxide and particulate matter. The definition "Volatile Organic Compound (VOC)" was added to section 3–1 as paragraph (gg). This definition has already been approved as part of Regulation No. 7, Regulation for Control of Volatile Organic Compounds, on January 27, 1989, at 54 FR 4020.

Several sentences were added to section 3–2, Registration and Permits, paragraph (b)(2)(ii)(A), to explain if and how emissions from source shutdowns or curtailments in production or operating hours could be used for offsets. Added to paragraph (e) was a brief description of the procedural requirements of 40 CFR 51.102 which is to be used for construction permit applications for new major sources or major modifications.

Paragraph (a)(1) of section 3–3, Prevention of Significant Deterioration (PSD) Review, pertains to the list of sources which have the potential to emit or emit 100 tons per year of any regulated air pollutant that is subject to PSD. The phrase, "any regulated air pollutant," has been deleted and replaced with "any pollutant subject to regulation under the Federal Clean Air Act."

Since EPA has not developed any maximum increase in emissions over the baseline concentration for particulate matter, Nashville revised paragraph (e)(2)(i) of section 3–3. The title of part (i) has been changed from "Particulate Matter" to "Total Suspended Particulate."

Section 3–3(f) has been updated to reference modeling guidance Supplement A (1987).

The de minimis air quality level for PM_{10} has been added to section 3–3(g)(6)(i). Also, the de minimis levels for lead, beryllium, and hydrogen sulfide have been revised to correspond to the federal levels.

Paragraphs g (7) and (8) were added to section 3–3. These paragraphs reference monitoring requirements for PM_{10}.

Emergency episode criteria were not included in this submittal. Nashville is in the process of developing those regulations. Action will be taken on the emergency episode criteria when they are submitted.

Final Action: EPA has reviewed the submitted material and found it to meet the requirements of 40 CFR part 51. Therefore, EPA is today approving the Tennessee PM_{10} revisions for Nashville/Davidson County.

For further information on EPA's analysis, the reader may consult a Technical Support Document which contains a detailed review of the materials submitted. This is available at the EPA address given above.

Under section 307(b)(1) of the Act, petition for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 12, 1990. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

This action has been classified as a Table 3 action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225). On January 6, 1989, the Office of Management and Budget waived Table 2 and 3 SIP revisions (54 FR 2222) from the requirements of section 3 of Executive Order 12291 for a period of two years.

"Nothing in this section should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements."

List of Subjects in 40 CFR Part 52

Air pollution control, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Note: Incorporation by reference of the State Implementation Plan for the State of Tennessee was approved by the Director of the Federal Register on July 1, 1982.

Dated: September 15, 1989.

Joe R. Franzmathes,

Acting Regional Administrator.

Part 52 of Chapter I, Title 40, Code of Federal Regulations, is amended as follows:

Subpart RR—Tennessee

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7642.

2. Section 52.2220 is amended by adding paragraph (c)(97) to read as follows:

§ 52.2220 Identification of plan.

* * * * *

(c) * * *

(97) Revisions to the Nashville/Davidson County portion of the Tennessee SIP which included PM_{10} regulations (Board Orders 10–88 and 88–15) submitted on December 14, 1988.

(i) *Incorporation by reference.* (A) Revisions to Nashville/Davidson County Regulation No. 3, "New Source Review" and Board Order 10–88 approved June 8, 1988. The following regulations are approved:

Section 3-1-Definition—(dd), (ee) and (gg)

Section 3-2-Registration and Permits—(b)(2) and (e)

Section 3-3-Prevention of Significant Deterioration (PSD) Review—(a)(1), (e)(2), (f), (g)(6), (g)(7) and (g)(8)

(B) Revisions to Nashville/Davidson County Metropolitan Code Chapter 4 Subchapter 1 "Air Pollution Control" and Board Order 88-15 approved on November 16, 1988. The following regulations are approved:

Section 4-1-1-Definitions—PM_{10} Emissions, Particulate Matter Emissions, Total Suspended Particulate, and Particulate Matter

Section 4-1-6-Incinerator Regulations—(f)

Section 4-1-16-Registration and Permits—(c) and f(3)

Section 4-1-18-Ambient Air Quality Standards

[FR Doc. 89-28963 Filed 12-11-89; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 8360

RIN 1004-AB60

Public Health, Safety and Comfort; Conduct of Visitors on Public Lands; Amendment of Regulations on Rules of Conduct of Visitors to the Public Lands

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule, correction.

SUMMARY: The Bureau of Land Management is correcting typographical errors made in the Authority Citation in the final rule establishing criminal penalties for illegal cultivation, manufacture, distribution, trafficking, or possession of controlled substances on public lands, which was published in the Federal Register on May 19, 1989 (54 FR 21623).

FOR FURTHER INFORMATION CONTACT: Walter Johnson, (202) 653-8815.

On page 21624, in the Federal Register of May 19, 1989, in the first column, amendatory instruction 1 and the authority citation are corrected to read as follows:

1. The authority citation for 43 CFR part 8360 continues to read as follows:

Authority: 43 U.S.C. 1701 et seq., 43 U.S.C. 315a, 16 U.S.C. 1281c, 16 U.S.C. 670 *et seq.*, 16 U.S.C. 4601-6a, 16 U.S.C. 1241 *et seq.*

Dated: November 28, 1989.

Scott Sewell,

Deputy Assistant Secretary of the Interior.

[FR Doc. 89-28956 Filed 12-11-89; 8:45 am]

BILLING CODE 4310-84-M

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 172 and 178

[Docket No. HM-189H, Amdt. Nos. 172-120 and 178-95]

Hazardous Materials Regulations; Editorial Corrections and Clarifications

AGENCY: Research and Special Programs Administration (RSPA), Department of Transportation (DOT).

ACTION: Final rule; corrections.

SUMMARY: This document makes certain corrections to a final rule issued under Docket HM-189H, which was published in the Federal Register on Friday, September 29, 1989 [54 FR 40066].

EFFECTIVE DATE: September 29, 1989.

FOR FURTHER INFORMATION CONTACT: Beth Romo, Standards Division, DHM-12, Office of Hazardous Materials Transportation, 400 Seventh St. SW., Washington, DC 20590. (202) 366-4488.

SUPPLEMENTARY INFORMATION: This document corrects editorial errors contained in a final rule published under Docket HM-189H on September 29, 1989 [54 FR 40066], and in a corrections document published on October 10, 1989 [54 FR 41447]. The following is a section-by-section summary of the corrections:

Section 172.101

In § 172.101, the Hazardous Materials Table, beginning on page 40068, is amended by adding the wording "Keep dry", in column (7)(c) for the entry "mono-(Trichloro) tetra-(monopotassium dichloro)-penta-s-triazinetrione, dry (containing over 39% available chlorine)". In the correction document, the entry "Sulfur, molten" was corrected by reinstating the alternative spelling, "Sulphur, molten". However, in the entry "Sulfur, molten or Sulphur, molten", the word "or" did not appear in italics to show that either term is acceptable. The entry is corrected to read "Sulfur, molten *or* Sulphur, molten" in this document. Also, in the final rule, the identification number prefix for the entry "Sulfur, molten *or* Sulphur, molten" was inadvertently changed from "UN" to "NA". The prefix is corrected to read "UN" in this document.

Section 178.115-6

The final rule inadvertently cited the table in "paragraph (b) of § 178.115-3". The table is correctly located in paragraph (b) of § 178.115-6. Therefore, in the table in § 178.115-6(b), the third entry under the column entitled "Gauge No." is amended by revising "30" to read "20".

List of Subjects

49 CFR Part 172

Hazardous materials transportation, Hazardous materials table.

49 CFR Part 178

Hazardous materials transportation, Packaging and containers.

In consideration of the foregoing, 49 CFR part parts 172 and 178 are amended as follows:

PART 172—HAZARDOUS MATERIALS TABLES AND HAZARDOUS MATERIALS COMMUNICATIONS REGULATIONS

1. The authority citation for part 172 continues to read as follows:

Authority: 49 U.S.C. App. 1803, 1804, 1808; 49 CFR part 1.

§ 172.101 [Amended]

2. In § 172.101, the Hazardous Materials Table is amended by correctly amending the entries listed below:

a. For the entry "mono-(Trichloro) tetra-(monopotassium dichloro)-penta-s-triazinetrione, dry (containing over 39% available chlorine)", the words "Keep dry" are added in Column (7)(c).

b. The entry "Sulfur, molten or Sulphur, molten" is correctly revised to read "Sulfur, molten *or* Sulphur, molten" in column (2), and the identification prefix is correctly revised to read "UN" in column (3A).

PART 178—SHIPPING CONTAINER SPECIFICATIONS

3. The authority citation for part 178 continues to read as follows:

Authority: 49 App. U.S.C. 1803, 1804, 1805, 1806, 1808; 49 CFR part 1, unless otherwise noted.

§ 178.115-6 [Correctly Amended]

4. In amendatory instruction

paragraph 25, on page 40069, in the Federal Register of September 29, 1989, the words "paragraph (b) of § 178.115–3" are corrected to read "paragraph (b) of § 178.115–6".

Issued in Washington, DC on December 5, 1989 under authority delegated in 49 CFR 1.53.

Travis P. Dungan,

Administrator.

[FR Doc. 89–28806 Filed 12–11–89; 8:45 am]

BILLING CODE 4910–60–M

Proposed Rules

Federal Register
Vol. 54, No. 237
Tuesday, December 12, 1989

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 61

Low-Level Radioactive Waste Disposal Facility; Availability of Publication Concerning Application of Quality Assurance for Characterizing a Radioactive Waste Disposal Site

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft for comment.

SUMMARY: The Nuclear Regulatory Commission (NRC) is announcing the availability of NUREG–1383 "Guidance on the Application of Quality Assurance for Characterizing a Low-Level Radioactive Waste Disposal Site" which provides guidance to an applicant in meeting the low-level radioactive waste (LLRW) disposal facility quality assurance requirements in 10 CFR Part 61.

DATES: The comment period expires January 31, 1990.

ADDRESSES: Copies of NUREG–1383, may be purchased by calling the U.S. Government Printing Office on (202) 275–2060 or 2171 or by writing to the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013–7082.

FOR FURTHER INFORMATION CONTACT: Clayton L. Pittiglio, Jr., Division of Low-Level Waste Management and Decommissioning, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: (301) 492–3438.

SUPPLEMENTARY INFORMATION: This document provides guidance to an applicant in meeting the quality control (QC) requirements of 10 CFR 61.12(j). The regulation requires that a license application for an LLW disposal facility include a description of the QC program to be applied to determining the proposed characteristics of the disposal site. The regulation also requires a QC program during design, construction, operation, and closure of the land disposal facility and the receipt, handling, and emplacement of waste. Audits and managerial controls must be included in the QC program. The purpose of the managerial controls, audits and QC program required by 10 CFR 61.12(j) is to ensure a planned, organized, and documented approach to meeting the performance objectives and the technical requirements of 10 CFR part 61. The requirements stated in 10 CFR 61.12(j) provide the bases for developing a QA program and the guidance provided.

To ensure that the site meets the regulatory requirements, an applicant should have management controls in place at the beginning of the investigation of the disposal site's characteristics and the analyses to establish a base for its suitability.

Site characterization is one of the initial and most significant activities for determining the suitability of a site and demonstrating performance of an LLRW disposal site. This document provides guidance on developing proper quality assurance procedures for site characterization activities.

Dated at Rockville, Maryland, this 5th day of December, 1989.

For the Nuclear Regulatory Commission

Michael J. Bell,

Chief, Division of Low-Level Waste Management and Decommissioning, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 89–28964 Filed 12–11–89; 8:45 am]
BILLING CODE 7590–01–M

10 CFR Part 71

RIN 3150—AC41

Transportation Regulations; Compatibility With the International Atomic Energy Agency (IAEA); Designation of End of Public Comment Period

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule: Designation of end of comment period.

SUMMARY: On June 8, 1988 (53 FR 21550), the Nuclear Regulatory Commission (NRC) published, for public comment, a proposed rule to make its transportation regulations in 10 CFR part 71 compatible with those of the International Atomic Energy Agency (IAEA) as contained in IAEA Safety Series No. 6, Regulations for the Safe Transport of Radioactive Material, 1985 edition. This rulemaking action, combined with a parallel action by the Department of Trnasportation (DOT), would make United States regulations for the safe transportation of radioactive material internationally compatible. Because it is important that the public have the opportunity to review and comment on the DOT and NRC proposed rules concurrently, NRC set its initial public comment period to expire on October 6, 1988, expecting the DOT rule to be available for publication by the end of June 1988. Due to delays in publishing the DOT proposed rule, the NRC published a notice on April 4, 1989, (54 FR 13528) in the Federal Register that NRC was extending its comment period to expire 60 days after the DOT proposed rule was published in the Federal Register. Furthermore, it was stated that when the DOT rule was published, the NRC would issue another notice which would include a specific date when the NRC comment period would expire. The DOT proposed rule has now been published in the Federal Register (54 FR 47454; November 14, 1989) with a public comment period expiring on February 9, 1990. To permit the NRC public comment period to run concurrently with that of the DOT, the NRC public comment period will expire on February 9, 1990.

DATES: The public comment period expires on February 9, 1990. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given as to comments received on or before this date.

ADDRESSES: Send comments to the Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, ATTN: Docketing and Service Branch. Hand deliver comments to 11555 Rockville Pike, Rockville, MD between 7:30 a.m. and 4:15 p.m. Examine comments received at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Donald R. Hopkins, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washignton, DC 20555, telephone (301) 492–3784.

Dated at Rockville, Maryland, this 6th day of December 1989.

For the Nuclear Regulatory Commission.
James M. Taylor,
Executive Director for Operations.
[FR Doc. 89-28965 Filed 12-11-89; 8:45 am]
BILLING CODE 7590-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 89-ANE-37]

Airworthiness Directives; Air Cruisers Company, TSO-C69a Emergency Evacuation Slide/Rafts System P/N D30659-( )

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt an Airworthiness Directive (AD) that would require relocation of the slide/raft life line on Air Cruisers Company TSO-C69a Emergency Evacuation Slide/Raft System, P/N D30659-( ), installed on Boeing Model 757 series airplanes. The proposed AD is needed to prevent the life line from being ingested into the aspirator during inflation. This could result in damage to the aspirator and prevent complete inflation of the slide/raft which could hinder the emergency evacuation of the airplane.

DATES: Comments must be received on or before January 31, 1990.

ADDRESSES: Comments on the proposal may be mailed in duplicate to Federal Aviation Administration, New England Region, Office of the Assistant Chief Counsel, Attn: Rules Docket No. 89-ANE-37, 12 New England Executive Park, Burlington, Massachusetts 01803, or delivered in duplicate to Room 311 at the above address.

Comments delivered must be marked: "Docket No. 89-ANE-37".

Comments may be inspected at the above location in Room 311, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

The applicable technical information may be obtained from Air Cruisers Company, P.O. Box 180, Belmar, New Jersey 07719-0180, or may be examined in the Regional Rules Docket.

FOR FURTHER INFORMATION CONTACT: Mr. Andrew Gfrerer, Aerospace Engineer, New York Aircraft Certification Office, Systems and Equipment Branch, ANE-173, Federal Aviation Administration, Engine and Propeller Directorate, Aircraft Certification Service, 181 South Franklin Avenue, Room 202, Valley Stream, New York 11581; telephone (516) 791-6427.

SUPPLEMENTARY INFORMATION: Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the FAA before any final action is taken on the proposed rule. The proposal contained in this notice may be changed in the light of comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Regional Rules Docket New England Region, Office of the Assistant Chief Council, Room 311, Burlington, Massachusetts 01803, for examination by interested persons. A report summarizing each FAA-public contact, concerned with the substance of the proposed AD, will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: Comments to Docket No. 89-ANE-37. The postcard will be date/time stamped and returned to the commenter.

The FAA has determined that the life line on Air Cruisers Company Emergency Evacuation Slide/Raft System, P/N D30659-( ), could be ingested into the lower tube aspirator during the initial inflation stage which could affect proper inflation and hinder the emergency evacuation of the airplane. During two Boeing Commercial Airplane Company slide/raft deployment tests, the slide/raft located on the left hand side at door 4 of a Boeing Model 757 series airplane failed to inflate properly. It was determined that this was caused by the life line webbing located on the lower tube aspirator side of the slide/raft forming an unrestrained loop when the slide/raft is folded. During the initial stages of inflation, the loop can be sucked into the lower tube aspirator. This action can damage the aspirator subsequently preventing the inflation of the lower tube, which could hinder the emergency evacuation of the airplane. Air Cruisers Company has issued Service Bulletin (SB) No. 105-25-30, Rev. 1, dated August 21, 1989, which addresses this problem. Since this condition is likely to exist or develop on other slide/rafts of the same design, the proposed AD would require relocation of the life line, and the re-identification of the slide-raft in accordance with Air Cruisers Company SB No. 105-25-30, Rev. 1, dated August 21, 1989, on Air Cruisers Company TSO-C69a Emergency Evacuation Slide/Raft System, P/N D30659-( ).

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this proposed regulation only involves 241 slide/rafts. One manhour labor is required for the accomplishment of this AD for each slide/raft, at a cost of $40 each. Parts will be supplied by Air Cruisers at no cost. Therefore, I certify that this action (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal; and (4) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, and Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 of the Federal Aviation Regulations (FAR) as folows:

PART 39—[AMENDED]

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421, and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended

2. Section 39.13 is amended by adding the following new airworthiness directive (AD):

Air Cruisers Company: Applies to Air Cruisers Company TSO-C69a Emergency Evacuation Slide/Raft System, P/N D30659-( ), installed on Boeing Model 757 airplanes, as listed below:

Slide/Raft System, P/N D30659-108, having Slide/Raft Assembly P/N D30656-106 (pre Service Bulletin (SB) 105-25-17);

Slide/Raft System, P/N D30659-109 and -112, having Slide/Raft Assemblies P/N D30656-118 and -115 respectively (post SB 105-25-17 and pre SB 105-25-27);

Slide/Raft System, P/N D30659-115 and -118, having Slide/Raft Assemblies P/N D30656-115 and -118 respectively (post SB 105-25-27 and pre SB 105-25-29);

Slide/Raft System, P/N D30659-121 and -124, having Slide/Raft Assemblies P/N D30656-121 and -124 respectively (post SB 105-25-29).

The above listed slide/raft assemblies bear the following serial numbers (S/N): 0001 through 0233, 0160MOD, 0164MOD, 0165MOD, 0205MOD, 0207MOD, 0225MOD, 0226MOD, and 0230MOD.

Compliance with the requirements of AD 89-19-06, Amendment 39-6321, published in the Federal Register on September 15, 1989 (54 FR 38209), is required prior to compliance with the requirements of this AD.

Compliance is required within 18 months after the effective date of this AD, unless already accomplished.

To prevent ingestion of the life line, which could hinder the emergency evacuation of the airplane, accomplish the following:

(a) Modify and re-identify the slide/raft in accordance with Paragraph 2 (Accomplishment Instructions) of Air Cruisers Company SB No. 105-25-30, Rev. 1, dated August 21, 1989.

(b) Aircraft may be ferried in accordance with the provisions of FAR 21.197 and 21.199 to a base where the AD can be accomplished.

(c) Upon submission of substantiating data by an owner or operator through an FAA Airworthiness Inspector, an alternate method of compliance with the requirements of this AD or adjustment to the compliance schedule specified in this AD may be approved by the Manager, New York Aircraft Certification Office, Federal Aviation Administration, Engine and Propeller Directorate, Aircraft Certification Service, 181 South Franklin Avenue, Valley Stream, New York 11581 may adjust the compliance time specified in this AD.

Issued in Burlington, Massachusetts, on November 27, 1989.

Jack A. Sain,

Manager, Engine and Propeller Directorate Aircraft Certification Service.

[FR Doc. 89-28938 Filed 12-11-89; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 133

Proposed Removal of Customs Regulation on Gray Market Goods

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: A recent decision of the U.S. Supreme Court invalidated a portion of § 133.21(c)(3) of the Customs Regulations (19 CFR 133.21(c)(3)) which denied protection against imported gray market goods where the trademarks or trade name on foreign-made merchandise was applied under authorization received from the U.S. owner. A review of the remaining portion of that provision has caused Customs to propose eliminating the provision in its entirety.

DATE: Comments must be received on or before February 12, 1990.

FOR FURTHER INFORMATION CONTACT: John F. Atwood, Value, Special Programs and Admissibility Branch, Commercial Rulings Division, Office of Regulations, and Rulings, (202-566-8933).

SUPPLEMENTARY INFORMATION:

Background

The U.S. Supreme Court issued a decision May 31, 1988, invalidating in part § 133.21(c)(3) of the Customs Regulations (19 CFR 133.21(c)(3)), relating to importations of foreign-made "gray market" goods. A "gray market" trademark is a genuine one applied to articles which are not authorized for importation by the owner of the trademark registration in the United States. The Court's opinion, cited as *K Mart Corporation* v. *Cartier, et al.; 47th Street Photo, Inc.* v. *Coalition to Preserve the Integrity of American Trademarks, et al., United States et al.* v. *Coalition to Preserve the Integrity of American Trademarks, et al.*, 486 U.S. 281 (1988) (COPIAT), obliges Customs to implement changes in 19 CFR 133.21

The COPIAT litigation concerned section 526(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1526(a)), which makes it unlawful (with certain exceptions) to import merchandise bearing a registered trademark "* * * owned by a citizen of, or by a corporation or association created or organized within, the United States" if a copy of the trademark registration is filed with the Secretary of the Treasury. The enforcement of this provision has been delegated to the Customs Service. In the implementation of that statute, the Customs Service, through its regulations, took the position that the seizure of articles bearing genuine trademarks was a remedy reserved to independent American firms. This position was based on the Government's view of the statute's legislative history, Customs long-standing practice and express Congressional recognition of that practice.

Section 133.21(c)(1) of the Customs Regulations denies protection against the importation of "gray market" goods where "[b]oth the foreign and the U.S. trademark or trade name are owned by the same person or business entity". Section 133.21(c)(1) similarly denies protection where "[t]he foreign and domestic trademark or trade name owners are parent and subsidiary companies or are otherwise subject to common ownership and control". Both §§ 133.21(c)(1) and 133.21(c)(2) were upheld by the Supreme Court, and Customs will continue its administration of those sections as in the past.

Section 133.21(c)(3) of the Customs Regulations denied protection against imports where "the articles of foreign manufacture bear a recorded trademark or trade name applied under authorization of the U.S. owner". This section dealt with authorized users or licensees. The Court's opinion concluded that § 133.21(c)(3) is not a permissible construction of 19 U.S.C. 1526(a). However, the Court did not rule on whether the regulation is inconsistent with 15 U.S.C. 1124. Accordingly, although § 133.21(c)(3) is clearly invalidated as to 19 U.S.C. 1526(a), it is not so clear that the regulation is invalidated as to 15 U.S.C. 1124. To resolve any remaining ambiguity, and maintain its longstanding practice of interpreting both statutory provisions in tandem, Customs is soliciting comments on its position that § 133.21(c)(3) is invalid as to 15 U.S.C. 1124 as well, and the proposal, accordingly, to delete § 133.21(c)(3) from the Customs regulations. Import protection would thus be accorded against goods of foreign manufacture bearing recorded trademarks and trade names applied under authorization of the U.S. owner.

Comments

Before adopting this proposal, consideration will be given to any written comments (preferably in

triplicate) timely submitted. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4, Treasury Department Regulations (31 CFR 1.4), and § 103.11(b) Customs Regulations (19 CFR 103.11(b)), on normal business days between the hours of 9:00 a.m. and 4:30 p.m. at the Regulations and Disclosure Law Branch, U.S. Customs Service Headquarters, Room 2119, 1301 Constitution Avenue, NW., Washington, DC 20229.

Regulatory Flexibility Act

Pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), it is certified that the amendment will not have a significant impact on a substantial number of small entities. Accordingly, it is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

Executive Order 12291

This document does not meet the criteria for a "major rule" as specified by E.O. 12291. Accordingly, no regulatory analysis has been prepared.

Drafting Information

The principal author of this document was Peter T. Lynch, Regulations and Disclosure Law Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 133

Trademarks, Trade Names, Importations.

Amendments to the Regulations

It is proposed to amend Part 133, Customs Regulations (19 CFR Part 133) as set forth below.

PART 133—TRADEMARKS, TRADE NAMES, AND COPYRIGHTS

1. The authority citation for part 133 is revised to read as follows:

Authority: 17 U.S.C. 101, 601, 602, 603; 19 U.S.C. 66, 1624; 31 U.S.C. 9701.

Section 133.21 also issued under 15 U.S.C. 1124, 19 U.S.C. 1526.

§ 133.21 [Amended]

2. Section 133.21(c) is amended by removing paragraph (c)(3) and by marking it "Reserved."

Michael H. Lane,

Acting Commissioner of Customs

[FR Doc. 89-28995 Filed 12-11-89; 8:45 am]

BILLING CODE 4820-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Part 404

RIN 0960-AC46

Reduction for Receipt of Government Pension

AGENCY: Social Security Administration, HHS.

ACTION: Proposed rules.

SUMMARY: In this proposed regulation, we are revising our rules on reducing the Social Security benefits of a worker's spouse who is also receiving a Government pension. Essentially, the revised rules require that an employee of the Federal Government who elects to be covered under Social Security after December 31, 1987, must work in covered Federal employment for at least 5 years after that date in order to avoid the reduction in his or her Social Security benefits as the spouse of a worker. This provision was added to the Social Security Act by section 9007 of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100-203), and was amended by section 8014 of the Technical and Miscellaneous Revenue Act of 1988 (Pub. L. 100-647).

DATES: To be sure that your comments are considered we must receive them no later than February 12, 1990.

ADDRESSES: Comments should be submitted in writing to the Commissioner of Social Security, Department of Health and Human Services, P.O. Box 1585, Baltimore, MD 21235, or delivered to the Office of Regulations, Social Security Administration, 3-B-1 Operations Building, 6401 Security Boulevard, Baltimore, MD 21235, between 8:00 a.m. and 4:30 p.m. on regular business days. Comments received may be inspected during these same hours by making arrangements with the contact person shown below.

FOR FURTHER INFORMATION CONTACT: Jack Schanberger, Room 3-B-1 Operations Building, 6401 Security Boulevard, Baltimore, MD 21235, (301) 965-8471.

SUPPLEMENTARY INFORMATION: The first half of this section provides information on recent changes in Social Security coverage of Federal Government employees. The last half explains provisions of this proposed rule.

The Social Security Amendments of 1977 (Pub. L. 95-216) amended section 202 of the Social Security Act (the Act) by requiring a dollar-for-dollar reduction of the Social Security benefits of a worker's spouse who is also receiving a Government pension based on work that was not covered by Social Security on the last day of Government employment. That amendment also provided exceptions to the reduction. Subsequent amendments to the Act added other exceptions and changed the rate of the reduction. These provisions are explained in 20 CFR 404.408a.

Before enactment of the Social Security Amendments of 1983 (Pub. L. 98-21), most employees of the Federal Government were not covered by Social Security. The 1983 Amendments extended Social Security coverage beginning January 1, 1984, to Federal employees hired after December 31, 1983, who prior to the Amendments would have been covered only by the Civil Service Retirement System (CSRS) or the Foreign Service Retirement and Disability System; to employees of the legislative branch of the Federal Government who were not participating in CSRS as of December 31, 1983; to Congress, the President, and the Vice President; and to sitting Federal judges and senior executive service employees.

After the Social Security Amendments of 1983 became effective, there were still many Federal employees covered by CSRS and not covered by Social Security. The Federal Employees' Retirement System (FERS) Act of 1986 (Pub. L. 99-335) provides that these employees could elect to transfer to FERS, and thus be covered by Social Security, during the open season period from July 1, 1987, through December 31, 1987. Similarly, foreign service employees could elect to enroll in the Foreign Service Pension System (FSPS) and thus be covered by Social Security. Federal employees who are automatically covered by Social Security and those who elected coverage by transferring to FERS or FSPS were not affected by the reduction requirement of 20 CFR 404.408a, because they would not have been working in noncovered employment on the last day of their employment.

However, section 9007 of the Omnibus Budget Reconciliation Act (OBRA) of 1987 (Pub. L. 100-203) amended section 202 (b), (c), (e), (f), and (g) of the Act to provide that the reduction required because of the receipt of a pension from noncovered employment applies to Federal employees who elected FERS after December 31, 1987. This reduction does not apply if the employee worked in covered Federal employment for a total of at least 60 months during the period from January 1, 1988, through the end of the month in which he or she first

became eligible for and applied for Social Security spouse's benefits.

The 1987 OBRA similarly amended section 202 of the Act to provide that legislative branch employees who elected Social Security coverage by withdrawing from CSRS after December 31, 1983, but did not receive a lump-sum payment of their CSRS contributions until after December 31, 1987, would have their Social Security spouse's benefits reduced because of the receipt of a pension from noncovered employment. The reduction does not apply if the employee meets a special condition of the 1987 OBRA. That condition is that a former employee who received the lump-sum payment after December 31, 1987, will not have his or her benefits reduced if he or she worked in covered Federal Employment for a total of at least 60 months during the period from January 1, 1988, through the end of the month in which he or she first became eligible for and applied for Social Security spouse's benefits. Also, employees of the legislative branch whose CSRS coverage had ceased after December 31, 1987 (other than by receipt of a lump-sum payment), but who continued their employment, will not be subjected to the reduction if they meet the same 60 months of covered work requirement.

More recently, the Technical and Miscellaneous Revenue Act of 1988 (Pub. L. 100-647) (TAMRA) further amended section 202 (b), (c), (e), (f), and (g) of the Social Security Act to provide that the reduction requirement of section 202 of the Social Security Act, as amended by the 1987 OBRA, also applies to Federal employees who elected FSPS after December 31, 1987, unless the 60 months of work requirement is met. In addition, TAMRA also amended section 205(p)(1) of the Social Security Act so that we will no longer look to the person's employer or pension-paying agency for a decision on whether his or her employment was covered and the periods of covered employment. If, however, we determine that the person's Federal employment was covered because the person elected to join FERS or FSPS, we will need to know from the employer or pension-paying agency the date of the election and its effective date.

We are proposing to revise 20 CFR 404.408a by listing the kinds of Federal employment to which the reduction provision of this section applies. In the revised section, we are adding the rules needed to implement section 9007 of Public Law 100-203 and section 8014 of Public Law 100-647, in addition to specifying the kinds of Federal employment that continue to be cause for the reduction. We also state that we will accept the statement of a person's employer or pension-paying agency as to the date the person elected FERS or FSPS.

Regulatory Procedures

Executive Order 12291

The Secretary has determined that this is not a major rule under Executive Order 12291 because the regulations do not meet any of the threshold criteria for a major rule. These changes are expected to result in negligible costs or savings. Therefore, a regulatory impact analysis is not required.

Regulatory Flexibility Act

We certify that these regulations will not, if promulgated, have a significant economic impact on a substantial number of small entities because they affect only the benefit amount payable to individuals. Therefore, a regulatory flexibility analysis as provided in Pub. L. 96-354, the Regulatory Flexibility Act, is not needed.

Paperwork Reduction Act

These regulations impose no new reporting/recordkeeping requirements needing Office of Management and Budget clearance.

(Catalog of Federal Domestic Assistance Programs Nos. 13.803 Social Security—Retirement Insurance; 13.805 Social Security—Survivors Insurance)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure; Death benefits; Disability benefits; Old-Age, Survivors, and Disability Insurance.

Dated: October 23, 1989.

Gwendolyn S. King,

Commissioner of Social Security.

Approved: November 16, 1989.

Louis W. Sullivan,

Secretary of Health and Human Services.

For the reasons set out in the preamble, subpart E of part 404 of 20 CFR chapter III is proposed to be amended as follows:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE

1. The authority citation for subpart E continues to read as follows:

Authority: Secs. 202, 203, 204 (a) and (e), 205(a), 222(b), 223(e), 224, 227, and 1102 of the Social Security Act; 42 U.S.C. 402, 403, 404 (a) and (e), 405(a), 422(b), 423(e), 424, 427, and 1302.

2. Section 404.408a is revised to read as follows:

§ 404.408a Reduction where spouse is receiving a Government pension.

(a) *When reduction is required.* Unless you meet one of the exceptions in paragraph (c) of this section, your monthly Social Security benefits as a wife, husband, widow, widower, mother, or father will be reduced each month you are receiving a monthly pension from a Federal, State, or local government agency (Government pension) for which you were employed in work not covered by Social Security on the last day of such employment. Once the reduction is applied, your monthly Social Security benefit as a spouse will continue to be reduced because of your Government pension even if you afterwards return to work for a Government agency and that work is covered by Social Security. If the Government pension is not paid monthly or is paid in a lumpsum, we will determine how much the pension would be if it were paid monthly and then reduce the monthly Social Security benefit accordingly. The number of years covered by a lump-sum payment, and thus the period when the Social Security benefit will be reduced, will generally be clear from the pension plan. If one of the alternatives to a lump-sum payment is a life annuity, and the amount of the monthly benefit for the life annuity can be determined, the reduction will be based on that monthly benefit amount. Where the period or the equivalent monthly pension benefit is not clear, it may be necessary for us to determine the reduction period on an individual basis.

(b) *Federal employment to which the reduction applies.* In determining whether your Federal employment was covered, we will apply the rules in subpart K of this part. If your employment was covered because you elected to join the Federal Employees' Retirement System or the Foreign Service Pension System, we will accept the statement of your employer or pension-paying agency regarding the date of your election and the date it became effective. Your Social Security spouse's benefits may be reduced if on the last day of your employment by the Federal Government:

(1)(i) You were employed by the legislative branch of the Federal Government and either had elected Social Security coverage by receiving a lump-sum payment of your contributions to the Civil Service Retirement System after December 31, 1987, or your Civil Service Retirement System coverage had otherwise ended after December 31, 1987; and

(ii) You were not employed in covered Federal employment for a total of at least 60 months during the period January 1, 1988, up to the end of the first month in which you became eligible for Social Security spouse's benefits and filed an application;

(2) You were covered by Social Security through the Federal Employees' Retirement System (see chapter 84 of title 5, United States Code and 5 CFR part 846) or through the Foreign Service Pension System (see chapter 22 of title I, United States Code) because you elected this coverage after December 31, 1987, and you were not employed in covered Federal employment for a total of at least 60 months during the period from January 1, 1988, up to the end of the first month in which you became eligible for benefits and filed an application;

(3) Your employment was excluded from Social Security coverage by section 210 of the Act; or

(4) You were covered by Social Security for Medicare purposes only.

(c) *Exceptions.* The reduction does not apply:

(1) If you are receiving a Government pension based on employment for an interstate instrumentality;

(2) If you received or are eligible to receive a Government pension for one or more months in the period December 1977 through November 1982 and you meet the requirements for Social Security benefits that were applied in January 1977, even though you don't claim benefits and you don't actually meet the requirements for receiving benefits until a later month. The January 1977 requirements are, for a man, a one-half support test (see paragraph (e) of this section), and, for a woman claiming benefits as a divorced spouse, marriage for at least 20 years to the insured worker. You are considered eligible for a Government pension for any month in which you meet all the requirements for payment, except that you are working or have not applied; or

(3) If you were receiving or were eligible (as defined in paragraph (c)(2) of this section) to receive a Government pension for one or more months before July 1983, and you meet the dependency test of one-half support that was applied to claimants for husband's and widower's benefits in 1977, even though you don't claim benefits, and you don't actually meet the requirements for receiving benefits until a later month. If you meet the exception in this paragraph, but you do not meet the exception in paragraph (c)(2) of this section, December 1982 is the earliest month for which the reduction will not affect your benefits.

(d) *Delayed eligibility for pension.*—If you would have been eligible for a pension in a given month except for a requirement which delayed eligibility for such pension until the month following the month in which all other requirements were met, we will consider you to be eligible in that given month for the purpose of meeting one of the exceptions in paragraphs (c) (2) and (3) of this section. If you meet an exception solely because of this provision, your benefits will be unreduced for months after November 1984 only.

(e) *The one-half support test.* For a man to meet the January 1977 requirements as provided in the exception in paragraph (c)(2) of this section and for a man or woman to meet the exception in paragraph (c)(3) of this section, he or she must meet a one-half support test. One-half support is defined in § 404.366 of this part. One-half support must be met at one of the following times:

(1) If the insured person had a period of disability which did not end before he or she became entitled to old-age or disability insurance benefits, or died, you must have been receiving at least one-half support from the insured either—

(i) At the beginning of his or her period of disability;

(ii) At the time he or she became entitled to old-age or disability insurance benefits; or

(iii) If deceased, at the time of his or her death.

(2) If the insured did not have a period of disability at the time of his or her entitlement or death, you must have been receiving at least one-half support from the insured either—

(i) At the time he or she became entitled to old-age insurance benefits; or

(ii) If deceased, at the time of his or her death.

(f) *Amount and priority of reduction.* (1) If you became eligible for a Government pension after June 1983, we will reduce (to zero, if necessary) your monthly Social Security benefits as a spouse by two-thirds the amount of your monthly pension. If the reduction is not a multiple of 10 cents, we will round it to the next higher multiple of 10 cents.

(2) If you became eligible for a Government pension before July 1983 and do not meet one of the exceptions in paragraph (c) of this section, we will reduce (to zero, if necessary) your monthly Social Security benefits as a spouse by the full amount of your pension for months before December 1984 and by two-thirds the amounts of your monthly pension for months after November 1984. If the reduction is not a multiple of 10 cents, we will round it to the next higher multiple of 10 cents.

(3) Your benefits as a spouse will be reduced, if necessary, for age and for simultaneous entitlement to other Social Security benefits before it is reduced because you are receiving a Government pension. In addition, this reduction follows the order of priority as stated in § 404.402(b).

(4) If the monthly benefit payable to you after the required reduction(s) is not a multiple of $1.00, we will reduce it to the next lower multiple of $1.00 as required by § 404.304(f).

(g) *When effective.* This reduction was put into the Social Security Act by the Social Security Amendments of 1977. It only applies to applications for benefits filed on or after December 1977 and only to benefits for December 1977 and later. The provisions of paragraphs (b) (1) and (2) of this section are effective for benefits for months after December 1987.

[FR Doc. 89-28903 Filed 12-11-89; 8:45 am]
BILLING CODE 4190-11-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 31, and 602

[EE-8-89]

RIN 1545-AN98

Employee Business Expenses—Reporting and Withholding on Employee Business Expense Reimbursements and Allowances

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations portion of this issue of the Federal Register, the Internal Revenue Service is issuing temporary regulations relating to the taxation of and reporting and withholding on employee business expense reimbursements and other expense allowance arrangements. The text of those temporary regulations also serves as the comment document for this notice of proposed rulemaking.

DATE: Written comments and requests for a public hearing must be delivered or mailed before February 12, 1990. The income tax provisions of these rules are effective for taxable years beginning on or after January 1, 1989. The reporting provisions of these rules are effective for payments made under reimbursement or

other expense allowance arrangements on or after January 1, 1989; however, a transition rule is provided for payments made prior to January 1, 1990. The provisions of these rules regarding withholding and payment of employment taxes are effective for payments made under reimbursement or other expense allowance arrangements on or after July 1, 1990.

ADDRESS: Send comments and requests for a public hearing to Internal Revenue Service, Attention: CC:CORP:T:R (EE–8–89), Room 4429, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Richard Pavel at telephone 202–377–9372 (Not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)). Comments on the collection of information should be sent to the Office of Management and Budget, Paperwork Reduction Project, (1545–1148), Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer T:FP, Washington, DC 20224.

The collection of information in this regulation is in § 1.62–2T. This information is required by the Internal Revenue Service to comply with section 62(c) of the Internal Revenue Code. This information will be used to determine whether amounts paid under a reimbursement or expense allowance arrangement are treated as paid under an accountable plan. The likely recordkeepers are individual employees. These estimates are an approximation of the average time expected to be necessary for a collection of information. They are based on such information as is available to the Internal Revenue Service. Individual recordkeepers may require greater or less time, depending on their particular circumstances. Estimated total annual burden per recordkeeper is 30 minutes.

Estimated number of recordkeepers: 1,419,456.

Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) under sections 62, 162, 274, and 6041 of the Internal Revenue Code and to the Employment Tax Regulations (26 CFR part 31) under sections 3121, 3231, 3306, and 3401 of the Internal Revenue Code.

The temporary regulations contain rules concerning the taxation of and reporting and withholding on payments with respect to employee business expenses under a reimbursement or other expense allowance arrangement. For the text of the temporary regulations, see T.D. 8276 published in the Rules and Regulations portion of this issue of the **Federal Register**. The preamble to the temporary regulations explains the regulations.

Special Analyses

It has been determined that these proposed rules are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and, therefore, an initial Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations will be submitted to the Administrator of the Small Business Administration for comment on their impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted, consideration will be given to any written comments that are submitted (preferably eight copies) to the Internal Revenue Service. All comments will be available for public inspection and copying. A public hearing will be held upon written request to the Internal Revenue Service by any person who also submits written comments. If a public hearing is held, notice of the time and place will be published in the Federal Register.

Drafting Information

The principal author of these regulations is Richard Pavel of the Office of the Assistant Chief Counsel (Employee Benefits and Exempt Organizations), Internal Revenue Service. However, personnel from other offices of the Service and Treasury Department participated in their development.

Fred T. Goldberg,

Commissioner of Internal Revenue

[FR Doc. 89–28942 Filed 12–7–89; 12:02 pm]

BILLING CODE 4830–01–M

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 9

[Notice No. 693]

Revision of The Boundary of the Chalk Hill Viticultural Area (88F–283P)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Bureau of Alcohol, Tobacco and Firearms (ATF), is considering revising the northern boundary of Chalk Hill viticultural area to include the portion of Chalk Hill Road north of Chalk Hill. The proposed boundary would create a new area of overlap with the Alexander Valley viticultural area. This proposal is the result of a petition submitted by Mr. T. Clifford Melim, Jr., of Chalk Hill Vineyards.

ATF believes that the establishment of viticultural areas and the subsequent use of viticultural area names as appellations of origin in wine labeling and advertising will help consumers identify the wines they may purchase. the establishment of viticultural areas also allows wineries to further specify the origin of wines they offer for sale to the public. ATF will approve a proposed viticultural area if the area satisfies the criteria of name, historical or current evidence concerning boundaries, and evidence relating to geographical features and climate. When overlapping viticultural areas are proposed, each area must meet the same requirements concerning the area's proposed name and the presence of distinguishing geographical characteristics.

DATE: Written comments must be received by January 26, 1990.

ADDRESS: Send written comments to: Chief, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 385, Washington, DC 20044–0385 (Notice No. 693). Copies of the petition, the proposed regulations, the appropriate maps, and written comments will be available for public inspection during normal business hours at: ATF Reading Room, Disclosure Branch, Room 4412, Ariel Rios Federal Building, 1200 Pennsylvania Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: David W. Brokaw, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms, Ariel Rios Federal Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20226, (202) 566–7626.

SUPPLEMENTARY INFORMATION:

Background

On August 23, 1978, ATF published Treasury Decision ATF-53 (43 FR 37672, 54624) revising regulations in 27 CFR, part 4. These regulations allow the establishment of definite viticultural areas. On October 2, 1979, ATF published Treasury Decision ATF-60 (44 FR 56692) which added a new part 9 to 27 CFR, providing for the listing of approved American viticultural areas, the names of which may be used as appellations of origin.

Section 4.25a(e)(1), title 27, CFR defines an American viticultural area as a delimited grape-growing region distinguished by geographical features, the boundaries of which have been recognized and defined in subpart C of part 9.

Section 4.25a(e)(2), title 27, CFR, outlines the procedure for proposing an American viticultural area. Any interested person may petition AFT to establish a grape-growing region as a viticultural area. The petition should include;

(a) Evidence that the name of the proposed viticultural area is locally and/or nationally known as referring to the area specified in the petition;

(b) Historical or current evidence that the boundaries of the viticultural area are as specified in the petition;

(c) Evidence realting to the geographical characteristics (climate, soil, elevation, physical features, etc.) which distinguish the viticultural features of the proposed area from surrounding areas;

(d) A description of the specific boundaries of the viticultural area, based on features which can be found on United States Geological Survey (U.S.G.S.) Maps of the largest applicable scale; and

(e) A copy or copies of the appropriate U.S.G.S. Map(s) with the proposed boundaries prominently marked.

Establishment of the Viticultural Areas

With the issuance of T.D. ATF-155 on October 21, 1983 and T.D. ATF-187 on October 24, 1984, ATF established, respectively, the Chalk Hill and the Alexander Valley viticultural areas in Sonoma County, California. On August 26, 1986, ATF issued T.D. ATF-233 which made several revisions to the boundary of the Alexander Valley viticultural area including the extension of the southern leg of the boundary to include the Digger Bend area east of Healdsburg. On May 13, 1988, ATF issued T.D. ATF-272 which revised the bundary common to the Alexander Valley and Chalk Hill viticultural areas so that vineyards immediately within the north-central leg of the boundary of the Chalk Hill viticultural area would be relocated to the southeastern corner of the Alexander Valley viticultural area.

Petition

The petition submitted by T. Clifford Melim, Jr., of Chalk Hill Vineyards seeks to revise the northern boundary of Chalk Hill viticultural area to include the portion of Chalk Hill Road north of Chalk Hill. It is not the petitioner's intention to remove the area in question from the Alexander Valley Viticultural Area. The proposed boundary would create a new area of overlap with the Alexander Valley viticultural area. This area has been called the "Chalk Hill Area of Alexander Valley." When revised to include this area, the boundary of the Chalk Hill viticultural area would follow the common boundary between Alexander Valley and Knights Valley north to Highway 128, then follow Highway 128 west to its intersection with Chalk Hill Road, then follow a straight line southwest to the point where the current boundary of Chalk Hill leaves the Russian River.

The petitioner provided several letters from vintners and winemakers indicating that the Chalk Hill area of Alexander Valley is a district transitional area of overlap between the Chalk Hill and Alexander Valley viticultural areas. The area in question has features common to both.

The realigned boundary proposed in the petition would add roughly 3,450 acres of territory and 500 acres of vineyards to the Chalk Hill viticultural area.

Evidence Concerning the Name

The southernmost portion of Alexander Valley is known as "the Chalk Hill area of Alexander Valley" due to its proximity to Chalk Hill, its dependence on Chalk Hill Road as its main access, and its physical similarities to the entire region associated with the name Chalk Hill. The Healdsburg Quadrangle of the 7.5 minute series U.S.G.S. maps labels the portion of Chalk Hill Road north of the Chalk Hill area as "Alexander Valley." Cyrus Alexander's first settlement was located in or near this area.

No district of Sonoma County is designated "Chalk Hill" on any local road map or U.S.G.S. Quadrangle. As a place name, the term is used locally to refer to the hilly region east of Windsor and Healdsburg. Each of these post offices serves a portion of the Chalk Hill area. The region is named after the landmark Chalk Hill and the road of the same name which traverses it. The petition for the establishment of the Chalk Hill viticultural area described the general features (elevation, climate, soil) that characterize the region.

The petitioner provided several illustrations of this area's association with the name "Chalk Hill," for example:

A. Popular Name Among Local Residents

One third of the total length of Chalk Hill Road lies north of Chalk Hill and outside of the current Chalk Hill viticultural area. The petitioner states that there seem to be more references to Chalk Hill north of this dividing line than along the more southerly two-thirds. An example of this is a residential subdivision called "Chalk Hill Estates," in the "Chalk Hill area" of Alexander Valley. Other examples are cited as well.

B. Views of The Original Chalk Hill Petitioners

As Mr. Byrd of Balverne winery and vineyards stated in his declaration attached to the petition, the original Chalk Hill appellation committee believed that the natural boundaries of the Chalk Hill viticultural area extended the entire length of Chalk Hill Road. The petitioner states that the portion north of Chalk Hill was not included in their original proposal only because of doubts regarding the acceptability to ATF of a partial overlap with the proposed Alexander Valley viticultural area.

C. Illustrated On Sonoma County Planning Department Map

Attached to the petition is a copy of a map entitled "Franz Valley Study Planning Units," prepared in September 1978 as part of the Franz Valley Specific Plan. This plan was developed and endorsed by a study team of the Sonoma Country Community and Environmental Services, together with a large committee of local citizens. This map clearly shows a "Chalk Hill" planning area that extends along Chalk Hill Road all the way to Highway 128. (The only portion of Chalk Hill Road omitted is the southermost end. Because the focus of the study was the Franz Valley/Knights Valley general area, the map does not extend west of Chalk Hill Road.)

D. Promoted In Real Estate Advertisement

A real estate brochure attached to the petition lists the first notable feature of a ranch adjacent to an Alexander Valley vineyard as, "95 acres of premiere property located in Sonoma County's most prestigous wine country—the Chalk Hill region of Alexander Valley."

Geographical Evidence

Climate

The fact that the climate of the Alexander Valley grows gradually warmer toward the north was one of the conclusions reached during the original Alexander Valley rulemaking process. This recognized phenomenon implies that the coolest, southern and of the Alexander Valley is transitional between the climate of Chalk Hill viticultural area and the increasingly warmer climate of the rest of Alexander Valley. Degree days listed in the petition show the similarity between the temperature of Chalk Hill and of the petitioned overlap area.

Geology

The geology of the area of proposed overlap represents a transitional area between the Chalk Hill viticultural area and the Alexander Valley viticultural area. The map, "Geology of Chalk Hill viticultural area and Southern Alexander Valley Viticultural Area," enclosed with the petition, illustrates this point.

The map shows a patchwork of geological formations in the area depicted. Although many different formations are represented, it is notable that the Huichica formation is by far the most dominant geological feature of Chalk Hill viticultural area. Along small streams and at lower elevations there is also a significant amount of newer alluvial deposits (marked "Alluvium") present.

The Huichica Formation continues to dominate as one crosses into the southern end of Alexander Valley. Along with areas of Alluvium, this formation is prevalent up to Highway 128. Beyond the proposed area of overlap, the Huichica Formation appears only infrequently, and the alluvial formation that characterizes most of the Alexander Valley becomes the outstanding feature.

Topography

The topography of the area of proposed overlap is transitional between the Alexander Valley and Chalk Hill viticultural areas. The terrain of the area in question is characterized by steep to gentle hills of low (up to around 400 feet) elevation set close to modest expanses of relatively flat alluvial lands along the Russian River, Franz Creek, and Maacama Creek.

The topography in large portions of the Chalk Hill viticultural area is quite rugged. There are, however, several places along Chalk Hill Road, south of Chalk Hill, where the terrain briefly levels out and soils become deeper. In the southern and western portions of the Chalk Hill viticultural area, as in the Chalk Hill area of Alexander Valley, the terrain becomes rolling foothills and—below approximately 200 feet elevation—is even more level than the area of proposed overlap.

Soils

The same light colored soils as in the current Chalk Hill viticultural area are visible in the cut banks along Chalk Hill Road to the north beyond Chalk Hill (the northernmost boundary of the current Chalk Hill viticultural area). The same terrain—primarily steep to rolling hills, with occasional relatively flat areas—predominates. These similarities give some indication as to why the southernmost end of Alexander Valley has been described as the "Chalk Hill area of Alexander Valley." The most common soil types found in the Chalk Hill viticultural area are the Arbuckle gravelly sandy loam, Haire gravelly loam, Huichica loam, Spreckels loam, Felta very gravelly loam, Laniger loam and Dibble clay loam. Many of these soils are light colored and/or have light colored subsoils that account for the characteristic appearance of "white"soil in the appellation. The Laniger, Felta, Spreckels, and Huichica soils are volcanic in origin.

The most widespread soils in Alexander Valley viticultural area are Cole clay loam, Cortina very gravelly loam, Pleasanton gravelly loam, Yolo sandy loam, Manzanita gravelly silt loam, and Zamora silty clay loam. In the area of proposed overlap the most prevalent soils are Haire gravelly loam, Laniger loam, and Arbuckle gravelly sandy loam. There are smaller amounts of Yolo, Cortina and other soils. Toward the northern end of the proposed Chalk Hill extension Clough gravelly loam becomes prevalent. This pattern gives way to the more characteristic Alexander Valley soil northwest of highway 128.

Regulatory Flexibility Act

It is hereby certified that this regulation will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required because the proposal, if promulgated as a final rule, is not expected (1) to have secondary, or incidental effects on a substantial number of small entities; or (2) to impose, or otherwise cause a significant increase in the reporting, recordkeeping, or other compliance burdens on a substantial number of small entities.

Executive Order 12291

It has been determined that this document is not a major regulation as defined in E.O. 12291 and a regulatory impact analysis is not required because it will not have an annual effect on the economy of $100 million or more; it will not result in a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies or geographical regions; and it will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1980, Pub. L. 96–511, 44 U.S.C. chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this notice because no requirement to collect information is proposed.

Public Participation—Written Comments

ATF requests comments from all interested persons. Comments received on or before the closing date will be carefully considered. Comments received after that date will be given the same consideration if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before the closing date.

AFT will not recognize any material in comments as confidential. Comments may be disclosed to the public. Any material which the commenter considers to be confidential or inappropriate for disclosure to the public should not be included in the comments. The name of the person submitting a comment is not exempt from disclosure.

Any interested person who desires an opportunity to comment orally at a public hearing on the proposed regulations should submit his or her request, in writing to the Director within the 45-day comment period. The Director, however, reserves the right to determine, in light of all circumstances, whether a public hearing will be held.

Drafting Information

The principal author of this document is David W. Brokow, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects in 27 CFR Part 9

Administrative practice and procedure, Consumer protection, Viticultural areas, Wine.

Authority and Issuance

27 CFR part 9, American Viticultural Areas, is amended as follows:

PART 9—[AMENDED]

Paragraph 1. The authority citation for part 9 continues to read as follows:

Authority: 27 U.S.C. 205.

Par. 2. Section 9.52(b) is revised to read as follows:

§ 9.52 Chalk Hill.

* * * * *

(b) *Approved maps.* The appropriate maps for determining the boundaries of the "Chalk Hill" viticultural area are 4 U.S.G.S. Quadrangle (7.5 Minute Series) maps titled:

"Mark West Springs Quadrangle, California," 7.5 minute series, 1958 (Photoinspected 1978).

"Mt. St. Helena Quadrangle, California," 7.5 minute series, 1959 (Photoinspected 1973).

"Healdsburg Quadrangle, California-Sonoma Co.," 7.5 minute series, 1955 (Photorevised 1980).

"Jimtown Quadrangle, California-Sonoma Co.," 7.5 minute series, 1955 (Photorevised 1975).

* * * * *

Par. 3. Section 9.52 is amended by removing paragraph (c) (12) through (22), adding new paragraphs (c) (12), (13), and (14), and redesignating paragraphs (c) (23), through (30) as (c) (15) through (22) respectively to read as follows:

* * * * *

(c) *Boundary* * * *

* * * * *

(12) Then northerly along the east line of sections 21, 16, and 9 to the place where Highway 128 crosses the east line of Section 9 on the "Mount St. Helena Quadrangle," map;

(13) Then generally westerly along Highway 128 to its intersection with Chalk Hill Road on the "Jimtown Guadrangle," map;

(14) Then southwesterly in a straight line to the point of intersection of the Russian River with the range line common to R. 8 W. and R. 9 W. in T. 9 N., on the "Healdsburg Quadrangle," map.

(15) Then southwesterly in a straight line to the point of a hill identified as having an elevation of 737 feet;

(16) Then south-southwesterly in a straight line to the point at the easterly terminus of Reiman Road;

(17) Then southwesterly in a straight line to the point at the intersection of the township line common to T. 8 N., and T. N., in R. 9 W., and the frontage road (a.k.a. Los Amigos Road) for U.S. Highway 101;

(18) Then west approximately 3,000 feet along the township line common to T. 8 N., and T. 9 N., in R. 9 W.;

(19) Then southerly for approximately 2,000 feet in a straight line to the point of intersection with an unnamed stream drainage;

(20) Then east in a straight line to the point of intersection with Eastside Road;

(21) Then northeasterly along Eastside road to the point of intersection with Redwood Highway;

(22) Then southeasterly along Redwood Highway to the point of beginning.

* * * * *

Signed: December 1, 1989.

Daniel R. Black,

Acting Director.

[FR Doc. 89-28901 Filed 12-11-89; 8:45 am]

BILLING CODE 4810-31-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 672 and 675

[Docket No. 90899-9278]

RIN 0648-AD04

Groundfish of the Gulf of Alaska; Groundfish Fishery of the Bering Sea and Aleutian Islands Area

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NOAA proposes regulations to implement the Observer Plan provided for by amendments 13 and 18 to the Fishery Management Plans for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area and Groundfish of the Gulf of Alaska, respectively. This action is necessary to provide the public an opportunity to comment on these provisions. It is intended to further the goals and objectives contained in the fishery management plans that govern these fisheries.

DATE: Comments are invited until December 21, 1989.

ADDRESS: Comments may be sent to Steven Pennoyer, Director, Alaska Region, National Marine Fisheries Service, P.O. Box 21668, Juneau, AK 99802. Copies of the environmental assessment/regulatory impact review/final regulatory flexibility analysis (EA/RIR/FRFA) that was prepared for Amendments 13 and 18 may be obtained from the same address.

FOR FURTHER INFORMATION CONTACT: Janet Smoker (Fishery Management Biologist, NMFS), 907-586-7230.

SUPPLEMENTARY INFORMATION:

Background

The domestic and foreign groundfish fisheries in the Exclusive Economic Zone (EEZ) of the Gulf of Alaska (GOA) and Bering Sea and Aleutian Islands (BSAI) areas are managed by the Secretary according to FMPs prepared by the North Pacific Fishery Management Council (Council) under the authority of the Magnuson Fishery Conservation and Management Act (Magnuson Act). The FMPs are implemented by regulations for the foreign fisheries at 50 CFR 611.92 and 611.93 and for the U.S. fisheries at 50 CFR parts 672 and 675. General regulations that also pertain to the U.S. fisheries are implemented at 50 CFR part 620.

The Secretary of Commerce (Secretary) approved amendments 13 and 18 under section 304(b) of the Magnuson Act. Those amendments contained certain management measures as listed in the final rule published at 54 FR 50386 (December 6, 1989). One of the listed measures authorized a comprehensive domestic observer program. An Observer Plan to implement provisions of this program has been prepared by the Secretary in consultation with the Council.

The preamble prepared for proposed regulations to implement amendments 13 and 18 contained the reasons for the observer program. At the time the proposed regulations were published, the Observer Plan was still being developed. NMFS has now prepared the Observer Plan, copies of which may be obtained from the Regional Director at the above address. It describes the responsibilities that will be imposed on NMFS, vessel operators, and managers of shoreside processing facilities, and NMFS-certified contractors who will act as agents of NMFS in providing observers to groundfish fishing vessels and shoreside processors. Minimum qualifications for observers are also stated in the Observer Plan. Descriptions of major parts of the Observer Plan are as follows:

Responsibilities of NMFS

NMFS is responsible for (1) the overall program administration, (2) training or certification of observers, (3) contractor certification, (4) final trip debriefing of observers, (5) specification of observer coverage for the subject fisheries, (6) logistical monitoring, and (7) management of the data collected by the

observers. Each of the aspects of NMFS responsibilities is further described as follows:

1. *Program administration.* Within this task, general program policy is established; observer duties, sampling methods, and data format are specified, observer qualifications and contractor certifications are specified, NMFS personnel and budgets are administered, and regulations are proposed that pertain to observer work, accommodations on board vessels and at shoreside processing facilities, and safety considerations.

2. *Observer training and certification.* Observers who meet the basic educational and experience qualifications stated in the Observer Plan and who are hired by certified contractors to be placed on board domestic vessels will be required to successfully complete a 2½ week training certification program conducted by NMFS, or its designated agent, prior to being deployed on board a domestic vessel or at a shoreside processing facility. Individuals who have successfully completed either a foreign or domestic groundfish observer deployment administered by NMFS will be only required to attend a 2–4 day briefing. Certification training will be provided at a minimum on a scheduled quarterly basis and more frequently if required. The training of observers is critical to the overall success of the observer program and the quality of information collected. Because observers will act as agents of NMFS to collect fisheries information for Federal management of the Alaska groundfish fisheries, training must be consistent and must respond to changing management and data collection needs. The observer certification may be revoked if the observer fails to perform assigned duties satisfactorily, or does not adhere to standards of conduct prescribed by NMFS.

3. *Contractor certification.* NMFS will certify contractors prior to their providing observers to the industry to assure that the contractors do not have a financial or personal conflict of interest with the fishing vessel or shoreside processing facility owners, and to assure that the contractors understand their responsibilities, which will be defined by NMFS. NMFS will review technical proposals submitted by prospective contractors that describe task performance to ensure that they are able to adequately provide the required services as an agent of NMFS under the mandatory observer program. The costs of providing observers will not be considered in the evaluation. Firms submitting proposals judged adequate to provide services and which do not have a financial or personal conflict of interest will be included in a list of certified contractors from which industry members can obtain their required observers. A contractor could lose certification if the contractor is found to have a financial or personal conflict of interest with either vessel or shoreside processor owners or the contractor is deficient in the performance of the duties prescribed by NMFS.

4. *Observer debriefing.* Debriefing observers will be done by staff of the NMFS observer program and by the Alaska Department of Fish and Game (ADF&G) staff located at debriefing sites. Debriefing sites will be at Dutch Harbor and Kodiak, Alaska, and such other major fishing ports as deemed necessary by NMFS, and at the Alaska Fisheries Science Center in Seattle, Washington. Observers will be debriefed between deployments to make information available for editing, assimilation, and analysis.

5. *Coordination of observer coverage and logistics.* NMFS will coordinate observer coverage with certified contractors to ensure scientifically adequate sampling and to ensure receipt of information from the observers.

6. *Data management.* NMFS is responsible for the entry, editing, and database management of the data collected by observers. Primary data storage of weekly catch data will be located at the NMFS Alaska Regional Office in Juneau with subsequent transmission to the Alaska Fisheries Science Center in Seattle. Primary data storage of trip reports will be at the Alaska Fisheries Science Center.

Responsibilities of Vessel Operators and Managers of Shoreside Processing Facilities

The vessel operators or owners and managers of shoreside processing facilities are responsible for the direct costs of deploying observers on board vessels or at shoreside processing facilities. They are also responsible for coordinating with NMFS-certified contractors to assure that observer coverage meets requirements contained in regulations. Any vessel operator or manager of a shoreside processing facility who is required to accommodate an observer is responsible for obtaining a NMFS-certified observer from any of the certified observer contractors.

The vessel operator or manager of a shoreside processing facility will pay the cost of the observer directly to the contractor. Prior to the vessel beginning fishing, the observer must notify NMFS that he/she is on board the vessel and prepared to perform his/her duties as an observer. Prior to receiving groundfish and commencement of processing operations by a shoreside processing facility, an observer must notify NMFS that he/she is on site and prepared to perform his/her duties.

A vessel operator must maintain safe conditions on the vessel for the protection of the observer during the time the observer is on board the vessel, by adhering to all U.S. Coast Guard and other applicable rules, regulations, or statutes pertaining to safe operation of the vessel and by keeping on board the vessel:

(a) Adequate fire fighting equipment;

(b) A life raft capable of holding all persons on board; and

(c) Any other equipment required by regulations pertaining to safe operation of the vessel.

Responsibilities of Certified Observer Contractors

Contractors must be certified by NMFS. Firms holding a contract with NMFS to provide observer services will be included in the list of certified observers. To obtain certification, a firm must not have a financial or personal conflict of interest with the fishing companies and vessels to which they are providing observers and must agree to provide directly to NMFS all data collected by observers. No limit is placed on the number of contractors which could participate in the observer program and a vessel owner or manager of a shoreside processing facility could choose to work with whichever contractor he chooses. As agents of NMFS, contractors are responsible for the following tasks:

1. Recruiting, evaluating, and hiring of qualified candidates to serve as observers.

2. Ensuring that prospective observers have obtained the required NMFS certification.

3. Providing observer salaries, benefits, and personnel services.

4. Providing workmen's compensation and insurance to cover and protect observers injured in the performance of their duties.

5. Providing all deployment logistics to place and maintain the observers on board the fishing vessels or at shoreside processing facilities.

6. Providing substitute observers in the event an observer has to be removed from, or leaves, a vessel or a shoreside processing facility.

7. Arranging observer debriefings at specified debriefing ports.

8. Assuring that all observer catch messages and other required transmissions between the observer and NMFS are delivered to NMFS within a time specified by the Regional Director.

9. Assuring that all trip data, reports, and specimens collected by observers are delivered to NMFS within five working days of the completion of each observer trip.

10. Assuring that all gear and equipment issued to observers by NMFS is returned to a storage place designated by NMFS within five working days of the completion of the observer trip.

Vessel Participation

During the development of a plan to implement the observer program, the Secretary considered the numbers of vessels that participate in the fishery and the value of information that an observer on any one vessel may provide. In doing so, the Secretary has considered the levels of observer coverage that will be required relative to the sizes of vessels on which observers will be deployed and the magnitude of their groundfish landings. All vessels would be required to comply with the observer coverage requested by the Regional Director during a fishing year.

For the 1990 fishing year, and possible for subsequent years, the Secretary proposes that operators of all domestic fishing and processing vessels equal to or longer than 125 feet will be required by the Regional Director to carry an observer at all times. Vessels of this size category harvest most of the groundfish off Alaska. For example, 63 vessels of this size harvested 59 percent of all the domestic annual processing (DAP) groundfish landings in 1988 off Alaska. Through September 1989, 61 vessels harvested 68 percent of all the DAP groundfish landings off Alaska. In both years, the numbers of vessels equal to or longer than 125 feet represented 4 percent of all the DAP vessels making groundfish landings. Because these large vessels harvest more than 50 percent of all the groundfish, requiring them to have higher observer coverage relative to smaller vessels and shoreside processing facilities is appropriate. Furthermore, a single observer onboard a vessel will observe less than 100 percent of a vessel's fishing or processing activity, and likely will result in only 25 to 30 percent observer coverage of a vessel's operation. This level of observer coverage is necessary, at least initially, to gather adequate information on variability factors associated with different fisheries, bycatch species, and the experience of vessel operators themselves. Future levels of observer coverage may be modified once adequate information is collected to enable valid sampling within different elements of the groundfish fleet. The 63 vessels 125 feet and longer in length that landed groundfish in 1988 fished an average of 142 days for that year. If similar patterns hold, 8,946 observer days could be required for this segment of the fleet in 1990 at a cost of $2,236,500, based on a cost estimate of $250 per observer day.

The Secretary also proposed for the 1990 fishing year that operators of all domestic fishing and processing vessels that are 50 feet and longer but less than 125 feet carry an observer, upon request by the Regional Director. Vessels must have observer coverage for at least 30 percent of the days they fish for each January-March, April-June, July-September, and October-December period of the fishing year. This level of observer coverage is proposed, because vessels of this size also harvest a singificant amount of the DAP harvest and should participate in the observer program. For example, 352 vessels of this size harvested 38 percent of all the DAP groundfish landings in 1988 off Alaska. Through September 1989, 317 vessels in this size category harvested 23 percent of all the DAP groundfish landings off Alaska. In these two years, the numbers of vessels of this size represented 20 and 23 percent respectively, of all the DAP vessels making groundfish landings. The amount of observer information that would be received from these vessels justifies the costs of carrying an observer during a portion of their fishing effort as determined by the Regional Director. The 352 vessels within this size category that landed groundfish in 1988 fished an average of 34 days per vessel. If similar patterns hold, 3590 observer days could be required for this segment of the fleet in 1990 at a cost of $897,500, based on a cost estimate of $250 per observer day.

The Secretary also proposes for the 1990 fishing year, and possibly subsequent years, that all vessels less than 50 feet in length should not be requested by the Regional Director to carry an observer. The overall groundfish catch by these vessels is small even though their aggregate number is large. For example, 1,314 vessels of this size harvested 3 percent of all the DAP groundfish landings in 1988 off Alaska. Through September 1989, 1,000 vessels of this size harvested only 8 percent of all the DAP groundfish landings off Alaska. In these two years, the numbers of vessels less than 50 feet in length represented 76 and 73 percent, respectively, of all the DAP vessels making groundfish landings. As a practical matter, the amount of observer information that would be received from these small vessels does not justify the costs of carrying an observer that would be imposed on them, nor the costs of program administration that would be imposed on NMFS.

Shoreside Processor Participation

The Secretary proposes that managers of shoreside facilities would be required to have an observer at the facility each day groundfish are received from regulated vessels, if requested to do so by the Regional Director. In 1988, a total of 85 shoreside processors recorded Alaska groundfish landings.

For the 1990 fishing year, and possibly for subsequent years, managers of shoreside facilities that annually receive 10,000 mt or more of groundfish would be requested by the Regional Director to have an observer at each such facility on each day it receives groundfish. Based on 1989 landings to date, an estimated 6 facilities will fall into this category, receiving groundfish an average of 250 days per year. If similar patterns hold, 1,500 observer days could be required for this category of processing facilities in 1990 at a cost of $375,000, based on a cost estimate of $250 per day.

Managers of shoreside facilities that annually receive between 1,000 mt and 10,000 mt of groundfish would be requested by the Regional Director to have an observer for 30 percent of the days they receive groundfish. It is estimated that 14 plants will fall into this category in 1989 and receive groundfish an average of 120 days. If similar patterns hold, 504 observer days could be required for this category of processing facility in 1990 at a cost of $126,000, based on a cost estimate of $250 per observer day.

Shoreside processing facilities that annually receive less than 1,000 mt of groundfish would not be requested by the Regional Director to have an observer.

Secretarial approval of the mandatory domestic observer program set forth in amendments 13 and 18 was based upon his finding that reliable observer information is necessary and appropriate for the conservation and management of the Alaskan groundfish fisheries. He proposes to implement specific provisions of the Observer Plan. The Secretary anticipates working with the industry to develop and refine the domestic observer program to meet the needs of both fishery management agencies and the fishing industry.

Classification

The Assistant Administrator for Fisheries, NOAA, (Assistant Administrator) has determined that this rule is necessary for the conservation and management of the groundfish fisheries off Alaska and that it is consistent with the Magnuson Act and other applicable law.

The Council prepared an environmental assessment (EA) for Amendments 13 and 18. The Assistant Administrator found that no significant impact on the quality of the environment will occur as a result of this rule. A copy of the EA may be obtained from the Regional Director at the address above.

The Under Secretary for Oceans and Atmosphere, NOAA, (Under Secretary) determined that this rule is not a "major rule" requiring a regulatory impact analysis under Executive Order 12291. This determination is based on the EA/RIR/FRFA prepared by the Council for Amendments 13 and 18. A copy of the EA/RIR/FRFA may be obtained from the Regional Director at the address above.

The Under Secretary concluded that this rule, if adopted, would have significant effects on a substantial number of small entities. Approximately 4 percent of the Alaska groundfish fleet would be required to carry observers full time at a cost of $2.2 million per year. A further 21 percent of the fleet would be required to carry observers for at least 30 percent of the days fished in each quarter at an annual cost of $0.9 million. Seven percent of the processing industry would require full time coverage at an annual cost of $0.4 million, while a further 16 percent would require 30 percent coverage at a cost of $0.1 million per year. The annual cost of observer coverage would represent about 0.66 percent of the projected 1989 exvessel value or 0.35 percent of the processed value of the groundfish fisheries of the EEZ off Alaska. These costs would be offset by a more effective utilization of the groundfish stocks made possible by the improved information base. The ability to safely set allowable harvest levels even 10 percent higher could result in an increase in exvessel revenues of approximately $56 million with a processed product value of over $100 million. These effects have been discussed in the EA/RIR/FRFA, a copy of which may be obtained from the Regional Director at the address above.

This rule does not contain a collection of information requirement subject to the Paperwork Reduction Act.

NOAA has determined that this rule will be implemented in a manner that is consistent to the maximum extend practicable with the approved coastal zone management program of the State of Alaska. This determination has been submitted for review by the responsible State agencies under section 307 of the Coastal Zone Management Act.

This proposed rule does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 12612.

List of Subjects in 50 CFR Parts 672 and 675

Fisheries, Fishing vessels, Reporting and recordkeeping requirements.

Dated: December 6, 1989.

James E. Douglas, Jr.,

Acting Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR parts 672 and 675 are proposed to be amended as follows:

PART 672—GROUNDFISH OF THE GULF OF ALASKA

1. The authority citation for part 672 reads as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. Section 672.27 is revised to read as follows:

§ 672.27 Observers.

(a) *Observer plan.* The operator of a fishing vessel subject to this part and the manager of a shoreside processing facility that receives groundfish from vessels subject to this part, must comply with the observer plan. The owner of a fishing vessel subject to this part or a shoreside processing facility that received groundfish from vessels subject to this part must ensure that the operator or manager complies with the observer plan and is jointly and severally liable for compliance with that plan. The observer plan has been prepared by the Secretary in consultation with the Council for purposes of providing data useful in management of the groundfish fishery.

(b) *Purpose.* The purpose of this section is to allow observers to collect Alaska fisheries data deemed by the Regional Director to be necessary and appropriate for research, management, and compliance monitoring of the groundfish fisheries, or for other purposes consistent with the Marine Mammal Protection Act, as amended.

(c) *General requirements.* (1) Compliance by vessels. Except when exempted under paragraph (f) of this section, an operator of a vessel subject to this part must carry an observer on board the vessel whenever fishing or processing operations are conducted, if the operator is requested to do so by the Regional Director.

(2) Compliance by shoreside processing facilities. Except as exempted under paragraph (f) of this section, a manager of a shoreside facility that receives groundfish from vessels regulated under this part must have an observer present at the facility whenever groundfish is received, if the manager is requested to do so by the Regional Director.

(d) *Responsibilities.* (1) An operator of a vessel must:

(i) Provide, at no cost to the observer or the United States, accommodations on a participating vessel for the observer which are equivalent to those provided for crew members of the participating vessel;

(ii) Maintain safe conditions on the vessel for the protection of the observer during the time the observer is on-board the vessel, by adhering to all U.S. Coast Guard and other applicable rules, regulations, or statutes pertaining to safe operation of the vessel and by keeping on board the vessel:

(A) Adequate fire fighting equipment;

(B) A life raft capable of holding all persons on board; and

(C) Other equipment required by regulations pertaining to safe operation of the vessel.

(iii) Allow the observer to use the vessel's communication equipment and personnel on request for the transmission and receipt of messages;

(iv) Allow the observer access to and the use of the vessel's navigation equipment and personnel on request to determine the vessel's position;

(v) Allow the observer free and unobstructed access to the vessel's bridge, trawl or working decks; holding bins, processing areas, freezer spaces, weight scales, cargo holds and any other space which may be used to hold, process, weigh, or store fish or fish products at any time;

(vi) Notify the observer at least 15 minutes before fish are brought on board or fish and fish products are transferred from the vessel to allow sampling the catch or observing the transfer, unless the observer specifically requests not to be notified;

(vii) Allow the observer to inspect and copy the vessel's daily fishing logbook, daily cumulative production logbook, transfer logbook, and any other logbook or document required by regulations, information from which will be kept confidential by the observer under Federal guidelines;

(viii) Provide all other reasonable assistance to enable the observer to carry out his or her duties;

(ix) Move the vessel to such places and at such times as may be designated by the contractor, as instructed by the Regional Director, for purposes of embarking and debarking the observer;

(x) Ensure that transfers of observers at sea via small boat or raft are carried out during daylight hours, under safe conditions, and with the agreement of the observer involved;

(xi) Notify the observer at least three hours before an observer is transferred so the observer can collect personal belongings, equipment, and scientific samples;

(xii) Provide a safe pilot ladder and conduct the transfer to ensure the safety of the observer during the transfer; and

(xiii) Provide an experienced crew member to assist the observer in the small boat or raft in which the transfer is made.

(2) A manager of a shoreside processing facility must:

(i) Maintain safe conditions at the processing facility for the protection of the observer by adhering to all applicable rules, regulations, or statutes pertaining to safe operation and maintenance of the processing facility;

(ii) Accept an observer, at no cost to the observer or the United States, for purposes of complying with the observer plan;

(iii) Notify the observer on a daily basis of the planned facility operations and expected receipt of groundfish;

(iv) Allow the observer to use the processing facility's communication equipment and personnel on request for the transmission and receipt of messages;

(v) Allow the observer free and unobstructed access to the processing facility's holding bins, processing areas, freezer spaces, weight scales, warehouses and any other space which may be used to hold, process, weigh, or store fish or fish products at any time;

(vi) Allow the observer to inspect and copy:

(A) The shoreside processing facility's daily cumulative production logbook, transfer logbook, and any other logbook or document required by regulations, information from which will be kept confidential by the observer under Federal guidelines, and

(B) The catcher vessel's daily fishing logbook, transfer logbook, and any other logbook or document required by regulations, information from which will be kept confidential by the observer under Federal guidelines; and

(vii) Provide all other reasonable assistance to enable the observer to carry out his or her duties.

(e) *Prohibited actions.* No person may:

(1) Forcibly assault, resist, oppose, impeded, intimidate, or interfere with an observer:

(2) Interfere with or bias the sampling procedure employed by an observer, including sorting or discarding any catch before sampling; or tamper with, destroy, or discard an observer's collected samples, equipment, records, photographic film, papers, or personal effects without the express consent of the observer;

(3) Prohibit or bar by command, impediment, threat, coercion, or by refusal of reasonable assistance, an observer from collecting samples, conducting product recovery rate determinations, making observations, or otherwise performing the observer's duties; or

(4) Harass an observer by conduct which has sexual connotations, has the purpose or effect of interfering with the observer's work performance, or otherwise creates an intimidating, hostile, or offensive environment. In determining whether conduct constitutes harassment, the totality of the circumstances, including the nature of the conduct and the context in which it occurred, will be considered. The determination of the legality of a particular action will be made from the facts on a case-by-case basis.

(f) *Exemptions.* An operator of a vessel or a manager of a shoreside processing facility who is requested by the Regional Director to have an observer under paragraph (c) of this section, must obtain and accept an observer unless a NMFS observer contractor notifies the Regional Director and the vessel operator or facility manager that an observer is not available at the time of the vessel's scheduled departure or within the time when a shoreside processing plant is scheduled to receive groundfish.

PART 675—GROUNDFISH FISHERY OF THE BERING SEA AND ALEUTIAN ISLANDS AREA

3. The authority citation for part 675 reads as follows:

Authority: 16 U.S.C. 1801 *et seq.*

4. Section 675.25 is revised to read as follows:

§ 675.25 Observers.

(a) *Observer Plan.* The operator of a fishing vessel subject to this part and the manager of a shoreside processing facility that receives groundfish from vessels subject to this part must comply with the observer plan. The owner of a fishing vessel subject to this part or a shoreside processing facility that receives groundfish from vessels subject to this part must ensure that the operator or manager complies with the observer plan and is jointly and severally liable for compliance with that plan. The observer plan has been prepared by the Secretary in consultation with the Council for purposes of providing data useful in management of the groundfish fishery.

(b) *Purpose.* The purpose of this section is to allow observers to collect from Alaska fisheries data deemed by the Regional Director to be necessary and appropriate for research, management, and compliance monitoring of the groundfish fisheries, or for other purposes consistent with the Marine Mammal Protection Act, as amended.

(c) *General requirements.* (1) Compliance by vessels. Except when exempted under paragraph (f) of this section, an operator of a vessel subject to this part must carry an observer on board the vessel whenever fishing or processing operations are conducted, if the operator is requested to do so by the Regional Director.

(2) Compliance by shoreside processing facilities. Except as exempted under paragraph (f) of this section, a manager of a shoreside facility that receives groundfish from vessels regulated under this part must have an observer present at the facility whenever groundfish is received, if the manager is requested to do so by the Regional Director.

(d) *Responsibilities.* (1) An operator of a vessel must:

(i) Provide, at no cost to the observer or the United States, accommodations on a participating vessel for the observer which are equivalent to those provided for crew members of the participating vessel;

(ii) Maintain safe conditions on the vessel for the protection of the observer during the time the observer is on board the vessel, by adhering to all U.S. Coast Guard and other applicable rules, regulations, or statutes pertaining to safe operation of the vessel and by keeping on board the vessel:

(A) Adequate fire fighting equipment;

(B) A life raft capable of holding all persons on board: and

(C) Other equipment required by regulating pertaining to safe operation of the vessel.

(iii) Allow the observer to use the vessel's communication equipment and personnel on request for the transmission and receipt of messages;

(iv) Allow the observer access to and the use of the vessel's navigation equipment and personnel on request to determine the vessel's position;

(v) Allow the observer free and unobstructed access to the vessel's bridge, trawl or working decks, holding bins, processing areas, freezer spaces, weight scales, cargo holds and any other space which may be used to hold, process, weigh or store fish or fish products at any time;

(vi) Notify the observer at least 15 minutes before fish are brought on board or fish products are transferred from the vessel to allow sampling the catch or observing the transfer, unless the observer specifically requests not to be notified;

(vii) Allow the observer to inspect and copy the vessel's daily fishing logbook, daily cumulative production logbook, transfer logbook, and any other logbook or document required by regulations, information from which will be kept confidential by the observer under Federal guidelines;

(viii) Provide all other reasonable assistant to enable the observer to carry out his or her duties;

(ix) Move the vessel to such places and at such times as may be designated by the conractor, as instructed by the Regional Director, for purposes of embarking and debarking the observer;

(x) Ensure that transfers of observers at sea via small boat or raft are carried out during daylight hours, under safe conditions, and with the agreement of the observer involved;

(xi) Notify the observer at least three hours before an observer is transferred so the observer can collect personal belongings, equipment, and scientific samples;

(xii) Provide a safe pilot ladder and conduct the transfer to ensure the safety of the observer during the transfer; and

(xiii) Provide an experience crew member to assist the observer in the small boat or raft in which the transfer is made.

(2) A manger of a shoreside processing facility must:

(i) Maintain safe conditions at the processing facility for the protection of the observer by adhering to all applicable rules, regulations, or statutes pertaining to safe operation and maintenance of the processing facility;

(ii) Accept an observer, at no cost to the observer or the United States, for purposes of complying with the observer plan;

(iii) Notify the observer on a daily basis of the planned facility operations and expected receipt of groundfish;

(iv) Allow the observer to use the processing facility's communication equipment and personnel on request for the transmission and receipt of messages;

(v) Allow the observer free and unobstructed access to the processing facility's holding bins, processing areas, freezer spaces, weight scales, warehouses and any other space which may be used to hold, process, weigh, or store fish or fish products at any time;

(vi) Allow the observer to inspect the copy;

(A) The shoreside processing facility's daily cumulative production logbook, transfer logbook, and any other logbook or document required by regulations, information from which will be kept confidential by the observer under Federal guidelines, and

(B) The catcher vessel's daily fishing logbook, transfer logbook, and any other logbook or document required by regulations, information from which will be kept confidential by the observer under Federal guidelines; and

(vii) Provide all other reasonable assistance to enable the observer to carry out his or her duties.

(e) *Prohibited actions.* No person may:

(1) Forcibly assault, resist, oppose, impede, intimidate, or interfere with an observer;

(2) Interfere with or bias the sampling procedure employed by an observer, including sorting or discarding any catch before sampling; or tamper with, destroy, or discard an observer's collected samples, equipment, records, photographic film, papers, or personal effects without the express consent of the observer;

(3) Prohibit or bar by command, impediment, threat, coercion, or by refusal of reasonable assistance, an observer from collecting samples, conducting product recovery rate determinations, making observations, or otherwise performing the observer's duties; or

(4) Harass an observer by conduct which has sexual connotations, has the purpose or effect of interfering with the observer's work performance or otherwise creates an intimidating, hostile, or offensive environment. In determining whether conduct constitutes harassment, the totality of the circumstances, including the nature of the conduct and the context in which it occurred, will be considered. The determination of the legality of a particular action will be made from the facts on a case-by-case basis.

(f) *Exemptions.* An operator of a vessel or a manager of a shoreside processing facility who is requested by the Regional Director to have an observer under paragraph (c) of this section, must obtain and accept an observer unless a NMFS certified observer contractor notifies the Regional Director and the vessel operator or facility manager that an observer is not available at the time of the vessel's scheduled departure or within the time when a shoreside processing plant is scheduled to receive groundfish.

[FR Doc. 89-28902 Filed 12-6-89; 5:00 pm]
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Notices

Federal Register
Vol. 54, No. 237
Tuesday, December 12, 1989

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF COMMERCE

Bureau of Export Administration

[Docket Nos. 9131-01, 9131-02]

ATC Lab Electronic Service

In the matter of: Andrezej Stefan Stanislaw Schmidt, individually and doing business as ATC Lab Electronic Service; Respondents

Summary

Pursuant to the November 7, 1989, recommended Decision and Order of the Administrative Law Judge (ALJ), which Decision and Order is attached hereto and affirmed by me, Andrezej Stefan Stanislaw Schmidt, individually and doing business as ATC Lab Electronic Service (hereafter Respondent), and all successors, assignees, officers, partners, representatives, agents and employees are hereby denied for a period of twenty years from the date hereof all privileges of participating, directly or indirectly, in any manner or capacity, in any transaction involving commodities or technical data exported from the United States in whole or in part, or to be exported, or that are otherwise subject to the Export Administration Regulations (15 CFR parts 768–799), but provided, however, that the last ten years of this sanction shall be suspended.

Order

On November 7, 1989, the ALJ entered his Recommended Decision and Order in the above-referenced matter. The Decision and Order, a copy of which is attached hereto and made a part hereof, has been referred to me for final action. Having examined the record and based on the facts in this case, I hereby affirm the Decision and Order of the ALJ.

This constitutes final agency action in this matter.

Dated: December 5, 1989.

Dennis E. Kloske,

Under Secretary for Export Administration.

Decision and Order

In the matter of: Andrezej [1] Stefan Stanislaw Schmidt, individually and doing business as ATC Lab Electronic Service; Respondents.

Appearance for Respondent: Andrezej Stefan Stanislaw Schmidt (pro se), Segelflygsgatan 35, 122 52 Enskede, Sweden.

Appearance for Agency: Louis K. Rothberg, Esq., Office of Chief Counsel for Export Administration, U.S. Department of Commerce, Room H–3837, 14th & Constitution Ave., NW., Washington, DC 20230.

Preliminary Statement

The Office of Export Enforcement ("the Agency"), Bureau of Export Administration, U.S. Department of Commerce issued a June 29, 1989 charging letter against Respondent Andrezej Stefan Stanislaw Schmidt, individually and doing business as ATC Lab Electronic Service. The letter was issued under the authority of the Export Administration Act of 1979 (50 U.S.C.A. app 2401-2420), as amended ("the Act"), and under the authority of the Export Administration Regulations ("the Regulations"), promulgated pursuant to the Act.[2]

The charging letter contained two allegations. First, it charged Respondent Schmidt with conspiring with others during 1984–87 to make unauthorized exports from the United States to Poland and Sweden, in violation of § 787.3(b) of the Regulations. Second, it charged him with attempting an unauthorized export to Sweden in 1987, in violation of § 787.3(a).

Respondent Schmidt filed an answer denying the charges, and made no further submission. The Agency made subsequent filings, including a submission that set forth the evidence for its charges against Respondents.

Discussion

The essence of the Agency's case was that Respondent Schmidt had been convicted, in a 1987 U.S. District Court in California, of two counts of a criminal indictment to which he had pled guilty; and these two counts were substantially the same as the two charges of the charging letter. Therefore, contended the Agency, he is collaterally estopped from denying his commission of the violations described in these two counts of the indictment.

To document its contention, the Agency introduced the indictment, the government's sentencing memorandum, and the judgment and probation/commitment order from this 1987 judicial proceeding (Agency's September 28, 1989 Submission, Exhibits 2–4). According to these documents, Respondent Schmidt was a Canadian citizen who was born in Poland and who owned Respondent ATC Lab Electronic Service, which was located in Sweden.

Count one of the indictment, to which Respondent Schmidt pled guilty, alleged a conspiracy and is, the Agency asserted, like charge 1 of its charging letter. Count one alleged that from about May 14, 1984 through about May 13, 1987 a conspiracy existed among Respondent Schmidt, Marek Cieslak, and others knowingly to export computer microprocessors and integrated circuits from the United States to Sweden and Poland without the required U.S. validated export licenses. Mr. Cieslak was named as a defendant in that same indictment, pled guilty to four counts therein, and in a subsequent administrative proceeding before this Tribunal based on that criminal conviction was subjected to a twenty-year denial of U.S. export privileges (54 FR 30436, July 20, 1989).

Count two of the indictment, the other count to which Respondent Schmidt pled guilty, alleged an attempted export without the required U.S. validated license and is, the Agency claimed, like charge 2 of its charging letter. The alleged attempt occurred on or about May 13, 1987 and involved 270 microprocessors that were intended to go from the United States to Sweden.

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[1] The Office of Export Enforcement ("the Agency"), Bureau of Export Administration, U.S. Department of Commerce in all its filings spelled Respondent Schmidt's first name as "Andrezej." Respondent Schmidt's single filing, and all the judicial documents concerning him filed by the Agency in its September 28, 1989 submission, spelled his first name as "Andrzej." This Decision and Order applies to Respondent Schmidt under either spelling of his first name.

[2] The Act was reauthorized and amended by the Export Administration Amendments Act of 1985, Pub. L. 99–64, 99 Stat. 120 (July 12, 1985), and amended by the Omnibus Trade and Competitiveness Act of 1988, Pub. L. 100–418, 102 Stat. 1107 (August 23, 1988).

The Regulations, formerly codified at 15 CFR parts 368–399, were redesigned as 15 CFR parts 768–799, effective October 1, 1988 (53 F.R. 37751, September 28, 1988).

In the criminal case, Respondent Schmidt was sentenced to five years of imprisonment, with the term suspended after the first 153 days. In this administrative proceeding, the Agency proposed a twenty-year denial of U.S. export privileges. The Agency noted that Respondent Schmidt's conduct was so serious as to entail a criminal prosecution including a multiple count indictment, that the U.S. commodities involved were controlled for national security reasons, and that Respondent Schmidt entered his guilty plea with retained counsel at his side. As for his answer filed in the instant proceeding, the Agency argued that it was simply a general denial, unsupported by any evidence.

Conclusion

The Agency has sufficiently made its case through the principle of collateral estoppel that it asserted. The two charges of the Agency's charging letter are substantially the same as the two counts of the criminal indictment to which Respondent Schmidt pled guilty and for which he was convicted, and accordingly they are established for purposes of this administrative proceeding. See, e.g., *Spawr Optical Research, Inc.* v. *Baldridge,* 649 F. Supp. 1366, 1369 (D.D.C. 1986)

Respondent Schmidt's answer fails to blunt the force of collateral estoppel, since his filing lacked any challenge to the validity or relevance of his criminal conviction. His answer lacked also any evidence to support its general denial of the charges.

As for a sanction, the Agnecy's proposed twenty-year denial period is severe. Respondent Schmidt's conduct, as established by the criminal conviction, does merit an extended denial period. But twenty years was the sanction that the Agency proposed also, and obtained, for Mr. Cieslak. The documents submitted by the Agency in the instant case from the judicial proceeding, while showing both Mr. Cieslak and Respondent Schmidt as seriously culpable, show Respondent Schmidt as less so. To reflect this difference, Respondent Schmidt will be subjected tc a twenty-year denial period that is moderated by a suspension of the last ten years.I84Order

I. For a period of twenty years from the date of the final Agency action, Respondent Andrezej Stefan Stanislaw Schmidt, individually and doing business as ATC Lab Electronic Service, Segelflygsgatan 35, 122 52 Enskede, Sweden, and all successors, assignees, officers, partners, representatives, agents, and employees hereby are denied all privileges of participating, directly or indirectly, in any manner or capacity, in any transaction involving commodities or technical data exported from the United States in whole or in part, or to be exported, or that are otherwise subject to the Regulations.

II. Commencing ten years from the date of the final Agency action, the denial of export privileges set forth in Paragraph I above shall be suspended, in accordance with Section 788.16 of the Regulations, for the remaining ten years of the twenty-year period set forth in Paragraph I above, and shall be terminated at the end of such twenty-year period, provided that Respondents have committed no further violations of the Act, the Regulations, or the final order entered in this proceeding. During the ten-year suspension period, Respondents may participate in transactions involving the export of U.S. commodities or technical data from the United States or abroad in accordance with the requirements of the Act and the Regulations. The provisions of Paragraphs V-VI of this Order shall also be suspended during such ten-year period.

III. Participation prohibited in any such transaction, either in the United States or abroad, shall incude, but not be limited to, participation:

(i) As a party or as a representative of a party to a validated or general export license application;

(ii) In preparing or filing any export license application or request for reexport authorization, or any document to be submitted therewith;

(iii) In obtaining or using any validated or general export license or other export control document;

(iv) In carrying on negotiations with respect to or in receiving, ordering, buying, selling, delivering, storing, using, or disposing of, in whole or in part, any commodities or technical data exported from the United States, or to be exported; and

(v) In the financing, forwarding, transporting, or other servicing of such commodities or technical data.

Such denial of export privileges shall extend to those commodities and technical data which are subject to the Act and the Regulations.

IV After notice and opportunity for comment, such denial of export privileges may be made applicable to any person, firm, corporation, or business organization with which any Respondent is now or hereafter may be related by affiliation, ownership, control, position of responsibility, or other connection in the conduct of trade or related services.

V. All outstanding individual validated export licenses in which Respondents appear or participate, in any manner or capacity, are hereby revoked and shall be returned forthwith to the Office of Export Licensing for cancellation. Further, all of Respondents' privileges or participating, in many manner or capacity, in any special licensing procedure, including, but not limited to, distribution licenses, are hereby revoked.

VI. No person, firm, corporation, partnership, or other business organization, whether in the United States or elsewhere, without prior disclosure to and specific authorization from the Ofice of Export Licensing, shall, with respect to commodities and technical data, do any of the following acts, directly or indirectly, or carry on negotiations with respect thereto, in any manner or capacity, on behalf of or in any association with any Respondent or any related person, or whereby any Respondent or any related person may obtain any benefit therefrom or have any interest or participating therein, directly or indirectly:

(i) Apply for, obtain, transfer, or use any license, Shipper's Export Declaration, bill of lading, or other export control document relating to any export, reexport, transshipment, or diversion of any commodity or technical data exported in whole or in part, or to be exported by, to, or for any Respondent or related person denied export privileges, or (ii) Order, buy, receive, use, sell, deliver, store, dispose of, forward, transport, finance or otherwise service or participate in any export, reexport, transshipment or diversion of any commodity or technical data exported or to be exported from the United States.

VII. This Order as affirmed or modified shall become effective upon entry of the Secretary's final action in this proceeding pursuant to the Act (50 U.S.C.A. app. 2412(c)(1)).

Dated: November 7, 1989.

Thomas W. Hoya,

Administrative Law Judge.

To be considered in the 30 day statutory review process which is mandated by section 13(c) of the Act, submissions must be received in the Office of the Under Secretary for Export Administration, U.S. Department of Commerce, 14th & Constitution Ave., NW., room 3898B, Washington, DC, 20230, within 12 days. Replies to the other party's submission are to be made within the following 8 days. 15 CFR section 388.23(b), 50 FR 53134 (1985). Pursuant to section 13(c) of the Act, the final order of the Under Secretary may be appealed to the U.S. Court of Appeals

for the District of Columbia within 15 days of its issuance.

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BILLING CODE 3510-01-M

International Trade Administration

[C-301-601]

Miniature Carnations From Colombia; Preliminary Results of Countervailing Duty Administrative Review

AGENCY: International Trade Administration/Import Administration; Commerce.

ACTION: Notice of preliminary results of countervailing duty administrative review.

SUMMARY: The Department of Commerce has conducted an administrative review of the agreement suspending the countervailing duty investigation on miniature carnations from Colombia. The review covers the period January 1, 1987 through December 31, 1987 and nine programs. We preliminarily determine that Colombian miniature carnation exporters have complied with the terms of the suspension agreement. We invite interested parties to comment on these preliminary results.

EFFECTIVE DATE: December 12, 1989.

FOR FURTHER INFORMATION CONTACT: Stephanie Moore or Paul McGarr, Office of Countervailing Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 377-2786.

SUPPLEMENTARY INFORMATION:

Background

On January 13, 1987, the Department of Commerce ("the Department") published in the **Federal Register** (52 FR 1353) an agreement suspending the countervailing duty investigation on miniature carnations from Colombia. On January 28, 1988, the petitioner, the Floral Trade Council, requested an administrative review of the suspension agreement. We initiated the review on March 2, 1988 (53 FR 6681). The Department has now conducted that review in accordance with section 751 of the Tariff Act of 1930 ("the Tariff Act")

Scope of Review

The United States, under the auspices of the Customs Cooperaton Council, has developed a system of tariff classification based on the international harmonized system of Customs nomenclature On January 1, 1989, the United States fully converted to the Harmonized Tariff Schedule (HTS), as provided for in section 1201 *et seq.* of the Omnibus Trade and Competitiveness Act of 1988. All merchandise entered, or withdrawn from warehouse, for consumption on or after that date is now classified solely according to the appropriate HTS item number(s).

Imports covered by this review are shipments of miniature carnations from Colombia. During the period of review, such merchandise was classifiable under item 192.1700 of the Tariff Schedules of the United States Annotated. This merchandise is currently classifiable under HTS item 0603.10.30. The HTS item numbers are provided for convenience and Customs purposes. The written description remains dispositive.

The review covers the period January 13, 1987 through December 31, 1987 and nine programs.

The producers and exporters listed in Appendix I, accounting for more than eighty-five (85) percent of the total exports of miniature carnations from Colombia to the United States, are signatories to the suspension agreement.

Analysis of Programs

(1) Tax Rebate Certificate

On April 1, 1984, the Colombian government pursuant to Law 48/83, established the Tax Rebate Certificate ("CERT") which replaced the Tax Reimbursement certificate Program ("CAT"). According to the Colombian government, the CERT rebates all or part of the indirect taxes paid by exporters. CERT is freely negotiable on the stock market and can be used for paying a variety of taxes.

The Government of Colombia provides payment to exporters of miniature carnations in the form of CERT. Rebates are calculated as a percentage of the value of the exported product attributable to the domestic value-added content.

As a term of the suspension agreement, the Colombian government terminated CERT payments on exports of miniature carnations to the United States. We verified that there were no CERT payments on shipments of miniature carnations to the United States and Puerto Rico during the review period.

(2) Resolutions 59 and 22

Resolution 59/72 provided working capital financing at preferential rates to firms that manufacture, store or sell products destined for export. This program was updated by Resolution 22/84. All industries were eligible, except producers of coffee, petroleum, and petroleum by-products. Resolution 22/84 loans are administered by the Export Promotion Fund ("PROEXPO"), an agency of the Colombian government. The loans are for 180 days and the interest is paid quarterly, in advance.

In the suspension agreement, we established a short-term interest rate benchmark of 22.5 percent, which was the average rate of the Fondo Financiero Agropecuario (FFA) and the Agrarian Fund as of March 31, 1986. The miniature carnation exporters are required not to apply for, or receive, any short-term export financing provided by PROEXPO other than that offered at or above the short-term benchmark interest rate of 22.5 percent. All loans with outstanding balances were to be repaid or refinanced by April 13, 1987, ninety days after notice of the suspension agreement was published in the Federal Register.

Resolution 3/87, which is an update to Resolution 22/84, was passed by PROEXPO on February 26, 1987. Resolution 3/87 changed the short-term interest rate to 22.5 percent, and required the interest rate on all outstanding loans that were taken out under Resolution 22/84 be refinanced at the interest rate benchmark. At the six companies we verified, all PROEXPO short-term loans outstanding were refinanced in March 1987 at the interest rate benchmark, and the adjusted interest differential was paid.

On December 21, 1987, PROEXPO passed Resolutions 11/87, which covers pre-shipment working capital loans, and 14/87, which provides working capital financing to export companies for various products, including miniature carnations. Resolution 11/87 established financing to flower exporters at the highest interest rate between 22.5 percent per year prepaid quarterly and the interest rate paid on certificates of deposit (DTF), payable at the end of each quarter. The certificates of deposit rate is a market-determined rate. Resolution 14/87 established financing to flower exporters by setting as the base rate the highest rate between 25 percent per year prepaid quarterly and the DTF rate. The actual rate charged varies depending on the size of the company. The Colombian government has moved away from the fixed-rate PROEXPO financing to the DTF rate, which more accurately reflects interest rate fluctuations in the market. No loans were taken out under Resolutions 11/87 or 14/87 during the review period. We preliminarily determine that the DTF interest rate is an appropriate market rate indicator for pre-shipment and post-shipment financing, and that miniature

carnation exporters have complied with the terms of the suspension agreement.

(3) Resolution 40

Resolution 40/78 was approved under Decree 2366 of 1974. Decree 2366/74 provides exporters with fixed assets financing. During the investigation, miniature carnations exporters received financing at preferential interest rates of 14 and 18 percent. The suspension agreement set at 21 percent benchmark interest rate. On February 26, 1987, PROEXPO passed Resolution 4/87, which changed the interest rate to 21 percent and required the miniature carnations exporters to refinance all outstanding loan balances at the new higher interest rate. We verified that all outstanding long-term loan balances were refinanced in March 1987 at the interest rate benchmark.

Resolution 13/87, passed by PROEXPO on December 21, 1987, sets the base rate at the highest rate between 25 percent per year prepaid quarterly and the DTF rate. The actual rate charged varies depending on the size of the company. There were no loans approved for miniature carnation exporters under Resolution 13/87 during the review period.

We preliminarily determine that the DTF rate is an appropriate market rate indicator for long-term loans and that miniature carnation exporters have complied with the terms of the suspension agreement.

(4) Duty and Tax Exemptions Under Plan Vallejo

Plan Vallejo exempts exporters from import duties on imported raw materials, intermediate products, and capital goods used to produce exported products. The exemption of customs duties and indirect taxes on imported inputs physically incorporate into exports is not countervailable. Exemptions on non-physically incorporated inputs, such as imported capital goods, are countervailable when the exemption is conditional upon exportation.

We verified that miniature carnations exporters paid the applicable duties and taxes on the capital goods imported. Therefore, we preliminarily determine that the signatories did not benefit from this program during the period of review.

(5) Resolution 10

The flower exporters, on a voluntary basis, allowed the Banco de la Republica to withhold a certain percentage of their CAT/CERT rebates earned on non-U.S. exports. As a result of the suspension agreement on roses and other cut flowers, the Banco de la Republica also held all CAT/CERT rebates that would have been paid on exports of the flowers subject to the suspension agreement from January 1983 until November 1985, when the rebate rate on those exports was reduced to zero. PROEXPO issued Resolution 10, effective July 23, 1986, to use these funds for the diversification and development of flowers and vegetables for external markets; transport and control procedures to prevent drug and narcotic traffic in exports of flowers and vegetables; development of new markets; and payment of legal and technical services required in Colombia and abroad. The resolution requires that any funds expended under this program be disbursed in a manner consistent with the suspension agreement.

During the period of review, expenditures from this fund were used for legal fees, narcotics control and security, generic promotion and development of new non-U.S. markets. We found no evidence to indicate that these funds were provided to exporters of miniature carnations to the United States, therefore, we preliminarily determine that exports of miniature carnations to the United States did not receive a countervailable benefit from this program.

(6) Other Programs

We examined the following programs and preliminarily determined that miniature carnation exporters did not use them during the review period;

(A) Fund for Agricultural Financing ("FFA");

(B) Fund for Industrial Financing ("FFI");

(C) Capital Formation Fund ("FCE"); and

(D) Fund for National Economic Development ("FONADE").

Preliminary Results of Review

As a result of our review, we preliminarily determine that the signatories have complied with the terms of the suspension agreement during the period January 13, 1987 through December 31, 1987.

The agreement can remain in force only as long as shipments from the signatories account for at least 85 percent of imports of the subject merchandise into the United States. Our information indicates that the signatories accounted for over 90 percent of imports of this merchandise into the United States during the review period.

Interested parties may submit written comments on these preliminary results within 30 days of the date of publication of this notice and may request disclosure and/or a hearing within 10 days of the date of publication. Any hearing, if requested, will be held 44 days from the date of publication or the first workday thereafter. Rebuttal briefs and rebuttals to written comments, limited to issues in those comments, must be filed not later than 37 days after the date of publication. Any request for an administrative protective order must be made no later than five days after the date of publication. The Department will publish the final results of its analysis of issues raised in any such written comments or at a hearing.

This administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) and § 355.22 of the Commerce Regulations published in the **Federal Register** on December 27, 1988 (53 FR 53254) (to be codified at 19 CFR 355.22).

Dated: December 5, 1989.

Eric I. Garfinkel,

Assistant Secretary for Import Administration.

Appendix I

Agricola la Maria Ltda.
Agricola Los Arboles
Agrodex Ltda.
Agroindustria del Rio Frio Ltda.
Agrosuba
Claveles Colombianos Ltda.
Daflor Ltda.
Fantasia Flowers Ltda.
Floramerica
Flores Aguila Ltda.
Flores Alfaya Ltda.
Flores Altamira
Flores Colon Ltda.
Flores de Funza S.A.
Flores de Los Amigos Ltda.
Flores del Bosque
Flores del Campo Ltda.
Flores del Potrero Ltda.
Flores el Danubio Ltda.
Flores el Zorro
Flores Generales Ltda.
Flores Sausalito
Flores Tiba Ltda.
Floresa
Florex S.A.
Horticultura de la Sabana
Innovacion Andina
Inversiones Oro Verde
Inversiones Santa Rita Ltda.
Iturrama
Las Amalias S.A.
Pompones Ltda.
Sandra Patricia Rey
Santa Helena S.A.
Santana Flowers Ltda.
Universal de Flores Ltda.

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BILLING CODE 3510-DS-M

[C-301-003]

Roses and Other Cut Flowers From Colombia; Preliminary Results of Countervailing Duty Administrative Review

AGENCY: International Trade Administration/Import Administration, Commerce.

ACTION: Notice of preliminary results of countervailing duty administrative review.

SUMMARY: The Department of Commerce has conducted an administrative review of the agreement, suspending the countervailing duty investigation on roses and other cut flowers from Colombia. The review covers the periods January 1, 1986 through December 31, 1986 and January 1, 1987 through December 31, 1987 and ten programs. We preliminarily determine that Colombian cut flower exporters have complied with the terms of the suspension agreement. We invite interested parties to comment on these preliminary results.

EFFECTIVE DATE: December 12, 1989.

FOR FURTHER INFORMATION CONTACT: Stephanie Moore or Paul McGarr, Office of Countervailing Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone (202) 377-2786.

SUPPLEMENTARY INFORMATION:

Background

On December 28, 1987, the Department of Commerce ("the Department") published in the **Federal Register** (52 FR 48846) the final results of its last administrative review of the agreement suspending the countervailing duty investigation on roses and other cut flowers from Colombia (48 FR 2158; January 18, 1983). On January 30, 1987 and on January 28, 1988, three domestic interested parties, Roses Inc., the California Floral Trade Council, and the Floral Trade Council, requested administrative reviews of the suspension agreement. We initiated the reviews on February 23, 1987 (52 FR 5479) and on March 2, 1988 (53 FR 6681). The Department has now conducted these reviews in accordance with section 751 of the Tariff Act of 1930 ("the Tariff Act").

Scope of Review

The United States, under the auspices of the Customs Cooperation Council, has developed a system of tariff classification based on the international harmonized system of Customs nomenclature. On January 1, 1989, the United States fully converted to the Harmonized Tariff Schedule (HTS), as provided for in section 1201 *et seq.* of the Omnibus Trade and Competitiveness Act of 1988. All merchandise entered, or withdrawn from warehouse, for consumption on or after that date is now classified solely according to the appropriate HTS item number(s).

Imports covered by these reviews are shipments of roses and other cut flowers from Colombia. During the periods of review, such merchandise was classifiable under items 192.1610 through 192.2192 of the Tariff Schedules of the United States Annotated. This merchandise is currently classifiable under HTS items 0603.10.60, 0603.10.70, 0603.10.80 and 0603.90.00. The HTS item numbers are provided for convenience and Customs purposes. The written description remains dispositive.

The review covers the periods January 1, 1986 through December 31, 1986 and January 1, 1987 through December 31, 1987 and ten programs.

The producers and exporters listed in Appendix I, accounting for more than eighty-five (85) percent of the total exports of roses and other cut flowers (excluding miniature carnations) from Colombia to the United States, are signatories to the suspension agreement.

Analysis of Programs

(1) Tax Rebate Certificate

On April 1, 1984, the Colombian government pursuant to Law 48/83, established the Tax Rebate Certificate ("CERT"), which replaced the Tax Reimbursement Certificate Program ("CAT"). According to the Colombian government, the CERT rebated all or part of the indirect taxes paid by exporters. CERT is freely negotiable on the stock market and can be used for paying a variety of taxes.

The Government of Columbia provides payment to exporters of roses and other cut flowers in the form of CERT. Rebates are calculated as a percentage of the value of the exported product attributable to the domestic value-added content.

As a term of the suspension agreement, the Colombia government terminated CERT payments on exports of cut flowers to the United States. We verified that there were no CERT payments on shipments of cut flowers to the United States and Puerto Rico during the period of review.

(2) Air Freight Rates

The Civil Aeronautics Board (DAAC), an agency of the Colombia government, established in Resolution 5833 air freight rates for a variety of products, including cut flowers. Resolution 6333 of September 25, 1981, which updates Resolution 5833, set a minimum air freight rate of U.S.$0.45 per kilo and a maximum rate of U.S.$0.62 per kilo for flowers exported to the United States. The rates established under Resolution 6333 were in effect during the periods of review.

Section D(3) of the suspension agreement states that the Department may consider rescinding the agreement if the air freight rates paid by cut flower exporters approach government mandated maximum rates set by the DAAC. If we found such rates, we might consider them indicative of government control rather than the result of competitive forces. We found that rates ranged from U.S.$0.53 per kilo to U.S.$0.65 kilo, including a U.S. $0.05 charge for handling and cooling services. Handling and cooling charges are not regulated by DAAC. The rates negotiated between cut flower exporters and air freight companies were competitively priced. Therefore, we preliminarily determine that this program does not provide any benefits to the cut flower exporters.

(3) Resolutions 59 and 22

Resolution 59/72, provided working capital financing at preferential rates to firms that manufacture, store or sell products destined for export. This program was updated by Resolution 22/84. All industries were eligible, except producers of coffee, petroleum, and petroleum by-products. Resolution 22/84 loans are administered by the Export Promotion Fund ("PROEXPO"), an agency of the Colombian government. The loans are for 180 days and the interest is paid quarterly, in advance. In December 1986, the maximum interest rate was 22.0 percent. Colombian cut flower exporters received working capital loans under Resolution 22/84 during 1986.

Since we found this program to be countervailable in the agreement suspending the countervailing duty investigation on certain textile mill products and apparel from Colombia (50 FR 9863, March 12, 1985), we included it in the December 15, 1986 revised suspension agreement. At that time, we established a short-term benchmark interest rate of 22.5 percent, which was the average rate of the Fondo Financiero Agropecuario (FFA) and the Agrarian Fund as of March 31, 1986. The revised suspension agreement required that the cut flower exporters not apply for, or receive, any short-term export financing provided by PROEXPO other than that offered at or above the short-term

benchmark interest rate of 22.5 percent. All loans with outstanding balances were to be repaid or refinanced by March 15, 1987, ninety days after notice of the revised suspension agreement was published in the **Federal Register.**

Resolution 3/87, which is an update to Resolution 22/84, was passed by PROEXPO on February 26, 1987. Resolution 3/87 changed the short-term interest rate to 22.5 percent and required the interest rate on all outstanding loans that were taken out under Resolution 22/84 be refinanced at the interest rate benchmark. At the nine companies we verified, all PROEXPO short-term loans outstanding were refinanced in March 1987 at the interest rate benchmark, and the adjusted interest differential was paid.

On December 21, 1987, PROEXPO passed Resolution 11/87, which covers pre-shipment working capital loans, and 14/87, which provides working capital financing to export companies for various products, including cut flowers. Resolution 11/87 established financing to flower exporters at the highest interest rate between 22.5 percent per year prepaid quarterly and the interest rate paid on certificates of deposit (DTF), payable at the end of each quarter. The certificates of deposit rate is a market-determined rate. Resolution 14/87 established financing to flower exporters by setting as the base rate the highest rate between 25 percent per year prepaid quarterly and the DTF rate. The actual rate charged varies depeding on the size of the company. The Colombian government has moved away from the fixed-rate PROEXPO financing to the DTF rate, which more accurately reflects interest rate fluctuations in the market. No loans were taken out under Resolution 11/87 or 14/87 during the review period. We preliminarily determine that the DTF interest rate is an appropriate market rate indicator for pre-shipment and post-shipment financing, and that cut flower exporters have complied with the terms of the suspension agreement.

(4) Resolution 40

Resolution 40/78 was approved under Decree 2366 of 1974. Decree 2366/74 provides exporters with fixed assets financing. During 1986. flower exporters received financing at preferential interest rates of 14 and 18 percent. The revised suspension agreement set a 21 percent benchmark interest rate. On February 26, 1987, PROEXPO passed Resolution 4/87, which changed the interest rate to 21 percent and required the flower exporters to refinance all outstanding loan balance at the new higher interest rate. We verified that all outstanding long-term loan balances were refinanced in March 1987 at the interest rate benchmark.

Resolution 13/87, passed by PROEXPO on December 21, 1987, sets the base rate at the highest rate between 25 percent per year prepaid quarterly and the DTF rate. The actual rate changed varies depending on the size of the company. There were no loans approved for cut flower exporters under Resolution 13/87 during the periods of review.

We preliminarily determine that the DTF is an appropriate market rate indicator for long-term loans and that cut flower exporters have complied with the term of the suspension agreement.

(5) Duty and Tax Exemptions Under Plan Vallejo

Plan Vallejo exempts exports from import duties on imported raw materials, intermediate products, and capital goods used to produce exported products. The exemption of customs duties and indirect taxes on imported imputs physically incorporated into exports is not countervailable. Exemptions on non-physically incorporated inputs, such as imported capital goods, are countervailable when the exemption is conditional upon exportation.

On December 15, 1986, we revised the suspension agreement to include renunciation of duty and tax exemptions for imported capital equipment under Plan Vallejo. Because of an administrative oversight and lack of communication between two Colombian government agencies, ten contracts were approved during the first quarter of 1987. Six signatories to the suspension agreement imported capital goods under Plan Vallejo in 1987.

We verified that the firms that utilized the Plan Vallejo contracts subsequently paid the applicable duties and taxes on the capital goods imported. Therefore, we preliminarily determine that the signatories did not benefit from this program in 1987.

(6) Resolution 10

The flower exporters, on a voluntary basis, allowed the Banco de la Republica to withhold a certain percentage of their CAT/CERT rebates earned on non-U.S. exports. The Banco de la Republica also held all CAT/CERT rebates that would have been paid in exports of roses and other cut flowers to the United States from January 1983, the effective date of the suspension agreement, until November 1985, when the established rebate rate for flowers subject to suspension agreement was reduced to zero. PROEXPO issued Resolution 10, effective July 23, 1986, to use these funds for the diversification and development of flowers and vegetables for external markets; transport and control procedures to prevent drug and narcotic traffic in exports of flowers and vegetables; development of new markets; and payment of logal and technical services required in Colombia and abroad. The resolution requires that any funds expended under this program be disbursed in a manner consistent with the suspension agreement.

During the periods of review, expenditures from this fund were used for legal fees, narcotics control and security, generic promotion and development of new non-U.S. markets. We found no evidence to indicate that these funds were provided to exporters of flowers to the United States, therefore, we preliminarily determine that exports of flowers to the United States did not receive a countervailable benefit from this program.

(7) Other Programs

We examined the following program and preliminarily determine that flower exporters did not use them during the periods of review:

(A) Fund for Agricultural Financing ("FFA");

(B) Fund for Industrial Financing ("FFI");

(C) Capital Formation Fund ("FCE"); and

(D) Fund for National Economic Development ("FONADE")

Preliminary Results of Review

As a result of our review, we preliminarily determine that the signatories have complied with the terms of the suspension agreement during the period January 1, 1986 through December 31, 1987.

The agreement can remain in force only as long as shipments from the signatories account for at least 85 percent of imports of the subject merchandise into the United States. Our information indicates that the signatories accounted for over 90 percent of imports of this merchandise into the United Stated during the period of review.

Interested parties may submit written comments on these preliminary results within 30 days of the date of publication of this notice and may request disclosure and/or a hearing within 10 days of the date of publication. Any hearing, if requested, will be held 44 days from the date of publication or the first workday thereafter. Rebuttal briefs and rebuttals to written comments,

limited to issues in those comments, must be filed not later than 37 days after the date of publication. Any request for an administrative protective order must be made no later than five days after the date of publication. The Department will publish the final results of its analysis of issues raised in any such written comments or at a hearing.

This administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) and § 355.22 of the Commerce Regulations published in the **Federal Register** on December 27, 1988 (53 FR 53254) (to be codified at 19 CFR 355.22).

Dated: December 5, 1989.

Eric I. Garfinkel,

Assistant Secretary for Import Administration.

Appendix I

Company

Abaco Tulipanes De Colombia S.A.
Achalay Ltda.
Agricola Ltda.
Agricola Benilda Ltda.
Agricola Bojaca Ltda.
Agricola Bonanza Ltda.
Agricola De La Fontanta y Cía Ltda.
Agricola de los Alisos Ltda.
Agricola de Occidente.
Agricola del Monte Ltda.
Agricola el Cactus S.A.
Agricola el Jardin
Agricola el Mortino Ltda.
Agricola el Redil
Agricola Floral Ltda.
Agricola Guali Ltda.
Agricola la Corsaria Ltda.
Agricola la Floresta Ltda.
Agricola la Maria Ltda.
Agricola los Arboles
Agricola los Gaques Ltda.
Agricola Malqui Ltda.
Agricola Papagayo Ltda.
Agro Koralia Ltda.
Agrodex Ltda.
Agroindustrias De Narino Ltda.
Agromec Ltda.
Agromonte Ltda.
Agroindustria Del Rio Frio Ltda.
Agropecuaria Cuernavaca
Agrorosas S.A.
Agrosuba
Ancas Ltda.
Arboles Azules Ltda.
Astro Ltda.
Astroflores Ltda.
Becerra Castellanos y Cia
Bogota Flowers Ltda.
Cienfuegos Ltda.
Claveles Colombianos Ltda.
Claveles de los Alpes Ltda.
Colinga Ltda.
Conbiflor
Confloresa Ltda.
Crop S.A.
Cult. del Caribe Ltda. "Florcaribe"
Cultivos Buenavista Ltda.
Cultivos el Lago
Cultivos Medellin Ltda.
Daflor Ltda.
De la Pava Guevara e Hijos Ltda.
Del Tropico Ltda.
Dianticola Colombiana Ltda.
Edir Ltda.
El Antelio S.A.
El Rancho Ltda.
El Timbul Ltda.
Exportaciones Bochica S.A.
Flomingo Flowers Ltda.
Flora Bellisma Ltda.
Flora Intercontinental Ltda.
Floral Ltda.
Floralex Ltda.
Floramerica
Florandia Herrera Camacho y Cia
Floreales Ltda.
Florenal Ltda.
Flores Acuarela S.A.
Flores Aguaclara Ltda.
Flores Aguila Ltda.
Flores Alborada S.A.
Flores Alcala Ltda.
Flores Alfaya Ltda.
Flores Andinas Ltda.
Flores Aurora Ltda.
Flores Bachue Ltda.
Flores Catalina Ltda.
Flores Cigarral Ltda.
Flores Colombianas Ltda.
Flores Colon Ltda.
Flores Condor de Colombia Ltda.
Flores Corinto
Flores de Cota Ltda.
Flores de Funza S.A.
Flores de Hunza Ltda.
Flores de la Pradera Ltda.
Flores de la Sabana
Flores Cajibio
Flores Catalina Ltda.
Flores de Hacaritama
Flores de la Vega Ltda. "Vegaflor"
Flores de las Mercedes Ltda.
Flores de los Amigos Ltda.
Flores de los Andes
Flores de los Arrayanes Ltda.
Flores de Nemocon Ltda.
Flores de Oriente Ltda.
Flores de Serrezuela S.A.
Flores de Suba Ltda.
Flores de Suesca
Flores de Tenjo
Flores De Ubate Ltda.
Flores del Bosque
Flores del Campo Ltda.
Flores del Cauca
Flores del Cielo Ltda.
Flores del Cortijo
Flores del Gallinero Ltda.
Flores del Lago Ltda.
Flores del Monte Ltda.
Flores del Pinar Ltda.
Flores del Prado Ltda.
Flores del Pretrero Ltda.
Flores del Rio
Flores del Tambo Leda.
Flores del Vino Ltda.
Flores Depina Ltda.
Flores Dos Hectareas Ltda.
Flores el Chircal Ltda.
Flores el Danubio Ltda.
Flores el Lobo Ltda.
Flores el Puente Ltda.
Flores el Rosal Ltda.
Flores el Trentino Ltda.
Flores Esmeralda S.A.
Flores Estrella Ltda.
Flores Galia Ltda.
Flores Generales Ltda.
Flores Guaicata Ltda.
Flores Hana Ichi de Col.
Flores Horizonte (Flores Monte Verde)
Flores Internacionales Ltda.
Flores Juananbu Ltda.
Flores Juncalito Ltda.
Flores la Conchita.
Flores la Conejera Ltda.
Flores la Estancia Ltda.
Flores la Fragancia S.A.
Flores la Macarena
Flores la Maria Ltda.
Flores la Pampa Ltda.
Flores la Union S.A.
Flores la Valvanera Ltda.
Flores Lano Grande Ltda.
Flores las Plamas Ltda.
Flores las Caicas-Davila Arbelaez Cia S.S.
Flores los Rosales Ltda.
Flores Marandua Ltda.
Flores Maria Elisa Ltda.
Flores Monserrate Ltda.
Flores Moungar Ltda.
Flores Palimana
Flores Petaluma Ltda.
Flores Ramo Ltda.
Flores Ruizort
Flores San Carlos
Flores Santa Fe Ltda.
Flores Santa Rosa Ltda.
Flores Sausalito
Flores Sindamonoi Vod Ltda.
Flores Tairona Ltda.
Flores Tecnicas
Flores Tejas Verdes Ltda.
Flores Tenerife Ltda.
Flores Tiba Ltda.
Flores Tibati Ltda.
Flores Timana Ltda.
Flores Tocarinda Ltda.
Flores Tokay H.I.S.A.
Flores Tomine Ltda.
Flores Tropicales Ltda.
Floresa
Florex S.A.
Florexpo Ltda.
Floricola la Gaitana
Floricultores Asociados Lorena "Lorena Ltda."
Florinda Ltda.
Hacienda Curubital
Hacienda la Embarrada Ltda.
Happy Candy Ltda.

Happy Flowers
Horticuldura de La Sabana
Industrial Agricola Ltda.
Internacional de Flores Ltda. "Interflores"
Inverpalmas Ltda.
Inversiones Calipso S.A.
Ingro Ltda.
Inv. Cubivan Ltda.
Inv. Mejia Landucci y Cia S.C.
Inv. Rodaz Ltda.
Inverflores Ltda.
Inversiones Agricolas M.T. Ltda.
Inversiones Almer Ltda.
Inversiones Cota Ltda.
Inversiones el Bambu Ltda.
Inversiones Istra
Inversiones Kluar Ltda.
Inversiones Marcote Ltda.
Inversiones Maria Alejandra
Inversiones Miraflores Ltda
Inversiones Nativa Ltda.
Inversiones Patxi Ltda.
Inversiones Penas Blancas Ltda.
Inversiones Santa Rosa S.R.W. Ltda.
Inversiones Targa S.A.
Inversiones la Serena
Inversiones Santa Rita Ltda.
Iturrama S.A.
Jaramillo and Daza Ltda.
Jardines Bacata
Jardines Chuntame
Jardines de Chia Ltda.
Jardines de Colombia Ltda.
Jardines de los Andes
Jardines del Muna.
Jardines Fredonia Ltda.
Jardines la Aurora S.S.
Jardines la Florida Ltda.
Jardines Natalia Ltda.
Kingdom S.A.
La Fleurette de Colombia S.A.
La Nueva Rosa Ltda.
La Plazoleta Ltda.
Las Amalias S.A.
Las Flores Ltda.
Linda Colombia Ltda.
Los Geranios Ltda.
Mac Flowers Ltda.
Nahecha Bustos Humberto
Manrique Fajardo Luciano
Marketing and Trade Company Ltda.
Martinez Zurbachen & Cia
Medellin Ltda.
Mejia Sendoya y Cia Sen C.
M.G. Consultores Ltda.
Microplantas Ltda.
Monserrate Ltda.—Represent. E. Invers.
Monteverde Ltda.
Multiflores Ltda.
Orquideas Acatayma Ltda.
Petalos de Colombia Ltda.
Pineros Putman Enrique
Pisochago Ltda.
Plantaciones Delta Ltda.
Plantas Ornamentales del Col.
Plantas S.A.
Pompones Ltda.
Productos el Rosal Ltda.
Rincon Diaz Olga Paulina
Rocicler Ltda.
Roselandia Ltda.
Rosaflor Ltda.
Rosales de Colombia "Rosalco"
Rosas Colombianas Ltda.
Rosas de Colombia Ltda.
Rosas de Exportacion "Rosex"
Rosas el Juncal Ltda.
Rosas Sabanilla
Rosas Sausalito Ltda.
Rosas y Flores Ltda.
Rosas y Jardines del Tropico Ltda.
Roses Tesalia
Royal Carnation
Sandra Patricia Rey
Sansa Flowers Ltda.
Santa Helena S.A.
Santana Flowers Ltda.
Sociedad Arawac S.A.
Sun Flowers Ltda.
Sunset Farms Ltda.
Super Rosas Ltda.
Taganga Ltda.
Tec. Agricola Ganadera Tag Ltda.
Tecniflores Ltda.
Tegeiro Repres. Internales. "Terinter"
The Beall Company
Tropiflora Ltda.
Tuchany S.A.
Universal de Flores Ltda.
Universal Flowers
Velez de Monchaux e Hijos y Cia S. en C.
Villa Diana Ltda.

[FR Doc. 89-28953 Filed 12-11-89; 8:45 am]
BILLING CODE 3510-DS-M

National Oceanic and Atmospheric Administration

Final Approval of Amendments No. 4 and 5 to the Alaska Coastal Management Program

AGENCY: National Oceanic and Atmospheric Administration, National Ocean Service, Office of Ocean and Coastal Resource Management.

ACTION: Approval of amendments to the Alaska Coastal Management Program.

Location: Northwest Arctic Borough and Bering Straits Coastal Resource Service Area (CRSA), Alaska.

SUMMARY: The Office of Ocean and Coastal Resource Management (OCRM), National Ocean Service, National Oceanic and Atmospheric Administration (NOAA) received requests from the State of Alaska to incorporate the Northwest Arctic Borough (formerly NANA) Coastal Management Program (NWAB CMP) and the Bering Straits CRSA Coastal Management Program (BSCMP) into the federally-approved Alaska Coastal Management Program (ACMP). The State's requests were made pursuant to section 306(g) of the Coastal Zone Management Act of 1972, as amended (CZMA), 16 U.S.C. 1455(g) and the regulations implementing the CZMA at 15 CFR 923.81. Both the NWAB CMP and BSCMP create new coastal boundaries for the ACMP and establish goals and policies for activities taking place in their respective districts. Both programs follow the guidelines and standards for local program development set forth in the ACMP. The NWAB CMP will be administered by the Borough and the State and the BSCMP will be administered by the CRSA Board and the State.

Notice is hereby given that the Director of OCRM has reviewed the amendment requests and has made a determination that the ACMP as amended by the NWAB CMP and the BSCMP will still constitute an approvable program and that the procedural requirements of section 306(g) of the CZMA have been met.

Notice of intent to approve the amendment was published in the **Federal Register** on Thursday, August 30, 1989, and interested parties had until September 30, 1989 to comment on the proposed changes. The proposed amendments along with the preliminary Determination of Approvability were distributed to Federal agencies and other interested parties. All comments received have been responded to and the Final Findings of Approvability have been approved by the Director of OCRM. The Federal consistency provisions of section 307 of the CZMA, 16 U.S.C. 1456, shall apply to the NWAB CMP and the BSCMP on the date that the respective programs are filed with the Lieutenant Governor of the State of Alaska.

FOR FURTHER INFORMATION CONTACT: James P. Burgess, Acting Regional Manager, Pacific Region, Office of Ocean and Coastal Resource Management, 1825 Connecticut Avenue, NW., Washington, DC 20235, (202) 673-5158.

Dated: December 5, 1989.

Virginia K. Tippie.

Assistant Administrator for Ocean Services and Coastal Zone Management.

Federal Domestic Assistance Catalog 11.419, Coastal Zone Management Program Administration

[FR Doc. 89-28977 Filed 12-11-89; 8:45 am]
BILLING CODE 3510-08-M

DEPARTMENT OF DEFENSE

Public Information Collection Requirement Submitted to OMB for Review

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Title, Applicable Form, and Applicable OMB Control Number: Air Force Academy Precandidate Questionnaire; USAFA Form 149; and OMB Control Number 0701-0087.

Type of Request: Extension of the Expiration Date of a Currently Approved Collection.

Average Burden Hours/Minutes Per Response: .4 Hours.

Frequency of Response: Reporting on Occasion.

Number of Respondents: 50,000.

Annual Burden Hours: 20,000.

Annual Responses: 50,000.

Needs and Uses: "Military Service Academies; Military Recruiting," The U.S. Air Force Academy needs this form to collect information from prospective candidates to conduct a preliminary assessment of a candidate's prospects, qualifications, and eligibility status for application and selection for entry into the Air Force Academy.

Affected Public. Individuals or Households.

Frequency: One time only.

Respondent's Obligation: Required to obtain or retain a benefit.

OMB Desk Officer: Dr. J. Timothy Sprehe. Written comments and recommendations on the proposed information collection should be sent to Dr. J. Timothy Sprehe at Office of Management and Budget, Desk Officer, Room 3235, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Ms. Pearl Rascoe-Harrison. Written request for copies of the information collection proposal should be sent to Ms. Rascoe-Harrison, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, Virginia 22202-4302.

Dated: December 6, 1989.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 89-28930 Filed 12-11-89; 8:45 am]

BILLING CODE 3810-01-M

Public Information Collection Requirements Submitted to OMB for Review

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Title, Applicable Form, and Applicable OMB Control Number: Professional Qualifications, Medical and Peer Reviewers, CHAMPUS Form 780, and No OMB Control Number.

Type of Request: New collection.

Average Burden Hours/Minutes Per Response: 15 minutes.

Frequency of Response: Once.

Number of Respondents: 60.

Annual Burden Hours: 15.

Annual Responses: 60.

Needs and Uses: The information collection requirement is necessary to obtain and record the professional qualifications of medical and peer reviewers utilized within CHAMPUS. The form is included as an exhibit in an appeal of hearing case file as evidence of the reviewer's professional qualifications to review the medical documentation contained in the case file.

Affected Public: Businesses or other for-profit and small businesses or organizations.

Frequency: Continuing.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Dr. J. Timothy Sprehe.

Written comments and recommendations on the proposed information collection should be sent to Dr. J. Timothy Sprehe at Office of Management and Budget, Desk Officer, Room 3235, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Ms. Peal Rascoe-Harrison.

Written request for copies of the information collection proposal should be sent to Ms. Rascoe-Harrison, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, Virginia 22202-4302.

Dated: December 7, 1989.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 89-28993 Filed 12-11-89; 8:45 am]

BILLING CODE 3810-01-M

Public Information Collection Requirement Submitted to OMB for Review

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Title, Applicable Form, and Applicable OMB Control Number: The 1989 Survey of High School Youth and Parents; No Applicable Form; and No OMB Control Number.

Type of Request: New.

Average Burden Hours/Minutes Per Response: .264 hours.

Frequency of Response: One-time.

Number of Respondents: 21,967.

Annual Burden Hours: 5,799.

Annual Responses: 21,967.

Needs and Uses: Potential impact of extraordinary changes to Army personnel policy and recruiting will be determined through analysis of survey administered to high school juniors, seniors and parents. Respondent attitudes towards enactment of a National Service Act compared to the present and proposed Army incentives will be examined.

Affected Public: Businesses or other for-profit; Small businesses or organizations.

Frequency: One-time.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Dr. J. Timothy Sprehe.

Written comments and recommendations on the proposed information collection should be sent to Dr. J. Timothy Sprehe at Office of Management and Budget, Desk Officer, Room 3235, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Ms. Pearl Rascoe-Harrison.

Written request for copies of the information collection proposal should be sent to Ms. Rascoe-Harrison, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, Virginia 22202-4302.

Dated: December 7, 1989.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 89-28992 Filed 12-11-89; 8:45 am]

BILLING CODE 3810-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ST90-0001-000 through ST90-0344-000]

K N Energy, Inc.; Self-Implementing Transactions

December 1, 1989.

Take notice that the following transactions have been reported to the Commission as being implemented pursuant to part 284 of the Commission's regulations, sections 311 and 312 of the Natural Gas Policy Act of 1978 (NGPA) and section 5 of the Outer Continental Shelf Lands Act.[1]

The "Recipient" column in the following table indicates the entity receiving or purchasing the natural gas in each transaction.

The "part 284 subpart" column in the following table indicates the type of transaction.

A "B" indicates transportation by an interstate pipeline on behalf of an intrastate pipeline or a local distribution company pursuant to § 284.102 of the Commission's regulations and section 311(a)(1) of the NGPA.

A "C" indicates transportation by an interstate pipeline on behalf of an intrastate pipeline or a local distribution company served by an interstate pipeline pursuant to § 284.122 of the Commission's regulations and section 311(a)(2) of the NGPA. In those cases where Commission approval of a transportation rate is sought pursuant to § 284.123(b)(2), the table lists the proposed rate and the expiration date of the 150-day period for staff action. Any person seeking to participate in the proceeding to approve a rate listed in the table should file a motion to intervene with the Secretary of the Commission on or before December 21, 1989.

A "D" indicates a sale by an interstate pipeline to an interstate pipeline or a local distribution company served by an interstate pipeline pursuant to § 284.142 of the Commission's Regulations and section 311(a)(2) of the NGPA. Any interested person may file a complaint concerning such sales pursuant to § 284.147(d) of the Commission's Regulations.

An "E" indicates an assignment by an intrastate pipeline to any interstate pipeline or local distribution company pursuant to § 284.163 of the Commission's regulations and section 312 of the NGPA.

A "G" indicates transportation by interstate pipeline on behalf of another interstate pipeline pursuant to § 284.222 and a blanket certificate issued under § 284.221 of the Commission's regulations.

A "G-S" indicates transportation by an interstate pipelines on behalf of shippers other than interstate pipelines pursuant to § 284.223 and a blanket certificate issued under § 284.221 of the Commission's regulations.

A "G-LT" or "G-LS" indicates transporation, sales or assignments by a local distribution company on behalf of or to an interstate pipeline or local distribution company pursuant to a blanket certificate issued under § 284.224 of the Commission's regulations.

A "G-HT" or "G-HS" indicates transporation, sales or assignments by a Hinshaw Pipeline pursuant to a blanket certificate issued under § 284.224 of the Commission's regulations.

A "K" indicates transporation of natural gas on the Outer Continental Shelf by an interstate pipeline on behalf of another interstate pipeline pursuant to § 284.303 of the Commission's regulations.

A "K-S" indicates transporation of natural gas on the Outer Continental Shelf by an intrastate pipeline on behalf of shippers other than interstate pipelines pursuant to § 284.303 of the Commission's regulations.

Lois D. Cashell,

Secretary.

[1] Notice of a transaction does not constitute a determination that the terms and conditions of the proposed service will be approved or that the noticed filing is in compliance with the Commission's regulations.

Docket number [1]	Recipient	Date filed	Part 284 subpart	Expiration date [2]	Transportation rate (c/MMBTU)
ST90-0001 K N Energy, Inc.	Associated Intrastate Pipeline Co	10-03-89	B		
ST90-0002 K N Energy, Inc	NGC Intrastate Pipeline Co	10-03-89	B		
ST90-0003 K N Energy, Inc	Northern Gas of Wyoming	10-03-89	B		
ST90-0004 Exxon Gas System, Inc	Longhorn Pipeline Co	10-03-89	C	03-0-90	12.80
ST90-0005 Trunkline Gas Co	Texpar Energy, Inc	10-03-89	G-S		
ST90-0006 Trunkline Gas Co	Bridgeline Gas Distribution Co	10-03-89	B		
ST90-0007 Trunkline Gas Co	Bishop Pipeline Corp	10-03-89	B		
ST90-0008 Trunkline Gas Co	Enron Gas Marketing, Inc	10-03-89	G-S		
ST90-0009 Trunkline Gas Co	Associated Natural Gas Co., Inc	10-03-89	G-S		
ST90-0010 Lone Star Gas Co	Natural Gas Pipeline Co. of America	10-03-89	C		
ST90-0011 Texas Gas Transmission Corp	Entrade Corp	10-03-89	G-S		
ST90-0012 Texas Gas Transmission Corp	Fina Oil and Chemical Co	10-03-89	G-S		
ST90-0013 Texas Gas Transmission Corp	PSI, Inc	10-03-89	G-S		
ST90-0014 Texas Gas Transmission Corp	Brooklyn Interstate Natural Gas Corp	10-03-89	G-S		
ST90-0015 Stingray Pipeline Co	Excel Intrastate Pipeline Co	10-03-89	B		
ST90-0016 Natural Gas Pipeline Co. of America	Rangeline Corp	10-03-89	G-S		
ST90-0017 Stingray Pipeline Co	EP Operating Co	10-03-89	K-S		
ST90-0018 Canyon Creek Compression Co	NGC Transportation, Inc	10-03-89	B		
ST90-0019 Canyon Creek Compression Co	Midcon Marketing Corp	10-03-89	G-S		
ST90-0020 Transcontinental Gas Pipeline Corp	Fina Oil and Chemical Co	10-03-89	G-S		
ST90-0021 Tennessee Gas Pipeline Co	North Atlantic Utilities, Inc	10-03-89	G-S		
ST90-0022 Panhandle Eastern Pipeline Co	Sunnybrook Transmission Inc	10-03-89	G-S		
ST90-0023 Panhandle Eastern Pipeline Co	Bishop Pipeline Corp	10-03-89	B		
ST90-0024 Panhandle Eastern Pipeline Co	Vesgas Co	10-03-89	B		
ST90-0025 Transcontinental Gas Pipeline Corp	South Jersey Energy Co	10-03-89	G-S		
ST90-0026 Transcontinental Gas Pipeline Corp	Baltimore Gas and Electric Co	10-03-89	B		
ST90-0027 Williams Natural Gas Co	Coastal Gas Marketing Co	10-03-89	G-S		
ST90-0028 Williams Natural Gas Co	Coastal Gas Marketing Co	10-03-89	G-S		
ST90-0029 Columbia Gas Transmission Corp	Columbia Gas Development Corp	10-03-89	G-S		
ST90-0030 Columbia Gulf Transmission Co	Florida Gas Transmission Co	10-03-89	G		
ST90-0031 Sea Robin Pipeline Co	Enron Gas Marketing, Inc	10-03-89	G-S		

Docket number [1]	Recipient	Date filed	Part 284 subpart	Expiration date [2]	Transportation rate (c/ MMBTU)
ST90-0032 United Gas Pipeline Co	Phoenix Gas Pipeline Co	10-03-89	G-S		
ST90-0033 United Gas Pipeline Co	Desoto Pipeline Co., Inc	10-03-89	B		
ST90-0034 United Gas Pipeline Co	Victoria Gas Corp	10-03-89	G-S		
ST90-0035 United Gas Pipeline Co	Delhi Gas Pipeline Corp	10-03-89	B		
ST90-0036 United Gas Pipeline Co	Ames Financial Inc	10-03-89	G-S		
ST90-0037 Columbia Gas Transmission Corp	Riley Natural Gas Co	10-03-89	G-S		
ST90-0038 Tarpon Transmission Co	Enron Gas Marketing, Inc	10-04-89	G-S		
ST90-0039 Tarpon Transmission Co	Unicorp Energy, Inc	10-04-89	G-S		
ST90-0040 Natural Gas Pipeline Co. of America	Phillips Petroleum Co	10-04-89	G-S		
ST90-0041 Texas Eastern Transmission Corp	Orange and Rockland Utilities, Inc	10-04-89	B		
ST90-0042 Texas Eastern Transmission Corp	Tennessee River Transmission Co	10-04-89	B		
ST90-0043 Texas Eastern Transmission Corp	Apollo Gas, Co	10-04-89	B		
ST90-0044 Texas Eastern Transmission Corp	Southeastern Natural Gas Co	10-04-89	B		
ST90-0045 Texas Eastern Transmission Corp	New Jersey Natural Gas Co	10-04-89	B		
ST90-0046 ANR Pipeline Co	Entrade Corp	10-04-89	G-S		
ST90-0047 ANR Pipeline Co	Hunt Petroleum Corp	10-04-89	G-S		
ST90-0048 ANR Pipeline Co	Steelcase, Inc	10-04-89	G-S		
ST90-0049 ANR Pipeline Co	Southern Gas Co	10-04-89	G-S		
ST90-0050 ANR Pipeline Co	Northern Illinois Gas Co	10-04-89	B		
ST90-0051 ANR Pipeline Co	Mobil Vanderbilt-Beaumont Pipeline Co	10-04-89	B		
ST90-0052 ANR Pipeline Co	Santanna Natural Gas Corp	10-04-89	G-S		
ST90-0053 ANR Pipeline Co	Wisconsin Fuel And Light Co	10-04-89	B		
ST90-0054 ANR Pipeline Co	Texas Eastern Gas Services Co	10-04-89	G-S		
ST90-0055 ANR Pipeline Co	Wisconsin Natural Gas Co	10-04-89	B		
ST90-0056 ANR Pipeline Co	St. Joseph Light & Power Co	10-04-89	B		
ST90-0057 ANR Pipeline Co	Tarpon Gas Marketing Ltd	10-04-89	G-S		
ST90-0058 ANR Pipeline Co	Tarpon Gas Marketing Ltd	10-04-89	G-S		
ST90-0059 ANR Pipeline Co	Equitable Resources Marketing Co	10-04-89	G-S		
ST90-0060 ANR Pipeline Co	Northern Illinois Gas Co	10-04-89	B		
ST90-0061 BP Gas Transmission Co	ANR Pipeline Co., et al	10-05-89	C	03-04-90	13.70
ST90-0062 Enogex Inc	Panhandle Eastern Pipeline Co	10-05-89	C	03-04-90	43.57
ST90-0063 Acadian Gas Pipeline System	Transcontinental Gas Pipeline Corp	10-05-89	C		
ST90-0064 Colorado Interstate Gas Co	Continental Natural Gas, Inc	10-05-89	G-S		
ST90-0065 ANR Pipeline Co	Michigan Consolidated Gas Co	10-05-89	B		
ST90-0066 ANR Pipeline Co	Entrade Corp	10-05-89	G-S		
ST90-0067 ANR Pipeline Co	Coastal Gas Marketing Co	10-05-89	G-S		
ST90-0068 Northern Natural Gas Co	NGC Transportation, Inc	10-06-89	B		
ST90-0069 Northern Natural Gas Co	Wisconsin Power and Light Co	10-06-89	B		
ST90-0070 Northern Natural Gas Co	Northern States Power Co	10-06-89	B		
ST90-0071 Williston Basin Interstate P/L Co	MGTC, Inc	10-06-89	B		
ST90-0072 Williston Basin Interstate P/L Co	MGTC, Inc	10-06-89	B		
ST90-0073 Williston Basin Interstate P/L Co	Quivira Gas Co	10-06-89	B		
ST90-0074 Williston Basin Interstate P/L Co	Montana-Dakota Utilities Co	10-06-89	B		
ST90-0075 Williston Basin Interstate P/L Co	Wyoming Gas Co	10-06-89	B		
ST90-0076 Williston Basin Interstate P/L Co	Longhorn Pipeline Co	10-06-89	B		
ST90-0077 Williston Basin Interstate P/L Co	Quivira Gas Co	10-06-89	B		
ST90-0078 Williston Basin Interstate P/L Co	MGTC, Inc	10-06-89	B		
ST90-0079 Williston Basin Interstate P/L Co	Montana-Dakota Utilities Co	10-06-89	B		
ST90-0080 Williston Basin Interstate P/L Co	Wyoming Gas Co	10-06-89	B		
ST90-0081 United Gas Pipeline Co	Ledco, Inc	10-06-89	G-S		
ST90-0082 United Gas Pipeline Co	Loutex Energy, Inc	10-06-89	G-S		
ST90-0083 ANR Pipeline Co	End Users Supply System	10-06-89	G-S		
ST90-0084 ANR Pipeline Co	Michigan Gas Utilities Co	10-06-89	B		
ST90-0085 ANR Pipeline Co	Consolidated Fuel Corp	10-06-89	G-S		
ST90-0086 Exxon Gas System, Inc	Transcontinental Gas P/L Corp., et al	10-10-89	C	03-09-90	12.80
ST90-0087 Questar Pipeline Co	NGC Transportation, Inc	10-10-89	G-S		
ST90-0088 Northern Border Pipeline Co	Northern Natural Gas Co	10-10-89	G		
ST90-0089 Northern Border Pipeline Co	Northern Natural Gas Co	10-10-89	G		
ST90-0090 Channel Industries Gas Co	Transcontinental Gas Pipe Line Corp	10-10-89	C		
ST90-0091 Channel Industries Gas Co	Amoco Gas Co	10-10-89	C		
ST90-0092 CNG Transmission Corp	O & R Energy Co	10-10-89	G-S		
ST90-0093 CNG Transmission Corp	Koski Construction	10-10-89	G-S		
ST90-0094 CNG Transmission Corp	PSI, Inc	10-10-89	G-S		
ST90-0095 CNG Transmission Corp	Central Allied Enterprises	10-10-89	G-S		
ST90-0096 Texas Gas Transmission Corp	Western Kentucky Gas Co	10-10-89	B		
ST90-0097 Texas Gas Transmission Corp	Columbia Gas Development Corp	10-10-89	G-S		
ST90-0098 Texas Gas Transmission Corp	Western Kentucky Gas Co	10-10-89	B		
ST90-0099 Texas Gas Transmission Corp	Western Kentucky Gas Co	10-10-89	B		
ST90-0100 Texas Gas Transmission Corp	Delhi Gas Pipeline Corp	10-10-89	B		
ST90-0101 Columbia Gulf Transmission Corp	Philadelphia Gas Works, Inc	10-10-89	B		
ST90-0102 Columbia Gulf Transmission Corp	Cincinnati Gas and Electric Co	10-10-89	B		
ST90-0103 Columbia Gulf Transmission Corp	Tenngasco, Inc	10-10-89	G-S		
ST90-0104 Arkla Energy Resources	Gulf States Pipeline Corp	10-10-89	B		
ST90-0105 Arkla Energy Resources	Union Natural Gas Pipeline Co	10-10-89	B		
ST90-0106 Texas Eastern Transmission Corp.[3]	Pennsylvania Gas and Water Co	10-11-89	B		
ST90-0108 Texas Eastern Transmission Corp	Apollo Gas, Co	10-11-89	B		
ST90-0109 Texas Eastern Transmission Corp	Yankee Gas Services Co	10-11-89	B		
ST90-0110 Algonquin Gas Transmission Corp	City of Norwich, Dept. of Public Util	10-11-89	G-S		
ST90-0111 United Gas Pipe Line Co	Graham Energy Marketing Co	10-11-89	G-S		
ST90-0112 Transcontinental Gas Pipe Line Corp	Peoples Natural Gas Co	10-12-89	B		

Docket number [1]	Recipient	Date filed	Part 284 subpart	Expiration date [2]	Transportation rate (c/ MMBTU)
ST90-0113 Texas Eastern Transmission Corp.	Stellar Pipeline Co.	10-12-89	B		
ST90-0114 Natural Gas Pipeline Co. of America	Chevron U.S.A., Inc.	10-12-89	G-S		
ST90-0115 Transtexas Pipeline	El Paso Natural Gas Co.	10-13-89	C		
ST90-0116 Valero Transmission, L.P.	El Paso Natural Gas Co.	10-13-89	C		
ST90-0117 Valero Transmission, L.P.	El Paso Natural Gas Co.	10-13-89	C		
ST90-0118 Southern Natural Gas Co.	Polaris Corp.	10-13-89	G-S		
ST90-0119 Southern Natural Gas Co.	Graham Energy Marketing Co.	10-13-89	G-S		
ST90-0120 Southern Natural Gas Co.	City of Denham Springs	10-13-89	B		
ST90-0121 Southern Natural Gas Co.	Heath Petra Resources, Inc.	10-13-89	G-S		
ST90-0122 Southern Natural Gas Co.	Polaris Corp.	10-13-89	G-S		
ST90-0123 Southern Natural Gas Co.	Texican Natural Gas Co.	10-13-89	G-S		
ST90-0124 Southern Natural Gas Co.	SNG Intrastate Pipeline, Inc.	10-13-89	B		
ST90-0125 Southern Natural Gas Co.	Alabama Power Co.	1 0-13-89	G-S		
ST90-0126 ANR Pipeline Co.	Midcon Marketing Corp.	10-13-89	G-S		
ST90-0127 ANR Pipeline Co.	Coastal Gas Marketing Co.	10-13-89	G-S		
ST90-0128 ANR Pipeline Co.	Wintershall Energy	10-13-89	G-S		
ST90-0129 ANR Pipeline Co.	Bishop Pipeline Corp.	10-13-89	B		
ST90-0130 ANR Pipeline Co.	Stone Container Corp.	10-13-89	G-S		
ST90-0131 ANR Pipeline Co.	Santanna Natural Gas Corp.	10-13-89	G-S		
ST90-0132 ANR Pipeline Co.	Hadson Gas Systems, Inc.	10-13-89	G-S		
ST90-0133 ANR Pipeline Co.	Northwestern Mutual Life Insurance Co.	10-13-89	G-S		
ST90-0134 ANR Pipeline Co.	Northwestern Mutual Life Insurance Co.	10-13-89	G-S		
ST90-0135 ANR Pipeline Co.	Apache Transmission Corp.	10-13-89	B		
ST90-0136 ANR Pipeline Co.	Northwestern Mutual Life Insurance Co.	10-13-89	G-S		
ST90-0137 ANR Pipeline Co.	West Michigan Shared Hospital Laundry	10-13-89	G-S		
ST90-0138 East Ohio Gas Co., The	Texas Eastern Transmission Corp.	10-13-89	G-HT		
ST90-0139 Panhandle Eastern Pipe Line Co.	Energy Pipeline Co.	10-13-89	B		
ST90-0140 Tennessee Gas Pipeline Co.	Prior Intrastate Corp.	10-13-89	B		
ST90-0141 Equitrans, Inc.	Columbia Gas of Pennsylvania, Inc.	10-16-89	B		
ST90-0142 ONG Transmission Co.	Northern Natural Gas Co.	10-16-89	C	03-15-90	24.32
ST90-0143 Seagull Shoreline System	Northern Natural Gas Co.	10-16-89	C	03-15-90	8.50
ST90-0144 Tennessee Gas Pipeline Co.	Delta Natural Gas Co.	10-16-89	B		
ST90-0145 United Gas Pipe Line Co.	Eagle Natural Gas Co.	10-16-89	B		
ST90-0146 United Gas Pipe Line Co.	Bishop Pipeline Corp.	10-16-89	B		
ST90-0147 United Gas Pipe Line Co.	Bishop Pipeline Corp.	10-16-89	B		
ST90-0148 United Gas Pipe Line Co.	Texaco Gas Marketing, Inc.	10-17-89	G-S		
ST90-0149 United Gas Pipe Line Co.	Texican Natural Gas Co.	10-17-89	G-S		
ST90-0150 United Gas Pipe Line Co.	Texaco Gas Marketing, Inc.	10-17-89	G-S		
ST90-0151 Valero Transmission, L.P.	Transwestern Pipeline Co.	10-17-89	C		
ST90-0152 Valero Transmission, L.P.	Natural Gas Pipeline Co. of America	10-18-89	C		
ST90-0153 Transtexas Pipeline	Transwestern Pipeline Co.	10-17-89	C		
ST90-0154 El Paso Natural Gas Co.	Texaco Gas Marketing, Inc.	10-18-89	G-S		
ST90-0155 El Paso Natural Gas Co.	Bridgegas U.S.A. Inc.	10-18-89	G-S		
ST90-0156 Tennessee Gas Pipeline Co.	American Central Gas Marketing Co.	10-18-89	G-S		
ST90-0157 Natural Gas Pipeline Co. of America	PSI, Inc.	10-18-89	G-S		
ST90-0158 ONG Transmission Co.	Mississippi River Transmission Co.	10-18-89	C	02-17-90	24.32
ST90-0159 Equitrans, Inc.	NGC Transportation, Inc.	10-18-89	G-S		
ST90-0160 United Gas Pipe Line Co.	Transworld Oil USA, Inc.	10-18-89	G-S		
ST90-0161 United Gas Pipe Line Co.	Texaco Gas Marketing, Inc.	10-18-89	G-S		
ST90-0162 United Gas Pipe Line Co.	Triumph Natural Gas L.P.	10-18-89	G-S		
ST90-0163 Delhi Gas Pipeline Corp.	Natural Gas Pipeline Co. of America	10-19-89	C		
ST90-0164 United Texas Transmission Co.	Northern Natural Gas Co.	10-19-89	C		
ST90-0165 United Texas Transmission Co.	Amoco Gas Co.	10-19-89	C		
ST90-0166 United Texas Transmission Co.	Northern Natural Gas Co.	10-19-89	C		
ST90-0167 Texas Gas Transmission Corp.	Eaton Corp.	10-19-89	G-S		
ST90-0168 Northwest Pipeline Corp.	Cyanco Co.	10-19-89	G-S		
ST90-0169 Texas Gas Transmission Corp.	Santa Fe Minerals	10-19-89	G-S		
ST90-0170 Natural Gas Pipeline Co. of America	United Gas Pipe Line Co.	10-19-89	G		
ST90-0171 United Gas Pipe Line Co.	Mobil Natural Gas, Inc.	10-20-89	G-S		
ST90-0172 Panhandle Eastern Pipe Line Co.	BP Gas Transmissioin Co.	10-20-89	B		
ST90-0173 Transcontinental Gas Pipe Line Corp.	Citizens Gas Supply Corp.	10-20-89	G-S		
ST90-0174 El Paso Natural Gas Co.	V.H.C. Gas System, L.P.	10-20-89	G-S		
ST90-0175 Equitrans, Inc.	Consolidated Fuel Corp.	10-20-89	G-S		
ST90-0176 Delhi Gas Pipeline Corp.	Arkla Energy Resources	10-23-89	C		
ST90-0177 Delhi Gas Pipeline Corp.	Natural Gas Pipeline Co. of America	10-23-89	C		
ST90-0178 Delhi Gas Pipeline Corp.	Northern Natural Gas Co.	10-23-89	C		
ST90-0179 Delhi Gas Pipeline Corp.	Arkla Energy Resources	10-23-89	C		
ST90-0180 Delhi Gas Pipeline Corp.	Transwestern Pipeline Co.	10-23-89	C		
ST90-0181 Northern Natural Gas Co.	Sunrise Energy Co.	10-19-89	B		
ST90-0182 Northern Natural Gas Co.	Arco Natural Gas Marketing, Inc.	10-19-89	G-S		
ST90-0183 Canyon Creek Compression Co.	Chevron U.S.A., Inc.	10-20-89	G-S		
ST90-0184 Northwest Pipeline Corp.	Union Pacific Resources Co.	10-20-89	G-S		
ST90-0185 Natural Gas Pipeline Co. of America	Midcon Marketing Corp.	10-20-89	G-S		
ST90-0186 Panhandle Eastern Pipe Line Co.	PSI, Inc.	10-23-89	G-S		
ST90-0187 Panhandle Eastern Pipe Line Co.	Indiana Gas Co.	10-23-89	B		
ST90-0188 Panhandle Eastern Pipe Line Co.	Anadarko Trading Co.	10-23-89	G-S		
ST90-0189 Panhandle Eastern Pipe Line Co.	Anadarko Trading Co.	10-23-89	G-S		
ST90-0190 Trunkline Gas Co.	NGC Transportation, Inc.	10-23-89	G-S		
ST90-0191 Stingray Pipeline Co.	Unicorp Energy, Inc.	10-23-89	K-S		
ST90-0192 Moraine Pipeline Co.	Carnation Co.	10-23-89	G-S		

Docket number [1]	Recipient	Date filed	Part 284 subpart	Expiration date [2]	Transportation rate (c/MMBTU)
ST90-0193 Moraine Pipeline Co.	BP Gas Marketing Co.	10-23-89	G-S		
ST90-0194 Natural Gas Pipeline Co. of America	Midcon Marketing Corp.	10-23-89	G-S		
ST90-0195 Tennessee Gas Pipeline Co.	Columbia Gas Transmission Corp.	10-23-89	G		
ST90-0196 K N Energy, Inc.	Mountain Fuel Supply Co.	10-23-89	B		
ST90-0197 Northwest Pipeline Corp.	Pacific Western Energy Co.	10-23-89	G-S		
ST90-0198 Texas Eastern Transmission Corp.	New Jersey Natural Gas Co.	10-23-89	B		
ST90-0199 Arkla Energy Resources	AER Intrastate Pipeline	10-23-89	B		
ST90-0200 Tennessee Gas Pipeline Co.	Colonial Gas Company	10-24-89	B		
ST90-0201 Stingray Pipeline Co.	Louisiana Resources Co.	10-24-89	B		
ST90-0202 Transcontinental Gas Pipe Line Corp.	Pentex Pipeline Co., Inc.	10-24-89	B		
ST90-0203 Transcontinental Gas Pipe Line Corp.	South Jersey Gas Co.	10-24-89	B		
ST90-0204 Transcontinental Gas Pipe Line Corp.	Tennessee Gas Pipeline Co.	10-24-89	G		
ST90-0205 Transcontinental Gas Pipe Line Corp.	Union Pacific Resources Co.	10-24-89	G-S		
ST90-0206 Valero Transmission, L.P.	Natural Gas Pipeline Co. of America	10-25-89	C		
ST90-0207 Natural Gas Pipeline Co. of America	Iowa Southern Utilities Co.	10-25-89	B		
ST90-0208 Natural Gas Pipeline Co. of America	Trans-American Gas Transmission Corp.	10-25-89	B		
ST90-0209 Williston Basin Interstate P/L Co.	MGTC, Inc.	10-25-89	B		
ST90-0210 Northern Border Pipeline Co.	Northern Natural Gas Co.	10-25-89	G		
ST90-0211 Williston Basin Interstate P/L Co.	Cody Gas Co.	10-25-89	B		
ST90-0212 Williston Basin Interstate P/L Co.	Montana-Dakota Utilities Co.	10-25-89	B		
ST90-0213 Williston Basin Interstate P/L Co.	Montana-Dakota Utilities Co.	10-25-89	B		
ST90-0214 Williston Basin Interstate P/L Co.	Neches Gas Distribution Co.	10-25-89	B		
ST90-0215 Williston Basin Interstate P/L Co.	Quivira Gas Co.	10-25-89	B		
ST90-0216 Williston Basin Interstate P/L Co.	Montana-Dakota Utilities Co.	10-25-89	B		
ST90-0217 ANR Pipeline Co.	Tejas Power Corp.	10-25-89	G-S		
ST90-0218 ANR Pipeline Co.	Exxon Corp.	10-25-89	G-S		
ST90-0219 ANR Pipeline Co.	City of Morning Sun	10-25-89	B		
ST90-0220 Algonquin Gas Transmission Co.	Citizens Gas Supply Corp.	10-25-89	G-S		
ST90-0221 Algonquin Gas Transmission Co.	Bay State Gas Co.	10-25-89	B		
ST90-0222 Algonquin Gas Transmission Co.	Dolphin Energy, Inc.	10-25-89	G-S		
ST90-0223 Algonquin Gas Transmission Co.	Orange & Rockland Utilities, Inc.	10-25-89	G-S		
ST90-0224 ANR Pipeline Co.	Stellar Gas Co.	10-25-89	B		
ST90-0225 ANR Pipeline Co.	Louisiana Gas System, Inc.	10-25-89	B		
ST90-0226 ANR Pipeline Co.	Michigan Consolidated Gas Co.	10-25-89	B		
ST90-0227 Natural Gas Pipeline Co. of America	Bethlehem Steel Corp.	10-26-89	G-S		
ST90-0228 Natural Gas Pipeline Co. of America	Mobil Natural Gas, Inc.	10-26-89	G-S		
ST90-0229 Natural Gas Pipeline Co. of America	Bethlehem Steel Corp.	10-26-89	G-S		
ST90-0230 Natural Gas Pipeline Co. of America	Quantum Chemical Corp.	10-26-89	G-S		
ST90-0231 Natural Gas Pipeline Co. of America	Bethlehem Steel Corp.	10-26-89	G-S		
ST90-0232 Natural Gas Pipeline Co. of America	Bethlehem Steel Corp.	10-26-89	G-S		
ST90-0233 El Paso Natural Gas Co.	Phillips 66 Natural Gas Co.	10-26-89	G-S		
ST90-0234 El Paso Natural Gas Co.	Mobil Natural Gas Inc.	10-26-89	G-S		
ST90-0235 Tennessee Gas Pipeline Co.	BP Gas Inc.	10-26-89	G-S		
ST90-0236 BP Gas Transmission Co.	Panhandle Eastern Pipe Line Co., et al.	10-26-89	C	03-25-90	28.80
ST90-0237 BP Gas Transmission Co.	Panhandle Eastern Pipe Line Co., et al.	10-26-89	C	03-25-90	28.80
ST90-0238 Transcontinental Gas Pipe Line Corp.	Consolidated Ed. Co. of NY, Inc., et al.	10-26-89	B		
ST90-0239 Northwest Pipeline Corp.	Rocky Mountain Natural Gas Co., Inc.	10-26-89	B		
ST90-0240 Northwest Pipeline Corp.	Union Pacific Resources Co.	10-26-89	G-S		
ST90-0241 Northern Natural Gas Co.	Apache Corp.	10-26-89	G-S		
ST90-0242 Northern Natural Gas Co.	Enron Oil & Gas Co.	10-26-89	G-S		
ST90-0243 Northern Natural Gas Co.	BHP Gas Marketing Co.	10-26-89	G-S		
ST90-0244 Northern Natural Gas Co.	PSI, Inc.	10-26-89	G-S		
ST90-0245 Colorado Interstate Gas Co.	Exxon Corp.	10-26-89	G-S		
ST90-0246 Delhi Gas Pipeline Corp.	K N Energy, Inc.	10-27-89	C		
ST90-0247 Delhi Gas Pipeline Corp.	United Gas Pipe Line Co.	10-27-89	C		
ST90-0248 Delhi Gas Pipeline Corp.	Tennessee Gas Pipeline Co.	10-27-89	C		
ST90-0249 Enogex Inc.	Natural Gas Pipeline Co. of America	10-26-89	C	03-25-90	43.57
ST90-0250 Tejas Gas Corp.	Natural Gas Pipeline Co. of America	10-27-89	C		
ST90-0251 Tennessee Gas Pipeline Co.	Arco Natural Gas Marketing, Inc.	10-27-89	G-S		
ST90-0252 Panhandle Eastern Pipeline Co.	Tarpon Gas Marketing LtD.	10-27-89	G-S		
ST90-0253 Tennessee Gas Pipeline Co.	Kimball Resources, Inc.	10-27-89	G-S		
ST90-0254 Tennessee Gas Pipeline Co.	Chevron U.S.A., Inc.	10-27-89	G-S		
ST90-0255 Black Marlin Pipeline Co.	Amoco Gas Co.	10-27-89	B		
ST90-0256 Lone Star Gas Co.	El Paso Natural Gas Co., et al.	10-27-89	C		
ST90-0257 Panhandle Eastern Pipe Line Co.	Kansas Power and Light Co.	10-27-89	B		
ST90-0258 Natural Gas Pipeline Co. of America	Mississippi River Transmission Corp.	10-27-89	G		
ST90-0259 Transwestern Pipeline Co.	Coastal Gas Marketing Co.	10-27-89	G-S		
ST90-0260 Transwestern Pipeline Co.	Southern California Gas Co.	10-27-89	B		
ST90-0261 Transwestern Pipeline Co.	Mobil Natural Gas, Inc.	10-27-89	G-S		
ST90-0262 Transwestern Pipeline Co.	Arco Natural Gas Marketing, Inc.	10-27-89	G-S		
ST90-0263 Transwestern Pipeline Co.	Enron Gas Marketing, Inc.	10-27-89	G-S		
ST90-0264 Transwestern Pipeline Co.	Texco Gas Marketing, Inc.	10-27-89	G-S		
ST90-0265 Gulf States Pipeline Corp.	Mississippi River Trans. Corp., et al.	10-27-89	C	03-26-90	15.00
ST90-0266 Natural Gas Pipeline Co. of America	Texaco Gas Marketing, Inc.	10-27-89	G-S		
ST90-0267 BP Gas Transmission Co.	ANR Pipeline Co., et al	10-27-89	C	03-26-90	13.70
ST90-0268 Natural Gas Pipeline Co. of America	Triumph Natural Gas L.P.	10-30-89	G-S		
ST90-0269 Natural Gas Pipeline Co. of America	Lone Star Gas Co.	10-30-89	B		
ST90-0270 Midwestern Gas Transmission Co.	People Gas Light & Coke Co.	10-30-89	B		
ST90-0271 Midwestern Gas Transmission Co.	Northern Illinois Gas Co.	10-30-89	B		
ST90-0272 Midwestern Gas Transmission Co.	Bishop Pipeline Corp.	10-30-89	B		

Docket number [1]	Recipient	Date filed	Part 284 subpart	Expiration date [2]	Transportation rate (c/ MMBTU)
ST90-0273 Midwestern Gas Transmission Co.	Northern Illinois Gas Co.	10-30-89	B		
ST90-0274 Midwestern Gas Transmission Co.	Yankee Gas Services Co.	10-30-89	B		
ST90-0275 Midwestern Gas Transmission Co.	Iesco Pipeline, Inc.	10-30-89	B		
ST90-0276 Tennessee Gas Pipeline Co.	Iesco Pipeline, Inc.	10-30-89	B		
ST90-0277 Tennessee Gas Pipeline Co.	Maxus Exploration Co.	10-30-89	G-S		
ST90-0278 Delhi Gas Pipeline Corp.	Northern Gas of Wyoming	10-30-89	C		
ST90-0279 Red River Pipeline	El Paso Natural Gas Co.	10-30-89	C		
ST90-0280 Red River Pipeline	El Paso Natural Gas Co.	10-30-89	C		
ST90-0281 Delhi Gas Pipeline Corp.	El Paso Natural Gas Co.	10-30-89	C		
ST90-0282 United Gas Pipe Line Co.	Gulf South Pipeline Co.	10-30-89	G-S		
ST90-0283 Columbia Gulf Transmission Co.	Elf Aquitaine, Inc.	10-30-89	G-S		
ST90-0284 Columbia Gulf Transmission Co.	Stellar Gas Co.	10-30-89	G-S		
ST90-0285 Columbia Gas Transmission Co.	South Jersey Energy Co.	10-30-89	G-S		
ST90-0286 Gulf States Pipeline Corp.	Southern Natural Gas Co.	10-27-89	C	03-26-90	15.00
ST90-0287 Natural Gas Pipeline Co. of America	Union Electric Co.	10-30-89	B		
ST90-0288 Delhi Gas Pipeline Corp.	Columbia Gas Transmission Crop.	10-30-89	C		
ST90-0289 Delhi Gas Pipeline Corp.	Northern Natural Gas Co.	10-30-89	C		
ST90-0290 Delhi Gas Pipeline Corp.	San Diego Gas & Electric Co.	10-30-89	D		
ST90-0291 Delhi Gas Pipeline Corp.	Northern Natural Gas Co.	10-31-89	C		
ST90-0292 Delhi Gas Pipeline Corp.	Northern Natural Gas Co.	10-31-89	C		
ST90-0293 Delhi Gas Pipeline Corp.	Natural Gas Pipeline Co. of America	10-31-89	C		
ST90-0294 El Paso Natural Gas Co.	Devon Energy Corp.	10-31-89	G-S		
ST90-0295 Texas Gas Transmission Corp.	Reliance Gas Marketing Co.	10-31-89	G-S		
ST90-0296 Texas Gas Transmission Corp.	Niagara Mohawk Power Corp.	10-31-89	B		
ST90-0297 Natural Gas Pipeline Co. of America	BP Gas Inc.	10-31-89	G-S		
ST90-0298 Moraine Pipeline Co.	Wisconsin Natural Gas Co.	10-31-89	B		
ST90-0299 Natural Gas Pipeline Co. of America	Acacia Gas Corp.	10-31-89	G-S		
ST90-0300 Stingray Pipeline Co.	Transcontinental Gas Pipe Line Corp.	10-31-89	K		
ST90-0301 Stingray Pipeline Co.	United Gas Pipe Line Co.	10-31-89	K		
ST90-0302 Colorado Interstate Gas Co.	Trigen Resources Corp.	10-31-89	G-S		
ST90-0303 Colorado Interstate Gas Co.	Trigen Resources Corp.	10-31-89	G-S		
ST90-0304 United Gas Pipe Line Co.	Laser Marketing Co.	10-31-89	G-S		
ST90-0305 United Gas Pipe Line Co.	Entex, Inc.	10-31-89	B		
ST90-0306 Colorado Interstate Gas Co.	City of Colorado Springs	10-31-89	B		
ST90-0307 Colorado Interstate Gas Co.	City of Colorado Springs	10-31-89	B		
ST90-0308 Colorado Interstate Gas Co.	City of Colorado Springs	10-31-89	B		
ST90-0309 Delhi Gas Pipeline Corp.	El Paso Natural Gas Co.	10-31-89	C		
ST90-0310 Midwestern Gas Transmission Co.	Michigan Consolidated Gas Co.	10-31-89	B		
ST90-0311 Midwestern Gas Transmission Co.	Llano, Inc.	10-31-89	B		
ST90-0312 Midwestern Gas Transmission Co.	SNG Intrastate Pipeline, Inc.	10-31-89	B		
ST90-0313 Tennessee Gas Pipeline Co.	Southern Natural Gas Co.	10-31-89	B		
ST90-0314 Midwestern Gas Transmission Co.	Northern Illinois Gas Co.	10-31-89	B		
ST90-0315 Tennessee Gas Pipeline Co.	Cabot Corp.	10-31-89	B		
ST90-0316 Midwestern Gas Transmission Co.	Northern Illinois Gas Co.	10-31-89	B		
ST90-0317 Panhandle Eastern Pipe Line Co.	Home Petroleum Corp.	10-31-89	G-S		
ST90-0318 Panhandle Eastern Pipe Line Co.	Entrade Corp.	10-31-89	G-S		
ST90-0319 Panhandle Eastern Pipe Line Co.	Columbia Gas of Ohio, Inc.	10-31-89	B		
ST90-0320 South Georgia Natural Gas Co.	City of Valdosta	10-31-89	B		
ST90-0321 Southern Natural Gas Co.	Texican Natural Gas Co.	10-31-89	G-S		
ST90-0322 Southern Natural Gas Co.	Catamount Natural Gas, Inc.	10-31-89	G-S		
ST90-0323 Trunkline Gas Co.	Mountain Iron & Supply Co.	10-30-89	G-S		
ST90-0324 Trunkline Gas Co.	Panhandle Trading Co.	10-30-89	G-S		
ST90-0325 United Gas Pipe Line Co.	Laser Marketing Co.	10-31-89	G-S		
ST90-0326 Midwestern Gas Transmission Co.	Michigan Consolidated Gas Co.	10-31-89	B		
ST90-0327 Midwestern Gas Transmission Co.	NGC Intrastae Pipeline Co.	10-31-89	B		
ST90-0328 Tennessee Gas Pipeline Co.	NGC Intrastate Pipleline Co.	10-31-89	B		
ST90-0329 Tennessee Gas Pipeline Co. [3]	Tenngasco Corp.	10-31-89	G-S		
ST90-0330 Colorado Interstate Gas Co.	Energy Pipeline Co.	10-30-89	B		
ST90-0331 Colorado Interstate Gas Co.	Coastal States Gas Transmission Co.	10-30-89	B		
ST90-0332 Colorado Interstate Gas Co.	Quivira Gas Co.	10-30-89	B		
ST90-0333 Colorado Interstate Gas Co.	Amoco Production Co.	10-30-89	G-S		
ST90-0334 Colorado Interstate Gas Co.	Williams Gas Co.	10-30-89	B		
ST90-0335 Colorado Interstate Gas Co.	Peoples Natural Gas Co.	10-30-89	B		
ST90-0336 Rhone-Pouleng Pipeline Co.	Colorado Interstate Gas Co., et al.	10-31-89	C	03-30-90	13.00
ST90-0337 ONG Transmission Co.	Natural Gas Pipeline Co. of America	10-31-89	C	03-30-90	24.32
ST90-0338 United Gas Pipeline Co.	Gulf South Pipeline Co.	10-31-89	G-S		
ST90-0339 United Gas Pipeline Co.	Gulf South Pipeline Co.	10-31-89	G-S		
ST90-0340 Williams Natural Gas Co.	Phillips 66 Natural Gas Co.	11-01-89	G-S		
ST90-0341 Williams Natural Gas Co.	Midstates Pipeline Co.	11-01-89	G-S		
ST90-0342 Transok, Inc.	Phillips Gas Pipeline Co.	10-31-89	C	03-30-90	32.50
ST90-0343 Enogex Inc.	Arkla Energy Resources	10-30-89	C	03-29-90	43.57
ST90-0344 Transok, Inc.	Arkla Energy Resources	10-31-89	C	03-30-90	32.50

[1] Notice of transactions does not constitute a determination that filings comply with commission regulations in accordance with order No. 436 (Final rule and notice requesting supplemental comments, 50 FR 42,372, 10/18/85).

[2] The intrastate pipeline has sought Commission approval of its transportation rate pursuant to section 284.123(B)(2) of the Commission's regulations (18 CFR 284.123(B)(2)). Such rates are deemed air and equitable if the Commission does not take action by the date indicated.

[3] ST89-107-000 has been withdrawn.

[FR Doc. 89-28642 Filed 12-11-89; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. CP90-286-000, et al.]

United Gas Pipe Line Co., et al.; Natural Gas Certificate Filings

December 5, 1989.

Take notice that the following filings have been made with the Commission:

1. United Gas Pipe Line Co.

[Docket No. CP90-286-000]

Take notice that on November 28, 1989, United Gas Pipe Line Company (United), Post Office Box 1478, Houston, Texas 77251-1478, filed in Docket No. CP90-286-000 a request pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to transport gas on an interruptible basis for Laser Marketing Company (Shipper), under its blanket certificate issued in Docket No. CP88-6-000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request on file with the Commission and open to public inspection.

United states that it proposes to transport for Shipper 618,000 MMBtu on a peak day, 618,000 MMBtu on an average day and 225,570,000 MMBtu on an annual basis. United also states that pursuant to a Transportation Agreement dated October 1, 1988 as amended on September 25, 1989, and September 26, 1989 between United and Shipper (Transportation Agreement) propose to transport natural gas for Shipper from points located in multiple counties in Alabama, Florida, Mississippi, Louisiana and Texas. The points of delivery and ultimate points of delivery are located in multiple counties in Louisiana, Mississippi, Texas, Florida and Alabama.

United further states that it commenced this service on September 25, 1989, as reported in Docket No. CP90-304-000.

Comment date: January 19, 1990, in accordance with Standard Paragraph G at the end of this notice.

2. Southern Natural Gas Co.

[Docket No. CP90-291-000]

Take notice that on November 30, 1989, Southern Natural Gas Company (Southern) P.O. Box 2563, Birmingham, Alabama 35202-2563, filed in Docket No. CP90-291-000 a request pursuant to §§ 157.205 and 284.223 (18 CFR 157.205 and 284.223) of the Commission's Regulations under the Natural Gas Act for authority to provide interruptible transportation service for the Polaris Corporation (Polaris), local distribution company, under Southern's blanket transportation certificate which was issued by Commission order on May 5, 1989, in Docket No. CP89-316-000, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Southern states that it will receive the gas from various points in, offshore Texas, offshore Louisiana and the states of Texas, Louisiana, Mississippi and Alabama for delivery to Polaris at various delivery points in Georgia.

Southern proposes to transport on an interruptible basis up to 70,000 MMBtu of gas equivalent on a peak day and 25,000 MMBtu on an average day and approximately, 9,125,000 MMBtu of gas annually. Southern states that the transportation service commenced under the 120-day automatic authorization of § 284.223(a) of the Commission's Regulations on September 28, 1989, pursuant to a transportation agreement dated August 31, 1989. Southern notified the Commission of the commencement of the transportation service in Docket No. ST90-118-000.

Comment date: January 19, 1990, in accordance with Standard Paragraph G at the end of this notice.

3. Southern Natural Gas Co.

[Docket No. CP90-293-000]

Take notice that on November 30, 1989, Southern Natural Gas Company (Southern), Post Office Box 2563, Birmingham, Alabama 35202-2563, filed a request with the Commission in Docket No. CP90-293-000 pursuant to Section 157.205 of the Commission's Regulations under the Natural Gas Act (NGA) for authorization to provide an interruptible transportation service for Catamount Natural Gas, Inc. (Catamount), a natural gas marketer, under its blanket certificate issued in Docket No. CP88-316-000 pursuant to Section 7 of the NGA, all as more fully set forth in the request which is open to public inspection.

Southern states that it would transport natural gas volumes for Catamount under its Rate Schedule IT from various receipt points on its system in Alabama, Louisiana, offshore Louisiana, Mississippi, Texas, and offshore Texas to various delivery points in Georgia, South Carolina, and Tennessee. Southern would transport up to 150,000 MMBtu equivalent of natural gas on a peak day, 1,100 MMBtu equivalent on an average day, and 27,000,000 MMBtu equivalent on an annual basis. Southern also states that while Catamount has requested 1,100 MMBtu equivalent for average daily transportation service, Catamount anticipates a future average daily transportation quantity request of 73,972 MMBtu equivalent. Southern states that it commenced service for Catamount on October 5, 1989, as reported in Docket No. ST90-322 pursuant to § 284.223(a)(1) of the Regulations.

Comment date: January 19, 1990, in accordance with Standard Paragraph F at the end of this notice.

4. Tennessee Gas Pipeline Co.

[Docket No. CP90-296-000]

Take notice that on November 30, 1989, Tennessee Gas Pipeline Company (Tennessee), P.O. Box 2511, Houston, Texas 77252, filed in Docket No. CP90-296-000 a request pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) and the Natural Gas Policy Act (18 CFR 284.223) for authorization to transport gas for Shell Gas Trading Company (Shell Gas) a marketer of natural gas, under Tennessee's blanket certificate issued in Docket No. CP87-115-000 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Tennessee proposes to transport on a firm basis up to 25,000 dekatherm (dt) of natural gas per day on behalf of Shell Gas pursuant to a transportation agreement dated October 23, 1989, between Tennessee and Shell Gas. Tennessee would receive gas at various existing points of receipt on its system in offshore Louisiana and redeliver equivalent volumes, less fuel and lost and unaccounted for volumes, at an existing delivery point in Louisiana.

Tennessee further states that the estimated average daily and annual quantities would be 25,000 dt and 9,125,000 dkt, respectively. Service under § 284.223(a) commenced on November 2, 1989, as reported in Docket No. ST90-557-000, it is stated.

Comment date: January 19, 1990, in accordance with Standard Paragraph G at the end of this notice.

5. Tennessee Gas Pipeline Co.

[Docket No. CP90-297-000]

Take notice that on November 30, 1989, Tennessee Gas Pipeline Company (Tennessee) filed in Docket No. CP90-297-000 a request pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act, to provide firm transportation service pursuant to its blanket certificate issued in Docket No. CP87-115-000 for Mobil Natural Gas Inc. (Mobil), a marketer, all as more fully set forth in the request on

file with the Commission and open to public inspection.

Tennessee estimates that the peak day and average daily volumes transported to be 80,000 dt and 29,200,000 dt on an annual basis. The volumes of natural gas would be transported from receipt points located Offshore Louisiana, and in the state of Louisiana and delivered to a point of interconnect with Transcontinental Gas Pipe Line Corporation at Heidelberg, Jasper County, Mississippi, it is explained. Tennessee also states that the ultimate points of delivery are located in the states of Alabama, Delaware, Georgia, New Jersey, New York, North Carolina, South Carolina, Pennsylvania, Virginia and Washington, DC.

Further, Tennessee indicates further that the transportation service commenced November 1, 1989, as reported in Docket No. ST90-556.

Comment date: January 19, 1990, in accordance with Standard Paragraph G at the end of this notice.

6. United Gas Pipe Line Co.

[Docket No. CP90-300-000]

Take notice that on December 1, 1989, United Gas Pipe Line Company (United), P.O. Box 1478, Houston, Texas 77251-1478, filed in Docket No. CP90-300-000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to provide an interruptible transportation service for American Central Gas Companies, Inc. (American Central), a marketer, under the blanket certificate issued in Docket No. CP88-6-000, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

United states that purusant to a transportation agreement dated November 9, 1988, as amended on September 15, 1989, under its Rate Schedule ITS, it proposes to transport up to 185,400 MMBtu per day equivalent of natural gs for American Central. United states that it would transport the gas from multiple receipt points as shown in Exhibit "A" of the transportation agreement and would deliver the gas to multiple delivery points shown in Exhibit "B" of the agreement.

United advises that service under § 284.223(a) commenced September 26, 1989, as reported in Docket No. ST90-702 (filed November 29, 1989). United further advises that it would transport 185,400 MMBtu on an average day and 67,671,000 MMBtu annually.

Comment date: January 19, 1990, in accordance with Standard Paragraph G at the end of this notice.

7. United Gas Pipe Line Co.

[Docket No. CP90-302-000]

Take notice that on December 1, 1989, United Gas Pipe Line Company (United), P.O. Box 1478, Houston, Texas 77251-1478, filed in Docket No. CP90-302-000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to provide an interruptible transportation service for LaSER Marketing Company (LaSER), a marketer, under the blanket certificate issued in Docket No. CP88-6-000, pursuant to section 7 of the National Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

United states that pursuant to a transportation agreement dated December 16, 1988, as amended, under its Rate Schedule ITS, it proposes to transport up to 618,000 MMBtu per day equivalent of natural gas for LaSER. United states that it would transport the gas from multiple receipt points as shown in Exhibit "A" of the transportation agreement and would deliver the gas to multiple delivery points shown in Exhibit "B" of the agreement.

United advises that service under § 284.223(a) commenced October 9, 1989, as reported in Docket No. ST90-345-000 (filed November 1, 1989). United further advises that it would transport 618,000 MMBtu on an average day and 225,570,000 MMBtu annually.

Comment date: January 19, 1990, in accordance with Standard Paragraph G at the end of this notice.

8. Columbia Gas Transmission Corp.

[Docket No. CP90-310-000]

Take notice that on December 1, 1989, Columbia Gas Transmission Corporation (Columbia), 1700 MacCorkle Avenue, SE., Charleston, West Virginia 25314, filed in Docket No. CP90-310-000, a request pursuant to § 157.205 of the Commission's Regulations (18 CFR 157.205) for authorization to provide a transportation service on behalf of South Jersey Energy Company (South Jersey) under Columbia's blanket certificate issued in Docket No. CP86-240-000 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request on file with the Commission and open to public inspection.

Columbia states that it proposes to transport up to 100,000 MMBtu equivalent to natural gas per day, on an interruptible basis, for South Jersey. Columbia further states that projected average day and annual quantities are 80,000 and 36,500,000 MMBtu, respectively. Columbia indicates that it would receive the natural gas at various receipt points on it system and would redeliver the natural gas for the account of South Jersey at an existing interconnection in the state of New Jersey.

Columbia states that service under § 284.223(a) of the Commission's Regulations (18 CFR 284.223(a)) commenced on October 1, 1989, as reported in Docket No. ST90-285-000.

Comment date: January 19, 1990, in accordance with Standard Paragraph G at the end of this notice.

9. Columbia Gas Transmission Corp.

[Docket No. CP90-312-000]

Take notice that on December 1, 1989, Columbia Gas Transmission Corporation (Columbia), P.O. Box 1273, Charleston, West Virginia 25325-1273, filed in Docket No. CP90-312-000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to transport natural gas on behalf of Riley Natural Gas Company (Riley) under its blanket authorization issued in Docket No. CP86-240-000 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Columbia would perform the proposed interruptible transportation service for Riley, pursuant to an interruptible transportation service agreement dated August 14, 1989. The transportation agreement is effective as of the date of its full execution and shall continue in full force and effect from month-to-month thereafter unless terminated by either party upon thirty days' written notice. Columbia proposes to transport up to a maximum of 20,000 MMBtu equivalent of natural gas per day; 16,000 MMBtu on an average day; and 2,400,000 MMBtu annually. Columbia proposes to receive and deliver the subject gas at various existing points located on its system. Columbia avers that no new facilities are required to provide the proposed service.

It is explained that the proposed service is currently being performed pursuant to the 120-day self-implementing provision of § 284.223(a)(1) of the Commission's Regulations. Columbia commenced such

self-implementing service on September 6, 1989, as reported in Docket No. ST90-37-000.

Comment date: January 19, 1990, in accordance with Standard Paragraph G at the end of this notice.

G. Any person or the Commission's staff may, within 45 days after the issuance of the instant notice by the Commission, file pursuant to rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 89-28909 Filed 12-11-89; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. RP88-34-000, RP88-34-001 and RP88-34-003]

ANR Pipeline Co; Proposed Changes in FERC Gas Tariff

December 5, 1989.

Take notice that on December 1, 1989, ANR Pipeline Company ("ANR") tendered for filing with the Federal Energy Regulatory Commission ("Commission") Third Substitute Fourth Revised Sheet No. 570 under Rate Schedule X-64 of Original Volume No. 2 of its FERC Gas Tariff to be effective for refund purposes for the period January 1, 1988, through December 31, 1988.

ANR states that this compliance filing is being made to reduce the rate of return underlying Rate Schedule X-64 to the same rate of return underlying the approved settlement agreement in ANR's Docket No. RP86-169, et al., in accordance with the Commission's Letter Orders dated December 31, 1987 February 19, 1988 and April 14, 1988 in Docket Nos. RP88-34-000, RP88-34-001 and RP88-34-002, respectively.

Any person desiring to be heard or to protest said filing should file a petition to intervene or to protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NW., Washington, DC 20426, in accordance with Rule 211 or Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such petitions or protests should be filed on or before December 13, 1989. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party to the proceeding must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 89-28910 Filed 12-11-89; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TQ90-2-31-000]

Arkla Energy Resources; Filing of Revised Tariff Sheets Reflecting Quarterly PGA Adjustment and Revised Take or Pay Recovery Amounts

December 5, 1989.

Take notice that on December 1, 1989, Arkla Energy Resources (AER), a division of Arkla, Inc., tendered for filing the following tariff sheets to become effective January 1, 1990:

Original Volume No. 3
6th Revised Sheet No. 185.1
First Revised Volume No. 1
53rd Revised Sheet No. 4
First Revised Volume No. 1
6th Revised Sheet No. 7A

These tariff sheets reflect AER's third quarterly PGA filing made subsequent to its annual PGA effective April 1, 1989, under the Commission's Order Nos. 483 and 483-A.

The proposed changes would decrease AER's system cost by $77,455 and its revenue from jurisdictional sales and service by $821 for the PGA period of January, February, and March 1990 as adjusted.

Also included in this filing are six copies of the following tariff sheets which reflect revised amounts previously accrued, that have been paid since June 1988 and allocated to Williams Natural Gas Company to be effective as noted:

Original Volume No. 3: 3rd Substitute 3rd Revised Sheet No. 185.1—Effective April 1, 1989; 3rd Substitute 4th Revised Sheet No. 185.1—Effective July 1, 1989; 1st Substitute 5th Revised Sheet No. 185.1—Effective October 1, 1989.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before December 13, 1989. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make Protestants parties to the proceeding. Any person wishing to become a party must file a petition to intevene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 89-28911 Filed 12-11-89; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TQ90-33-000 and TM90-2-33-000]

El Paso Natural Gas Co.; Proposed Change in Rates

December 5, 1989.

Take notice that El Paso Natural Gas Company ("El Paso"), on December 1, 1989, tendered for filing pursuant to part 154 of the Federal Energy Regulatory Commission ("Commission") Regulation Under the Natural Gas Act, a notice of:

(i) A Quarterly Adjustment in Rates for jurisdictional gas service rendered to sales customers served by El Paso's interstate gas transmission system under rate schedules affected by and subject to section 19, Purchased Gas Cost Adjustment Provision ("PGA"), of the General Terms and Conditions in El Paso's FERC Gas Tariff, First Revised Volume No. 1; and

(ii) A decrease in the Gas Research Institute ("GRI") funding unit adjustment component of El Paso's rates for certain sales and transportation services subject to sections 20 and 18, Gas Research Institute General Research, Development and Demonstration Funding Unit Adjustment Provision, of the General Terms and Conditions in El Paso's FERC Gas Tariff, First Revised Volume No. 1 and Original Volume No. 1-A, respectively.

El Paso states it is tendering the tariff shares to become effective January 1, 1990.

El Paso states it is tendering certain tariff sheets in compliance with the PGA and GRI Tariff provisions, which reflect a net increase of $0.0094 per dth above those Quarterly PGA rates placed in effect on October 1, 1989 at Docket No. TQ90-1-33-000. Such net increase is comprised of (i) an increase in purchased gas costs of $0.0111 per dth, and (ii) a reduction in the GRI funding unit adjustment component of ($0.0017) per dth.

El Paso also states the rates set forth on the tendered tariff sheets reflect a net increase of $0.1629 per dth above those Interim PGA rates placed in effect on November 1, 1989 at Docket No. TF90-1-33-000, and currently in effect. Such net increase is comprised of (i) a Current Adjustment of $0.1646 per dth, and (ii) a reduction in the GRI funding unit adjustment component of ($0.0017) per dth.

With respect to the Account 191 Surcharge Adjustment, El Paso further states it will continue to suspend collection of its surcharge in accordance with the Commission's September 29, 1989 order accepting and suspending El Paso's quarterly PGA filing at Docket No. TQ90-1-33-000, *et al.*, effective October 1, 1989.

By Opinion No. 334 issued October 10, 1989 at Docket No. RP89-187-000, the Commission amended and approved the GRI's application for advance approval of its 1990 research and development program and related five (5) year plan for 1990-1994. In so doing, the Commission approved the GRI's 1990 funding requirement which is to be raised through a funding unit of 1.26 cents per dth. Accordingly, the tendered revised tariff sheets, when accepted for filing and permitted to become effective, will decrease the GRI funding unit adjustment component of El Paso's rates for certain sales and transportation services from the currently effective 1.43 cents per dth to the 1.26 cents per dth approved by the Commission in Opinion No. 334.

Copies of the filing were served upon all of El Paso's interstate pipeline system sales customers and shippers, and all interested state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with § 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before December 13, 1989. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestant parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 89-28914 Filed 12-11-89; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TA90-1-51-001, TQ90-2-51-001, and TM90-2-51-000]

Great Lakes Gas Transmission Co.; Proposed Changes in FERC Gas Tariff Purchased Gas Adjustment Clause Provisions

December 5, 1989.

Take notice that Great Lakes Gas Transmission Company ("Great Lakes") on December 1, 1989 tendered for filing the following to its FERC Gas Tariff.

First Revised Volume No. 1

Substitute Twenty-Fifth Revised Sheet Nos. 57(i) and 57(ii).
First Revised Substitute Twenty-Fifth Revised Sheet Nos. 57(i) and 57(ii).
Substitute First Revised Twenty-Fifth Revised Sheet Nos. 57(i) and 57(ii).
Second Revised Substitute Twenty-Fifth Revised Sheet Nos. 57(i) and 57(ii).
Substitute Eleventh Revised Sheet No. 57(v).
First Revised Substitute Eleventh Revised Sheet No. 57(v).
Second Revised Substitute Eleventh Revised Sheet No. 57(v).

Substitute Twenty-Fifth Revised Sheet Nos. 57(i) and 57(ii) and Substitute Eleventh Revised Sheet No. 57(v) were filed to reflect the appropriate current purchased gas cost adjustment for its quarterly PGA for the period November 1, 1989 through January 1990.

First Revised Substitute Twenty-Fifth Revised Sheet Nos. 57(i) and 57(ii) and First Revised Substitute Eleventh Revised Sheet No. 57(v) were filed to reflect revised current PGA rates for the months of November and December, 1989 and January, 1990. The tariff sheets were filed as an out-of-cycle PGA to reflect the latest estimated gas cost as provided to Great Lakes by its sole supplier of natural gas, TransCanada Pipelines Limited ("TransCanada"). These pricing arrangements are the result of contract renegotiation between each of Great Lakes' resale customers and the supplier.

Substitute First Revised Twenty-Fifth Revised Sheet Nos. 57(i) and 57(ii) were filed to reflect the addition of a firm transportation service for Northridge Petroleum Marketing, Inc. under Rate Schedule T-27. Initial tariff sheets reflecting Rate Schedule T-27 were filed on November 2, 1989.

Second Revised Substitute Twenty-Fifth Revised Sheet Nos. 57(i) and 57(ii) and Second Revised Substitute Eleventh Revised Sheet No. 57(v), First Revised Volume No. 1, were filed to reflect the Gas Research Institute's 1990 Research and Development Program and GRI funding unit of 1.26 cents approved pursuant to the Commission's Opinion No. 334 issued on October 10, 1989. These tariff sheets were proposed to become effective January 1, 1990.

Great Lakes requested waiver of the notice requirements so as to permit the above tariff sheets to become effective November 1, December 1, 1989 and January 1, 1990, in order to implement the gas pricing agreements between Great Lakes' resale customers and TransCanada on a timely basis.

Any person desiring to be heard or to protest said filing should file a Motion to Intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC, 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such petitions or protests should be filed on or before December 13, 1989. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 89-28915 Filed 12-11-89; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TQ90-2-5-000, TM90-3-5-000 and RP88-140-007]

Midwestern Gas Transmission Co.; Rate Filing Pursuant to Tariff Rate Adjustment Provisions

Take notice that on December 1, 1989, Midwestern Gas Transmission Company (Midwestern) filed Third Revised Sheet No. 5 to First Revised Volume No. 1 of its FERC Gas Tariff, to be effective January 1, 1990.

Midwestern states that the current Purchased Gas Cost Rate Adjustments reflected on Third Revised Sheet No. 5 consist of a $.4270 per dekatherm adjustment applicable to the gas component of Midwestern's sales rates, a $1.01 per dekatherm adjustment applicable to the Demand D-1 component, and a $(.0003) per dekatherm adjustment applicable to the Demand D-2 component.

Midwestern states that copies of the filing have been mailed to all of its jurisdictional customers on its system

and affected stated regulatory commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such petitions or protests should be filed on or before December 13, 1989. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene; provided, however, that any person who had previously filed a petition to intervene in this proceeding is not required to file a further petition. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 89-28924 Filed 12-11-89; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. TA90-1-16-001, TM90-4-16-000]

National Fuel Gas Supply Corp.; Proposed Changes in FERC Gas Tariff

December 5, 1989.

Take notice that on December 1, 1989, Nationl Fuel Gas Supply Corporation ("National") tendered for filing Substitute Twenty-Fifth Revised Sheet No. 4 as part of its FERC Gas Tariff, First Revised Volume No. 1, proposed to become effective January 1, 1990.

National states that the purpose of this filing is to reflect a revision to the Current Adjustment shown in National's annual Purchased Gas Cost Adjustment ("PGA") filed on October 31, 1989, Docket No. TA90-1-16-001. In addition, the Gas Research Institute (GRI) surcharge has been reduced to reflect the latest Commission-approved rate.

Twenty-Fifth Revised Sheet No. 4 reflects a commodity current adjustment of 30.13 cents per Dth from National's revised October 1989 quarterly PGA, Docket No. TA90-1-16-001. The filing also reflects an average commodity cost of purchased gas of $2.7995 per Dth, and an RQ and DC sales commodity rate of $2.9676 per Dth.

National further states that copies of this filing were served on National's jurisdictional customers and on the Regulatory Commissions of the States of New York, Ohio, Pennsylvania, Delaware, Massachusetts and New Jersey.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 214 or 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211). All such motions to intervene or protests should be filed on or before December 13, 1989. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 89-28912 Filed 12-11-89; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TA90-1-18-000]

Texas Gas Transmission Corp.; Proposed Changes in FERC Gas Tariff

December 5, 1989.

Take notice that Texas Gas Transmission Corporation (Texas Gas), on December 1, 1989, tendered for filing the following revised tariff sheets to its FERC Gas Tariff, Original Volume No. 1:

Twenty-third Revised Sheet No. 10.
Twenty-third Revised Sheet No. 10A.

Texas Gas states that these tariff sheets reflect changes in projected purchased gas costs and the unrecovered purchased gas cost surcharge pursuant to the Annual PGA provision of the Purchased Gas Adjustment clause of its FERC Gas Tariff and are proposed to be effective February 1, 1990. Texas Gas further states that the proposed tariff sheets reflect a commodity rate increase of $.0431 per MMBtu, a D-1 demand rate increase of $.03 per MMBtu, and a D-2 demand rate decrease of $.0022 per MMBtu from the rates set forth in the quarterly PGA filed September 29, 1989 (Docket No. TQ90-1-18).

Copies of the filing were served upon Texas Gas's jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such protests or motions should be filed on or before December 27, 1989. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 89-28913 Filed 12-11-89; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TA90-1-17-000]

Texas Eastern Transmission Corp.; Proposed Changes in FERC Gas Tariff

December 5, 1989.

Take notice that Texas Eastern Transmission Corporation (Texas Eastern) on December 1, 1989 tendered for filing as part of its FERC Gas Tariff, six copies each of the tariff sheets:

Fifth Revised Volume No. 1

Twentieth Revised Sheet No. 50
Thirteenth Revised Sheet No. 50A
Thirteenth Revised Sheet No. 50B
Thirteenth Revised Sheet No. 50C
Thirteenth Revised Sheet No. 50D
Fourteenth Revised Sheet No. 51
Eighth Revised Sheet No. 51A
Eighth Revised Sheet No. 51B
Eighth Revised Sheet No. 51C
Eighth Revised Sheet No. 51D

Original Volume No. 2

Thirty-sixth Revised Sheet No. 235
Twenty-eighth Revised Sheet No. 241
Thirty-sixth Revised Sheet No. 322

Texas Eastern states that the above tariff sheets are being issued pursuant to section 23, Purchased Gas Cost Adjustment, and section 26, Electric Power Cost (EPC) Adjustment, contained in the General Terms and Conditions of Texas Eastern's FERC Gas Tariff. This filing constitutes Texas Eastern's Regular Annual PGA filing to be effective February 1, 1990 pursuant to 18 CFR 154.305.

Texas Eastern states that in compliance with § 154.305(a)(2) of the Commission's Regulations, a report containing detailed computations which show the derivation of the current adjustments and a surcharge rate to be applied to Texas Eastern's effective rates is attached and enclosed in 9-track computer tape format as prescribed by FERC Form No. 542-PGA (Revised) for formal filing with the Commission.

Texas Eastern states that the PGA changes proposed in this filing consist of Current Adjustments and Surcharge Adjustments as follows for the components of Texas Eastern's sales rates:

Rate component	Current adjustment	Surcharge adjustment
Demand-1	$0.052/dth	$(0.006)/dth
Demand-2	$0.0019/dth	$(0.0218)/dth
Commodity	$0.1096/dth	$(0.0332)/dth

Texas Eastern states that these Current Adjustments represent the change in Texas Eastern's projected quarterly cost of purchased gas from Texas Eastern's last scheduled PGA filing of September 29, 1989 in Docket No. TQ90-1-17. The Surcharge Adjustments are designed to amortize the Current Deferral Subaccount Balance in Account 191 as of September 30, 1989 over the 12-month period beginning on February 1, 1990.

Texas Eastern also states that this filing constitutes Texas Eastern's semiannual adjustment to reflect changes in electric power costs pursuant to section 26. These changes in rates for Sales and Transportation services are based upon the projected annual electric power cost incurred in the operation of transmission compressor stations with electric motor prime movers for the 12 months beginning February 1, 1990 and to also reflect the EPC Surcharge which is designed to clear the balance in the Deferred EPC Account as of October 31, 1989.

The proposed effective date of the above tariff sheets is February 1, 1990.

Copies of the filing were served on Texas Eastern's jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before December 27, 1989. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 89-28916 Filed 12-11-89; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TQ90-1-11-000]

United Gas Pipe Line Co.; Filing of Revised Tariff Sheets

December 5, 1989.

Take Notice that on December 1, 1989, United Gas Pipe Line Company (United) tendered for filing the following tariff sheets:

Second Revised Volume No. 1

First Revised Sheet No. 4
First Revised Sheet No. 4A
First Revised Sheet No. 4B
First Revised Sheet No. 4D
First Revised Sheet No. I

The proposed effective date of the above referenced tariff sheets in this docket is January 1, 1990. The above referenced tariff sheets are being filed pursuant to Section 154.308 of the Commission's regulations to reflect changes in United's purchased gas cost adjustment as provided in Section 19 of United's FERC Gas Tariff, Second Revised Volume No. 1.

United states that it has filed tariff sheets to reflect a 12.95¢ per Mcf increase in gas commodity costs compared to what was filed in Docket No. TA90-1-11-001. In addition, this PGA filing reflects the base tariff rate terms and conditions of the tariff filing made by United on November 27, 1989 in compliance with the Commission's order issued October 27, 1989 in Docket Nos. RP85-209 *et al.* United states that it reserves its rights to reflect such modification to the rates filed herein as may be required to reflect final Commission approval of that filing.

United also states that it will continue to suspend its right to collect an 18¢ per Mcf Settlement Surcharge for the same reasons given in Docket No. TQ89-3-11-000, subject to its right to reinstate the 18¢ per Mcf Settlement Surcharge prospectively upon 30 days written notice.

United states that the revised tariff sheets and supporting data are being mailed to its jurisdictional sales customers and to interested state commissions.

Any person desiring to be heard or to protest said filing should file a Motion to Intervene or Protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in such accordance with §§ 385.214 and 385.211 of the Commission's regulations. All such petitions or protests should be filed on or before December 13, 1989.

Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a Motion to Intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 89-28917 Filed 12-11-89; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TQ90-1-35-000]

West Texas Gas, Inc.; Filing

December 5, 1989.

Take notice that on December 1, 1989, West Texas Gas, Inc. (WTG) filed Seventeenth Revised Sheet No. 3a to its FERC Gas Tariff, Original Volume No. 1, proposed to be effective January 1, 1990. Seventeenth Revised Sheet No. 3a and the accompanying explanatory schedules constitute WTG's quarterly PGA filing submitted in accordance with the Commission's purchased gas adjustments regulations.

Copies of the filing were served upon WTG's customers and interested state commissions.

Any persons desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NW., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214 (1989)). All such motions or protests should be filed on or before December 13, 1989. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lous D. Cashell,

Secretary.

[FR Doc. 89-28925 Filed 12-11-89; 8:45 am]

BILLING CODE 6717-01-M

Office of Fossil Energy

[FE Docket No. 89-59-NG]

Amoco Energy Trading Corp.; Order Granting Blanket Authorization To Export Natural Gas to Mexico

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of order granting blanket authorization to export natural gas to Mexico.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting Amoco Energy Trading Corporation (AETC) blanket authorization in FE Docket No. 89-59-NG to export up to 146 Bcf of natural gas from the United States to Mexico over a two-year period beginning on the date of first delivery.

A copy of this order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F-056, Forrestal Building, U.S. Department of Energy, 1000 Independence Avenue, SW, Washington, DC 20585, (202) 586-9478. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, December 6, 1989.

Constance L. Buckley,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 89-28998 Filed 12-11-89; 8:45 am]

BILLING CODE 6450-01-M

[FE Docket No. 89-80-NG]

Dome Petroleum Corp.; Application To Extend Blanket Authorization To Import Natural Gas From Canada

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of application for extension of blanket authorization to import natural gas from Canada.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy DOE) gives notice of receipt on November 13, 1989, of an application filed by Dome Petroleum Corp. (Dome) requesting that blanket authorization previously granted in DOE/ERA Opinion and Order No. 85 (Order 85), issued July 2, 1985 (ERA Docket No. 85-11-NG), and extended in DOE/ERA Opinion and Order No. 204 (Order 204), issued October 30, 1987 (ERA Docket No. 87-30-NG), be further extended for two years beginning on December 1, 1989, the expiration of its current import authorization, through the period ending November 30, 1991. Under the extension requested, Dome would be authorized to import volumes not to exceed, in the aggregate, 200 Bcf of Canadian natural gas over a two-year period. Dome further requests that FE expedite this application because the current authorization expires on December 1, 1989.

The application is filed under Section 3 of the Natural Gas Act and DOE Delegation Order Nos. 0204-111 and 0204-127. Protests, motions to intervene, notices of intervention, and written comments are invited.

DATE: Protests, motions to intervene or notices of intervention, as applicable, requests for additional procedures, and written comments are to be filed at the address listed below no later than 4:30 p.m., e.s.t., January 11, 1990.

ADDRESS: Office of Fuels Programs, Fossil Energy, U.S. Department of Energy, Forrestal Building, Room 3F-056, FE-50, 1000 Independence Avenue, SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT:

Robert Groner, Office of Fuels Programs, Fossil Energy, U.S. Department of Energy, Forrestal Building, Room 3H-087, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-1657.

Diane Stubbs, Natural and Mineral Leasing, Office of General Counsel, U.S. Department of Energy, Forrestal Building, Room 6E-042, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-6667.

SUPPLEMENTARY INFORMATION:

Dome is a North Dakota corporation with its registered office in Bismarck, North Dakota, and its principal place of business in Calgary, Alberta. Dome is a wholly-owned subsidiary of Amoco Canada Petroleum Company, Ltd., which is a wholly owned subsidiary of Amoco Corporation, an Indiana corporation. Amoco Corporation is an integrated company engaged in the exploration, production, refining, transportation, and marketing of oil, natural gas, and other hydrocarbons.

Dome states that the imported gas would continue to be supplied by individual producers, producer groups, associations, and pipeline companies, and sold by Dome on a short-term or spot basis to, among others, industrial end users, agricultural users, electric utilities, pipelines, and local distribution companies. Dome expects that the majority of short-term and spot sales of Canadian natural gas sold to U.S. purchasers will be used to displace higher priced energy supplies. Dome asserts that each sale will be market responsive and that imports would be accomplished using existing pipeline capacity and no new construction would be involved. Dome also would continue to file reports with FE within 30 days after the end of each calendar quarter giving the details of the individual transactions. Dome's prior quarterly reports filed with FE indicate that approximately 23.6 Bcf of natural gas was imported under Orders 85 and 204 through September 30, 1989.

So that sales can commence and the authorization can be utilized during the winter heating season, Dome requests that FE expedite the consideration of this application. It is clear that the applicant's November 13 filing did not allow the DOE to publish a notice in the **Federal Register** providing a shortened, much less a full 30-day public comment period and still issue a new decisional order in this docket by the now past November 30 expiration date under Order 204. The DOE hereby reminds Dome and other potential applicants that DOE's procedural regulations, specifically 10 CFR 590.201, state that applications shall be filed a minimum of 60 days in advance of the proposed import or export or other requested action, unless a later date is permitted for good cause shown. Dome, it is noted, furnished no such reason.

The decision on the application for import authority will be made consistent with the DOE's gas import policy guidelines, under which the competitiveness of an import arrangement in the markets served is the primary consideration in determining whether it is in public interest (49 FR 6684, February 22, 1984). Parties that may oppose this application should comment in their responses on the issue of competitiveness as set forth in the policy guidelines. The applicant asserts that this import arrangement will be competitive and thus in the public interest. Parties opposing the arrangement bear the burden of overcoming this assertion.

NEPA Compliance

The DOE has determined that compliance with the National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.*, can be accomplished by means of a categorical exclusion. On March 27, 1989, the DOE published in the **Federal Register** (54 FR 12474) a notice of amendments to its guidelines for compliance with NEPA. In that notice, the DOE added to its list of categorical exlcusions the approval or disapproval of an import/export authorization for natural gas in cases not involving new construction. Application of the categorical exclusion in any particular case raises a rebuttable presumption that the DOE's action is not a major Federal action

under NEPA. Unless the DOE receives comments indicating that the presumption does not or should not apply in this case, no further NEPA review will be conducted by the DOE.

Public Comment Procedures

In response to this notice, any person may file a protest, motion to intervene or notice of intervention, as applicable and written comments. Any person wishing to become a party to the proceeding and to have the written comments considered as the basis for any decision on the application must, however, file a motion to intervene or notice of intervention, as applicable. The filing of a protest with respect to this application will not serve to make the protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the application. All protests, motions to intervene, notices of intervention, and written comments must meet the requirements that are specified by the regulations in 10 CFR part 590. Protests, motions to intervene, notices of intervention, requests for additional procedures, and written coments should be filed with the Office of Fuels Programs at the above address.

It is intended that a decisional record will be developed on the application through responses to this notice by parties, including the parties, written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures be provided, such as additional written comments, an oral presentation, a conference, or trial-type hearing. Any request to file additional written comments should explain why they are necessary. Any request for an oral presentation should identify the substantial questions of fact, law, or policy at issue, show that it is material and relevant to a decision in the proceeding, and demonstrate why an oral presentation is needed. Any request for a conference should demonstrate why the conference would materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is necessary for a full and true disclosure of the facts.

If an additional procedure is scheduled, notice to all parties will be provided. If no party requests additional procedures, a final opinion and order may be issued based on the official record, including the application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

A copy of Dome's application is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F–056, at the above address, (202) 586–9478. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, December 6, 1989.

Constance L. Buckley,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 89–28999 Filed 12–11–89; 8:45 am]

BILLING CODE 6450–01–M

[FE Docket No. 89–82–NG]

Goetz Energy Corp.; Application To Extend Blanket Authorization To Import Natural Gas From Canada

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of application for extension of blanket authorization to import natural gas.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of receipt on November 20, 1989, of an application filed by Goetz Energy Corporation (formally Goetz Oil Corporation) (Goetz) requesting that the blanket authority previously granted in DOE/ERA Opinion and Order No. 196 (Order 196), issued October 19, 1987 (ERA Docket No. 87–41–NG), be extended for two years beginning when its current import authorization expires on January 15, 1990. Under the extension requested, Goetz would be authorized to import up to a maximum of 140 Bcf of Canadian natural gas over a two-year period.

The application is filed under section 3 of the Natural Gas Act and DOE Delegation Order Nos. 0204–111 and 0204–127. Protests, motions to intervene, notices of intervention, and written comments are invited.

DATES: Protests, motions to intervene or notices of intervention, as applicable, requests for additional procedures and written comments are to be filed at the address listed below no later than 4:30 p.m., e.s.t., January 11, 1990.

ADDRESSES: Office of Fuels Programs, Office of Fossil Energy, U.S. Department of Energy, Forrestal Building, Room 3F–056, FE–50, 1000 Independence Avenue, SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT:

Larine A. Moore, Office of Fuels Programs, Office of Fossil Energy, U.S. Department of Energy, Forrestal Building, Room 3F–056, FE–53, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9478.

Diane Stubbs, Natural Gas and Mineral Leasing, Office of General Counsel, U.S. Department of Energy, Forrestal Building, Room 6E–042, GC–32, 1000 Independence Avenue, SW., Washington, DC. 20585, (202) 586–6667.

SUPPLEMENTARY INFORMATION: Goetz, a New York corporation with its principal place of business in Buffalo, New York, is a marketer of oil and natural gas in the United States. Goetz requests authority to continue to import competitively priced natural gas from reliable Canadian producers for sale to purchasers in the United States on a short-term or spot basis. Goetz proposes to import natural gas for either its own account or as agent for U.S. purchasers and/or Canadian suppliers. Goetz intends to use existing facilities for the transportation of the gas. Goetz also would continue to file reports with FE within 30 days after the end of each calendar quarter giving the details of the individual transactions. Goetz's prior quarterly reports filed with FE indicate that approximately 996 MMcf of natural gas was imported under Order 196 through September 30, 1989.

The decision on the application for import authority will be made consistent with the DOE's gas import policy guidelines, under which the competitiveness of an import arrangement in the markets served is the primary consideration in determining whether it is in the public interest (49 FR 6684, February 22, 1984). Parties that may oppose this application should comment in their responses on the issue of competitiveness as set forth in the policy guidelines. The applicant asserts that this import arrangement will be competitive and thus in the public interest. Parties opposing the arrangement bear the burden of overcoming this assertion.

NEPA Compliance:

The DOE has determined that compliance with the National Environmental Policy Act (NEPA), 42 U.S.C. 4321, *et seq.*, can be accomplished by means of a categorical exclusion. On March 27, 1989, the DOE published in the **Federal Register** (54 FR 12474) a notice of amendments to its guidelines for compliance with NEPA. In that notice, the DOE added to its list of

categorical exclusions the approval or disapproval of an import/export authorization for natural gas in cases not involving new construction. Application of the categorical exclusion in any particular case raises a rebuttable presumption that the DOE's action is not a major Federal action under NEPA. Unless the DOE receives comments indicating that the presumption does not or should not apply in this case, no further NEPA review will be conducted by the DOE.

Public Comment Procedures

In response to this notice, any person may file a protest, motion to intervene or notice of intervention, as applicable, and written comments. Any person wishing to become a party to the proceeding and to have the written comments considered as the basis for any decision on the application must, however, file a motion to intervene or notice of intervention, as applicable. The filing of a protest with respect to this application will not serve to make the protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the application. All protests, motions to intervene, notices of intervention, and written comments must meet the requirements that are specified by the regulations in 10 CFR part 590. Protests, motions to intervene, notices of intervention, requests for additional procedures, and written comments should be filed with the Office of Fuels Programs at the above address.

It is intended that a decisional record will be developed on the application through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures be provided, such as additional written comments, an oral presentation, a conference, or trial-type hearing. Any request to file additional written comments should explain why they are necessary. Any request for an oral presentation should identify the substantial question of fact, law, or policy at issue, show that it is material and relevant to a decision in the proceeding, and demonstrate why an oral presentation is needed. Any request for a conference should demonstrate why the conference would materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is necessary for a full and true disclosure of the facts. If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final opinion and order may be issued based on the official record, including the application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

A copy of Goetz's application is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F-056 at the above address. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC., December 6, 1989.

Constance L. Buckley,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 89-29000 Filed 12-11-89; 8:45 am]

BILLING CODE 12-11-89

[ERA Docket No. 88-63-NG]

Vector Energy (U.S.A.) Inc.; Order Amending an Authorization To Import Natural Gas From Canada

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of an order amending an authorization to import natural gas.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice that it has issued an order amending an authorization granting Vector Energy (U.S.A.) Inc. (Vector) authority to import up to 13.14 Bcf per year of Canadian natural gas over a term beginning December 1, 1989, through November 30, 2009. The order issued in ERA Docket No. 88-63-NG reflects pricing amendments to the gas supply and purchase agreements.

A copy of this order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F-056, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-9478. The Docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, December 2, 1989.

Constance L. Buckley,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 89-29001 Filed 12-11-89; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-3696-3]

Pollution Prevention Research Awards

AGENCY: U.S. Environmental Protection Agency.

ACTION: Notice.

SUMMARY: Notice is hereby given that the USEPA has entered into cooperative agreements with six (6) states: California, Connecticut, Illinois, Minnesota, New Jersey, and Washington, to participate in a new pollution prevention research program called Waste Reduction Innovative Technology Evaluation (WRITE). This pilot program provides funding to evaluate innovative pollution prevention technology in these states. This program encompasses cooperative agreements planned to run for a three-year period and evaluate a target of five (5) technologies per state.

DATES: These states entered into cooperative agreements on the following dates.

CA	June 30, 1989
CT	Sept. 1, 1989
IL	June 7, 1989
MN	June 8, 1989
NJ	Aug. 2, 1989
WA	June 2, 1989

ADDRESSES: Copies of the supporting documentation are available for public inspection upon request at the following locations:

Robert Ludwig, State of California, Department of Health Services, 714/744 P Street, P.O. Box 942732, Sacramento, CA 94234-7320, (916/324-2659).

Frederick Kaeser, Connecticut Hazardous Waste Management Service, 900 Asylum Avenue, Suite 360, Hartford, CT 06105-1904, (203/244-2007).

Gary Miller, Illinois Hazardous Waste Research and Information Center, 1808 Woodfield Drive, Savoy, Illinois 61874, (217/333-8942).

Cindy McComas, Minnesota Technical Assistance Program (MnTAP), 420 Delaware Street, SE., P.O. Box 197 Mayo, University of Minnesota, Minneapolis, MN 55455, (612/625-4949).

Kevin Gashlin, New Jersey Department of Environmental Protection, 401 East State Street, 5th Floor West CN-028, Trenton, NJ 08625, (609/292-8341).

Robert C. Burmark, Department of Ecology, State of Washington, Mail Stop PV-11, 4407 Woodview Drive SE., Lacey, WA 98504, (206/438-7370).

FOR FURTHER INFORMATION CONTACT: Ivars J. Licis, U.S. Environmental Protection Agency, Risk Reduction Engineering Laboratory, Waste Minimization, Destruction and Disposal Research Division, Waste Minimization Branch, 26 West Martin Luther King Drive, Cincinnati, OH 45268, Telephone: Comm. 513/569-7718, FTS-684-7718.

E. Timothy Oppelt,

Director, Risk Reduction Engineering Laboratory.

[FR Doc. 89-28975 Filed 12-11-89; 8:45 am]

BILLING CODE 6560-50-M

[FRL-3696-1]

Superfund Program; Interim Municipal Settlement Policy

AGENCY: Environmental Protection Agency.

ACTION: Request for public comment.

SUMMARY: The Agency is publishing the "Interim Policy on CERCLA Settlements Involving Municipalities or Municipal Wastes" (referred to as the Municipal Settlement Policy) today to inform the public about this interim policy and to solicit public comment. This interim policy focuses on settlements involving municipalities or municipal wastes under section 122 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund) as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA). It also addresses how the treatment of municipalities and municipal wastes affects the treatment of private parties and certain kinds of commercial, institutional, or industrial wastes in the Superfund settlement process as well.

DATE: Comments must be provided no later than February 12, 1990.

ADDRESS: Comments should be addressed to Kathleen MacKinnon, U.S. Environmental Protection Agency, Office of Waste Programs Enforcement, Guidance and Oversight Branch (OS-510), 401 M Street, SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Kathleen MacKinnon at the above address or at (202) 475-6771.

SUPPLEMENTARY INFORMATION: The following supplemental information is provided to assist the public in reviewing and commenting on EPA's interim policy:

I. Effective Date of Interim Policy and Role of Public Comment
II. Purpose of Interim Policy
III. Focus of Interim Policy
IV. Why Settlement Involving Municipalities or Municipal Wastes Is An Issue
V. Discussion of Interim Policy
A. Public Input
B. EPA Consideration of Competing Public Interests

I. Effective Date of Interim Policy and Role of Public Comment

This interim policy is effective immediately. However, the Agency emphasizes that this is an interim policy and that there is an important role for public comment. We are providing the public with 60 days to review and submit comments in writing. Based upon public comment or on our experience in implementing the interim policy, the Agency may address additional issues or revise the interim policy accordingly.

II. Purpose of Interim Policy

The primary purpose of this interim policy is to provide interim guidance to EPA Regional offices on how they should exercise their enforcement discretion in dealing with municipalities and municipal wastes in the Superfund settlement process. An additional purpose is to provide municipalities and private parties who may be potentially liable under section 107(a) of CERCLA with information about how EPA will handle them in the settlement process. We believe this interim policy is important for establishing a national framework that will help facilitate our ability to reach settlements and will ensure that sites involving municipalities or municipal wastes are addressed consistently throughout the country.

III. Focus of Interim Policy

The interim policy focuses on how EPA will proceed in attempting to reach settlements at sites involving municipalities or municipal wastes. Focusing on settlements means the interim policy indicates how EPA will attempt to reach voluntary agreements for responsible party financing and/or cleanup of sites involving municipalities or municipal wastes. Nothing in the interim policy affects any party's potential legal liability under CERCLA. Any decision EPA makes in exercising its enforcement discretion under this interim policy does not mean that potential CERCLA legal liability no longer applies. In particular, nothing in the interim policy precludes a third party from initiating a contribution action.

Focusing on settlements involving municipalities or municipal wastes means that the primary intent of the interim policy is to address questions about how EPA should handle municipalities or municipal wastes in the Superfund settlement process. However, in the process of addressing those questions we found it necessary to address other issues relating to private parties and certain kinds of commercial, institutional, or industrial wastes. We have addressed these related issues because private parties sometimes handle municipal wastes, private parties generate some waste streams that are similar in nature to municipal wastes, and municipal and industrial wastes are sometimes co-disposed at the same site (particularly municipal landfills).

Specific questions that have been examined by EPA as part of this interim policy relate to who should be included in the information gathering process, who should be notified as potentially responsible parties, how municipalities should be handled in the settlement process, and how the treatment of municipalities and municipal wastes affects the Agency's treatment of private parties and certain kinds of commercial, institutional, or industrial wastes.

IV. Why Settlement Involving Municipalities or Municipal Wastes Is An Issue

Involving municipalities and municipal wastes in the Superfund settlement process is an issue because questions have been raised about how such parties and wastes should be treated in the settlement process. Until the development of this interim policy, EPA had not addressed these questions from a national perspective. This issue is important because there are a significant number of proposed and final sites on the National Priorities List (NPL) that involve municipalities or municipal wastes, and EPA expects more of these sites to be added to the NPL in the future.

EPA has identified 320 (about 25%) of the 1219 proposed and final NPL sites that may involve municipalities or municipal wastes. Of those sites, 236 (about 20%) have been classified as municipal landfills. EPA defines a municipal landfill as any landfill, either publicly or privately owned, which has received municipal, solid waste. Although it is difficult to accurately predict how many of those sites involving municipalities or municipal wastes may be added to the NPL, historically about 20% of each NPL update has included municipal landfills. Municipal landfills are particularly complex sites to address because they typically involve multiple responsible

parties (sometimes hundreds of different parties), multiple sources of wastes (often municipal and industrial wastes), as well as diverse waste streams (in terms of amount and toxicity).

V. Discussion of Interim Policy

In the development of this interim policy, EPA has examined a variety of issues and options for addressing these issues. We have also made an effort to provide meaningful opportunities for interested parties to participate in the debate about municipal settlements. EPA has listened to all sides of the debate and has attempted to develop an approach that is both fair and manageable.

A. Public Input

Throughout the development of this interim policy, EPA has established and maintained an extensive dialogue with a full range of interested parties. For example, in March of 1988 EPA sponsored a Municipal Settlement Conference attended by over 100 representatives from State and local governments and organizations; industry, environmental, and other groups; as well as Congressional staff. EPA sought input from all interested parties to facilitate our efforts to develop a fair assessment of the issue, particularly from municipal and industrial representatives who are most directly affected by the interim policy. Both municipalities and private parties are affected by this interim policy because, as mentioned above, both municipalities and private parties handle municipal waste, private parties generate waste streams that have similar characteristics to municipal waste streams, and municipal and industrial waste streams are often co-disposed at individual sites.

As a followup to this conference, EPA established the Municipal Settlement Discussion Group. The discussion group met in June, August, and October of 1988 and was generally comprised of the same groups and interests that participated in the March conference. All discussion group meetings were open to the public and a notice of each meeting was published in the **Federal Register.**

The purpose of this dialogue has been for EPA to inform the public about the issues that the Agency is addressing as part of our effort to develop the Municipal Settlement Policy. At the same time, the Agency has sought to stimulate the public debate about these issues by providing a public forum for the exchange of ideas. The conference and discussion group activities have been conducted as an information exchange and public debate exercise. EPA has not requested recommendations nor attempted to reach a consensus among the various parties. Minutes of all meetings have been prepared and are available to the public upon request.

A final meeting of the discussion group is expected to be held in January 1990, before the close of the 60-day public comment period. The purpose of this meeting will be to discuss the interim policy and to further facilitate public consent. A notice of this meeting will be published in the **Federal Register.** Minutes of this meeting will be kept and made available to the public upon request.

B. EPA Consideration of Competing Public Interests

Input from the public has played an important role in EPA's development of this interim policy. Within the context of CERCLA's statutory language and objectives, EPA has considered the competing interests and objectives of the various parties interested in this issue, especially municipalities and private parties who are directly affected by the interim policy. EPA has developed an interim policy which the Agency believes is appropriate, is in the interest of the public, and is fair to both municipalities and private parties as well as one which can be managed and implemented by EPA's Regional offices. The following examples highlight how EPA considered competing interests on key issues. The discussion below only summarizes (and sometimes paraphases) certain key aspects of the interim policy; readers should refer to the interim policy itself for an indication or clarification of how EPA will proceed.

1. *Treatment of municipalities as owners/operators.* Some interested parties expressed uncertainty about whether potential CERCLA liability should apply to municipal owners/operators of facilities where hazardous substances are present. In addition, there are different views about how municipal owners/operators should be handled in the settlement process. For example, some municipal representatives have suggested that when potential owner/operator liability applies that municipalities should be given "special treatment" (e.g., provided with an early opportunity to meet with EPA to resolve their potential liability). Industry representatives have indicated that municipal owner/operators should be handled the same as other PRPs and should be part of the larger settlement process that may involve other parties, including private parties.

EPA's interim policy clarifies that municipal owners/operators may be potentially liable just like private parties, and that such parties will generally be notified and handled in the same manner during the settlement process as private parties.

2. *Treatment of generators/transporters of municipal wastes and certain kinds of commercial, institutional, or industrial wastes.* There are different views on whether the generators/transporters of municipal wastes (e.g., municipal solid waste and sewage sludge) (usually municipalities) should be notified that they are considered to be potentially responsible parties and brought into the Superfund settlement process. Municipalities and some States do not believe it is appropriate to include the generators/transporters of municipal wastes as potentially responsible parties. Industry representatives have generally taken the opposite view.

EPA's approach to this issue is as follows: when the source of the municipal waste is believed to come from households, regardless of whether household hazardous waste may be present, the general policy is to exclude such municipal wastes from the Superfund settlement process, unless the Region obtains site-specific information that the municipal solid waste or sewage sludge contains a hazardous substance from a commercial, institutional, or industrial process or activity.

The only exception to this general policy is that EPA may consider bringing generators/transporters of municipal solid waste that contains a hazardous substance derived only from households into the settlement process as potentially responsible parties if the total privately generated commercial, institutional, and industrial waste at the site is insignificant compared to the municipal solid waste. EPA expects this exception to be sparingly applied.

When we are dealing with industrial wastes (including low-hazardous industrial wastes), the generator/transporters of the wastes will generally be notified as potentially responsible parties because the source of the waste is a commercial, institutional, or industrial process or activity.

One question raised by the interim policy relates to how EPA will handle trash from a commercial, institutional, or industrial entity which is very similar to municipal solid waste that is derived from households. Although the source of the waste in this situtation is not households, when the generator/transporter shows EPA that its waste is

very similar to that generated by households and that it is not the result of a commercial, institutional, or industrial process or activity, the generator/transporter generally will not be notified as a potentially responsible party by EPA and brought into the Superfund settlement process.

In carrying out this approach, EPA is exercising its enforcement discretion in determining whether we will treat generator/transporters as potentially responsible parties for certain categories of wastes. EPA believes this approach is fair and manageable. For example, this approach treats municipalities and private parties that handle the same waste streams in the same manner (e.g., municipal generators/transporters of municipal solid waste are treated the same as private party generators/transporters of such waste.)

This approach also treats different waste streams in a logical and consistent manner. A key factor in determining whether to notify generators/transporters of municipal solid waste, sewage sludge, trash from a commercial, institutional, or industrial entity, or low-hazardous industrial wastes is tied to whether a hazardous substance is present that is derived from a commercial, institutional, or industrial process or activity.

Finally, this approach is one that can be effectively managed and implemented by EPA's Regional offices. For example, based on our experiences at Superfund sites, especially municipal landfills, we believe that it is generally not a cost-effective use of our enforcement resources to pursue those generators/transporters whose only contribution at a Superfund site appears to have been substances that may have been contaminated only with relatively small quantities of household hazardous waste (e.g., municipal solid waste). The resource-intensive nature of obtaining sufficient evidence to demonstrate the presence of household hazardous waste as well as the potentially increased transaction costs of settlement and/or litigation far outweigh the possible benefit the Government may derive from obtaining cleanup costs from such parties. The Agency believes that its enforcement resources are better spent on pursuing other potentially responsible parties to achieve the cleanups needed to effectively implement the Superfund program and to protect human health and the environment.

3. *Role of municipalities in the settlement process.* There are also different views on the appropriate treatment of municipalities vis-a-vis private parties in the settlement process (i.e., whether municipalities should receive "special treatment" because they are governmental entities). Municipalities generally believe they should be treated differently than private potentially reponsible parties while industry generally believes they should not.

EPA believes that municipalities and private parties should generally be handled in the same manner in the settlement process. Handling municipalities and private parties the same means that EPA will seek information in appropriate circumstances from all parties, including municipalities. This also means that all parties who are owners/operators of facilities will generally be notified as potentially responsible parties.

Relating to municipal solid waste or sewage sludge, all parties who are generators/transporters (either municipalities or private parties) are generally exempt from notification unless we obtain site-specific information that the waste contains a hazardous substance from a commercial, institutional, or industrial activity or process. In instances relating to notification as a potentially responsible party, we focus on the nature/source of the waste, not whether the party is a municipality or private party.

The interim policy also handles municipalities and private parties essentially in the same manner once they are notified as potentially responsible parties by attempting to negotiate and settle with such parties as one group, unless separate settlements such as *de minimis* settlements pursuant to section 122 (g) of CERCLA are appropriate. Nevertheless, EPA does recognize that municipalities have unique characteristics as governmental entities which EPA may take into account when designing specific settlements (e.g., by considering delayed payments, delayed payment schedules, or in-kind contributions under appropriate circumstances).

Dated: December 6, 1989.

Don R. Clay,

Assistant Administrator, Office of Solid Waste and Emergency Response.

Memorandum

Subject: Interim Policy of CERCLA Settlements Involving Municipalities or Municipal Wastes

From: Don R. Clay, Assistant Administrator

To: Regional Administrators, Regions I—X

I. Introduction

(A) Focus of Interim Policy

This memorandum establishes EPA's interim policy on settlements involving municipalities or municipal wastes under section 122 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund) as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA). In particular, this interim policy indicates how EPA will exercise its enforcement discretion when pursuing settlements which involve municipalities or municipal wastes.[1] The municipal wastes addressed by this interim policy are municipal solid waste (MSW) and sewage sludge as defined below. This interim policy has been developed to provide a consistent Agency-wide approach for addressing municipalities and municipal wastes in the Superfund settlement process.

Although this interim policy focuses on municipalities and municipal wastes, it addresses how private parties and certain kinds of commercial, institutional, or industrial wastes will be handled in the settlement process as well. It is important to address private parties and certain kinds of commercial, institutional, or industrial wastes in this interim policy because private parties sometimes handle municipal wastes or wastes of a similar nature and because municipal and private party waste streams are sometimes co-disposed at sites, particularly municipal landfills. The kinds of commercial, institutional, or industrial wastes covered by this interim policy include "trash from a commercial, institutional, or industrial entity" and "low-hazardous industrial wastes" as defined below.

There are three fundamental issues addressed by this interim policy. First is whether to notify generators/transporters of MSW or sewage sludge that they are considered to be potentially responsible parties (PRPs) and to include them in the Superfund settlement process. Such parties are usually municipalities, although they may include private parties as well. Second is how municipalities should be handled in the Superfund settlement process when the decision is made to notify them that they are PRPs under section 107(a) of CERCLA. Third is how the treatment of municipalities and muncipal wastes under this interim policy affects the treatment of private parties and certain kinds of commercial, institutional, or industrial wastes in the Superfund settlement process.

Key questions specifically addressed as part of this interim policy include the following:

- *Information Gathering:* Should municipalities be included in the Agency's information gathering process? Should generators/transporters of MSW or sewage sludge be included in the information gathering process?
- *Notification:* Should municipalities be notified that they are PRPs? Should generators/transporters of MSW or sewage sludge be notified as PRPs?
- *Settlements:* How should municipalities be handled in the Superfund settlement

[1] This interim policy does not provide an exemption from potential CERCLA liability for any party; potential liability continues to apply in all situations covered under section 107 of CERCLA.

process? What settlement process and settlement tools should be used to facilitate settlement involving municipalities or municipal wastes?

• *Private Parties:* How does the treatment of municipalities and municipal wastes affect the Agency's treatment of private parties and certain kinds of commercial, institutional, or industrial wastes?

(B) Key Terms Used in Interim Policy [2]

The following defines the key terms used in this interim policy:

• The term "municipalities" refers to any political subdivision of a State and may include cities, counties, towns, townships, and other local governmental entities.

• The term "municipal solid waste" refers to solid waste generated primarily by households, but may include some contribution of wastes from commercial, institutional and industrial sources as well. As defined under the Resource Conservation and Recovery Act (RCRA), MSW contains only those wastes which are not required to be managed as hazardous wastes under Subtitle C of RCRA (e.g., non-hazardous substances, household hazardous wastes (HHW), or small quantity generator (SQG) wastes). Although the *actual* composition of such wastes varies considerably at individual sites, MSW is *generally* composed of large volumes of non-hazardous substances (e.g., yard waste, food waste, glass, and aluminum) and may contain small quantities of household hazardous wastes (e.g., pesticides and solvents) as well as small quantity generator wastes.[3] Many industrial solid wastes and some commercial and institutional solid wastes are managed separately from household wastes, but may enter the MSW waste stream.

• The term "municipal landfill" refers to any landfill, whether publicly or privately owned, that has received municipal solid waste for disposal.

• The term "sewage sludge" refers to any solid, semi-solid, or liquid residue removed during the treatment of municipal waste water or domestic sewage.[4]

• The term "trash from a commercial, institutional, or industrial entity" refers to waste which is very similar to the MSW that is derived from households. This term covers only those wastes that are essentially the same as what one would expect to find in common household trash. This term does not include hazardous substances that are derived from a commercial, institutional, or industrial process or activity.

• The term "low-hazardous industrial wastes" refers to high volume wastes that contain small quantities of hazardous substances derived from an industrial, commercial, or institutional process or activity. Examples may include certain paint sludges or industrial wastewaters.

II. CERCLA Liability

Important questions have been raised about whether municipalities may be PRPs and whether municipal wastes (i.e., MSW and sewage sludge) may be considered hazardous substances under CERCLA.

(A) Municipalities as PRPs

The statute does not provide an exemption from liability for municipalities. Municipalities may be PRPs like private parties if municipalities fall within the categories of liability specified under section 107(a) of CERCLA. In general, section 107(a) establishes liability for past and present owners or operators of facilities as well as generators or transporters of hazardous substances for the release or threatened release of hazardous substances. Such parties may be liable for the costs of responding to a release or threatened release of hazardous substances as well as for resulting damages to natural resources. The specific categories of liable parties under section 107(a) are:

1. The owner and operator of a vessel or a facility,

2. Any person who at the time of disposal of any hazardous substance owned or operated any facility at which such hazardous substances were disposed of,

3. Any person who by contract, agreement, or otherwise arranged for disposal or treatment, or arranged with a transporter for transport for disposal or treatment, of hazardous substances owned or possessed by such person, by any other party or entity, at any facility or incineration vessel owned or operated by another party or entity and containing such hazardous substances, [commonly referred to as "generators" [5]], and

4. Any person who accepts or accepted any hazardous substances for transport to disposal or treatment facilities, incineration vessels, or sites selected by such person [commonly referred to as "transporters"].

Section 107(a) describes liable parties as "persons" and the definition of "person" under Section 101(21) includes municipalities and political subdivisions of a State. Municipalities may, therefore, be PRPs as part of CERCLA's broad definition of who is potentially liable.

(B) Municipal Wastes as Potential CERCLA Hazardous Substances

Similarly, the statute does not provide an exemption from liability for municipal wastes. Municipal wastes may be considered hazardous substances if they are covered under the definition of hazardous substances in section 101(14) of CERCLA. As indicated under the definitions of MSW and sewage sludge, these municipal wastes are *generally* characterized by large volumes of non-hazardous substances and may contain small quantities of household hazardous or other wastes, although the *actual* composition of the waste streams vary considerably at individual sites. To the extent municipal wastes contain a hazardous substance that is covered under section 101(14) of CERCLA and there is a release or threatened release, such municipal wastes may fall within the CERCLA liability framework.

III. Information Gathering

The Regions should inlcude all municipal and private party owners/operators and generators/transporters in the information gathering process, including the generators/transporters of municipal wastes. This means that municipal owners/operators as well as municipal generators/transporters should generally receive section 104(e) information request letters and should otherwise be fully included in the information gathering process like private parties. Information obtained through such letters or through other means is important for determining (among other things) whether it is appropriate to notify a party as a PRP, including whether to notify a generator/transporter of MSW or sewage sludge as discussed below.[6]

IV. Notification of Potential Responsibility

(A) Owners/Operators

The same approach will be used for both municipalities and private parties when determining whether to notify them as owners/operators. Specifically, such parties will generally be notified where they were past owners or operators of facilities at the time of disposal of hazardous substances, or they are present owners or operators of facilities where hazardous substances have been released or there is a threatened release.

(B) Generators/Transporters [7]

1. Municipal solid waste. Municipalities and private parties will be treated the same

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[2] The definitions provided under this section are for the purpose of this interim policy only. Where possible, this interim policy includes already existing definitions used under other Federal environmental programs (e.g., under the Resource Conservation and Recovery Act or the Clean Water Act). However, nothing in this interim policy affects the regulatory efforts of these other programs.

[3] All household wastes, including household hazardous wastes, are unconditionally exempt from the Federal hazardous waste regulations promulgated under subtitle C of RCRA (See 40 CFR § 261.4(b)(1)). With regard to non-household sources of solid waste, if such waste is not a listed or characteristic hazardous waste accumulated in quantities exceeding the small quantity generator limitations (i.e., less than 100 kg/month of hazardous wastes and less than 1 kg/month for acute hazardous wastes), such waste is not required to be managed in a RCRA subtitle C hazardous waste treatment, storage, or disposal facility (See 40 CFR § 261.5). "Household hazardous wastes" refers to those wastes which are generated by households and would be managed as hazardous wastes under RCRA subtitle C if they were generated by a non-household in quantities exceeding the small quantity generator limitations.

[4] The definition of sewage sludge is contained in the National Pollutant Discharge Elimination System Sewage Sludge Permit Regulations published in the Federal Register as a final rule May 2, 1989 (See 40 CFR part 122.2).

[5] Persons who fall into this category are commonly referred to as "generators," although liability under this section extends beyond "true generators" of hazardous substances to include persons who arranged for the disposal or treatment of hazardous substances owned or possessed by such party or another party. The term "generator" is used throughout this document to refer to any party who is potentially liable under section 107(a)(3).

[6] The Regions may accept and consider credible site specific information from any party to supplement their own information gathering efforts as appropriate.

[7] The categories of wastes discussed below, i.e., relating to municipal solid waste, sewage sludge, trash from a commercial, institutional, or industrial entity, and low-hazardous industrial wastes, are defined in the "Introduction" to this interim policy (See I.B.).

when determining whether to notify them as PRPs when they are generators/transporters of MSW. Specifically, such parties will not generally be notified unless:

- The Region obtains site-specific information that the MSW contains a hazardous substance;[8] and
- The Region has reason to believe that the hazardous substance is derived from a commercial, institutional, or industrial process or activity.

This means that EPA will not generally notify municipalities or private parties who are generators/transporters of MSW if only household hazardous wastes (HHW) are present, unless the truly exceptional situation discussed below exists. The general policy of not notifying parties who are generators/transporters of HHW extends to "HHW collection day programs" as well.[9]

This also means that such parties may be notified as PRPs if the MSW contains hazardous substances from non-household sources. Non-household sources include, but are not limited to, small quantity generator (SQG) wastes from commercial or industrial processes or activities, or used oil or spent solvents from private or municipally-owned maintenance shops.

Notwithstanding the above general policy, there may be truly exceptional situations where EPA may consider notifying generators/transporters of MSW which contains a hazardous substance derived only from households. Such notification may be appropriate where the total contribution of commercial, institutional, and industrial hazardous waste by private parties to the site is insignificant when compared to the MWS.[10] In this situation, the Regions should seriously consider notifying the generators/transporters of MSW containing a hazardous substance from households as PRPs and include them in the settlement process where it would promote either settlement or response action at the site.

2. *Sewage sludge.* Municipalities and private parties will be treated the same when determining whether to notify them as PRPs when they are generators/transporters of sewage sludge. Specifically, such parties will not generally be notified unless:

- The Region obtains site-specific information that the sewage sludge contains a hazardous substance; and
- The Region has reason to believe that the hazardous substance is derived from a commercial, institutional, or industrial process or activity.

3. *Trash from a commercial, institutional, or industrial entity.* Parties who are generators/transporters of trash from a commercial, institutional, or industrial entity will not generally be notified as PRPs if such parties demonstrate to the Region that:

- None of the hazardous substances contained in the trash are derived from a commercial, institutional, or industrial process or activity; and
- The amount and toxicity of the hazardous substances contained in the trash does not exceed that which one would expect to find in common household trash.

4. *Any other hazardous substance, including low-hazardous industrial wastes.* Municipalities or private parties who are generators/transporters of "any other hazardous substance" will generally be notified as PRPs if the Region obtains information that the substance is hazardous or that it contains a hazardous substance. This includes notification of private parties who are the generators/transporters of low-hazardous industrial wastes. "Any other hazardous substance" in this category refers to any hazardous substance covered under section 101(14) of CERCLA other than hazardous substance that may be contained in MSW, sewage sludge, or trash from a commercial, institutional, or industrial entity (as discussed under IV.B.1., or IV.B.2., or IV.B.3. above). The generators/transporters of hazardous substances that may be contained as part of the waste streams discussed under IV.B.1., or IV.B.2., or IV.B.3. should be addressed as specified above.

V. Settlements

(A) Settlement Process

Once the notification decision is made, the general goal and overall process for reaching settlement at sites involving municipalities or municipal wastes is the same as for other sites. The general goal remains to negotiate with PRPs to reach one settlement agreement that provides complete resolution of all pending CERCLA claims, and is consistent with both applicable statutory requirements and EPA's Interim CERCLA Settlement Policy.[11] This means that at sites where both municipal and private PRPs exist, EPA will attempt to include both types of parties on one settlement agreement.

Although one settlement agreement is the goal for each site, separate settlement agreements may be used at any site to facilitate settlement, where appropriate. This includes sites involving municipalities or municipal wastes. Separate settlements are not automatically available to municipalities and are generally available to such parties under the same conditions as for private parties. Examples of separate settlements are section 122(g) *de minimis* settlements and cash-outs which may be used when they are consistent with applicable statutory requirements and existing EPA guidance.[12]

(B) Settlement Provisions That May Be Particularly Suitable for Certain Municipalities

As indicated, once parties are notified as PRPs, the overall process and goals for reaching settlement at sites involving municipalities or municipal wates is the same as for other Superfund sites. Nonetheless, there are some settlement provisions (e.g., delayed payments, delayed payment schedules, and in-kind contributions) that may be particularly suitable for facilitating settlement with certain municipal PRPs because they take into account a municipality's status as a governmental entity.[13]

Such settlement provisions are not routinely available to municipalities. As a general rule, they must be considered where a municipality has successfully demonstrated to EPA that they are appropriate (e.g., where valid ability to pay or procedural constraints that affect the timing of payment exist). These settlement provisions may be embodied in separate settlements or they may be folded into a larger settlement that includes private parties. In addition, although these settlement provisions may be particularly suitable for municipalities, they may also be available to private parties, such as certain small businesses, where appropriate.

The following discusses how delayed payments, delayed payment schedules, and in-kind contributions may be used:

1. *Delayed payment.* If a municipality has demonstrated difficulty providing a lump-sum payment upfront for past costs or for cleanup needs, the settlement could be structured to allow the municipality to pay at a specified future date. This would allow the municipality time to raise the money needed

[8] The term "site-specific" information refers to information pertaining to a particular Superfund site. "Site-Specific" information does not generally include, for example, "general studies" conducted by EPA or other parties which draw general conclusions about whether MSW or sewage sludge typically contain a certain percentage of hazardous substances, unless the "general study" includes "site-specific" information obtained from the PRP or superfund site in question. "General studies" may nonetheless be used to supplement "site-specific" information.

[9] The term "HHW collection day programs" refers to programs that have generally been sponsored by municipalities or community organizations whereby residents voluntarily remove their HHW from their household waste. The HHW is then typically disposed of in a RCRA Subtitle C hazardous waste facility and the household waste is typically disposed of in a RCRA subtitle D solid waste facility.

[10] The Regions should consider both the volume and the toxicity of the commercial, institutional, and industrial hazardous waste when determining whether it is insignificant when compared to the MSW. In determining whether the volume is insignificant, the Regions should consider the total volume of such waste contributed by all private parties. In determining whether the toxicity is insignificant, the Regions should consider whether such waste is significantly more toxic than the MSW and whether such waste requires a disproportionately high treatment and disposal cost or requires a different or more costly remedial technique than that which otherwise would be technically adequate for the site.

[11] "Interim CERLA Settlement Policy", February 5, 1985, 50 FR 5034.

[12] For example, see "Interim Guidance on Settlements with *De Minimis* Waste Contributors," June 30, 1987, 52 FR 24333.

[13] In some circumstances a municipality's governmental status may impose practical constraints on its ability to carry out its legal obligation as a PRP under CERCLA. For example, a municipality may need to hold a special vote involving its legislative body or its citizens to gain approval to issue a bond or arrange other financing to cover cleanup costs at a Superfund site where it is a PRP. These settlement provisions are designed to take into account these types of unavoidable constraints that may exist.

to cover its contribution. This may include an interest payment.

2. *Delayed payment schedules (payments over time).* An alternative to a delayed payment is to allow a delayed payment schedule where the settlement is structured to allow the municipality to pay over time based upon a predetermined schedule of payments. The payment schedule would be adjusted in such a way that the discounted present value of the payment would be greater than or equal to the settlement.[14]

3. *In-kind contributions.* The settlement could be structured to allow for an in-kind contribution, especially where a municipality can provide only a portion of its share of costs or is unable to provide a monetary payment. In-kind contributions may be made in conjunction with or in lieu of cash. Factors the Regions may use in considering the appropriateness of an in-kind contribution may include the overall financial health of the municipality, the amount of the municipality's share, the value of the in-kind contribution, and the effect of the in-kind contribution on the overall effort to achieve settlement.

One mechanism for allowing an in-kind contribution could be a "carve-out" order when, for example, the municipal PRP has agreed to provide the operation and maintenance at the facility. Other in-kind contributions could include the use of trucks and equipment to carry out cleanup activities, the installation of fences and the provision of other security measures to control public access to the site, or the use of the municipality's sewage treatment plant.

(C) Contribution Protection

Nothing in this interim policy affects the rights of any party in seeking contribution from another party, unless such party has entered into a settlement with the United States or a State and obtained contribution protection pursuant to section 113(f) of CERCLA.[15]

VI. Disclaimer

This interim policy is intended solely for the guidance of EPA personal. It is not intended and can not be relied upon to create any rights, substantive or procedural, enforceable by any party in litigation with the United States. The Agency reserves the right to act at variance with this policy and to change it at any time without public notice.

VII. For Further Information

For further information or questions about this interim policy, the Regions may contact Kathleen MacKinnon in the Office of Waste Programs Enforcement at FTS-475-9812. Inquires by other persons should be directed to Ms. MacKinnon at 202-475-6771.

[FR Doc. 89-28878 Filed 12-11-89; 8:45 am]

BILLING CODE 6560-50-M

[14] Delayed payment schedules may include "structured settlements" which are settlements paid over time generally through an annuity. EPA is currently developing guidance, titled "Interim Guidance on the Use of Structured Settlements Under CERCLA," which will establish criteria for evaluating whether a particular site is good candidate for a structured settlement. EPA expects to issue this interim guidance in the Spring of 1990.

[15] Under section 113(f), where EPA determines that settlement is in the best interest of the Federal government, CERCLA provides contribution protection to the settling parties for matters covered by the settlement. This may include a party who has not been notified as a PRP by EPA but wishes to settle its potential CERCLA liability.

FEDERAL MARITIME COMMISSION

Agreement(s) Filed MSC/AEL Service Agreement

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street, NW., room 10325. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 203-011265

Title: MSC/AEL Service Agreement.

Parties:

Mediterranean Shipping Company SA ("MSC")

Atlantik Express Linie, Thien & Heyenga Schiffahrts GmbH & Co.

Synopsis: The Agreement authorizes the parties to engage in slot/space charter and sailing rationalization arrangements in the trades between and via North European and United States ports. The parties are also authorized to discuss and exchange information on rates, charges, service contracts and other terms and conditions of transport. The parties have no obligation under this Agreement, other than voluntarily, to adhere to any consensus or agreement reached. The Parties have requested a shortened review period.

By Order of the Federal Maritime Commission.

Dated: December 6, 1989.

Joseph C. Polking,

Secretary.

[FR Doc. 89-28907 Filed 12-11-89; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

Barclays Bank PLC, et al.; Acquisitions of Companies Engaged in Permissible Nonbanking Activities

The organizations listed in this notice have applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated for the application or the offices of the Board of Governors not later than December 27, 1989.

A. Federal Reserve Bank of New York (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. *Barclays Bank PLC,* London, England; Barclays PLC, London, England; Baybanks, Inc., Boston, Massachusetts; Chemical Banking Corporation, New York, New York; Manufacturers Hanover Corporation, New York, New York; National Westminster Bank, PLC, London,

England; Natwest Holdings, Inc., New York, New York; Northeast Bancorp, Inc., New Haven, Connnecticut; The Bank of New York Company, Inc., New York, New York; The Chase Manhattan Corporation, New York, New York; The HongKong and Shanghai Banking Corporation Limited, Hong Kong, B.C.C.; Kellett NV, Curacao, Netherlands Antilles; HSBC Holdings, BV, Amsterdam, The Netherlands; and Marine Midland Banks, Inc., Buffalo, New York, to acquire Key Services Corporation and thereby engage in data processing and related activities pursuant to § 225.25(b)(7) of the Board's Regulation Y.

B. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *Springfield Investment Company,* Springfield, Minnesota; to acquire Morgan Insurance Agency, Morgan, Minnesota, and thereby engage in insurance activities pursuant to § 225.25(b)(8)(iv) of the Board's Regulation Y. These activities will be conducted in Springfield, Minnesota, and Morgan, Minnesota.

Board of Governors of the Federal Reserve System, December 6, 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89-28945 Filed 12-11-89; 8:45 am]

BILLING CODE 6210-01-M

Change in Bank Control; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than December 28, 1989.

A. Federal Reserve Bank of Philadelphia (Thomas K. Desch, Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105:

1. *C. Ward Braceland,* Exton, Pennsylvania; Robert W. Brandl, Exton, Pennsylvania; Kathleen M. Byrnes, West Chester, Pennsylvania; John E. Difebaugh, Newtown Square, Pennsylvania; Patricia J. Difebaugh, Newton Square, Pennsylvania; James S. Fay, Royersford, Pennsylvania; Christine M. Garchinsky, Clifton Heights, Pennsylvania; Hugh J. Garchinsky, Clifton Heights, Pennsylvania; James E. Greenwood, Pottstown, Pennsylvania; James A. Hinz, Swarthmore, Pennsylvania; Mary H. Hinz, West Chester, Pennsylvania; William J. Jackson, West Chester, Pennsylvania; Donal L. Kimmel, Norristown, Pennsylvania; Thomas L. Kimmel, Mont Clare, Pennsylvania; Frank P. Lemaster, West Chester, Pennsylvania; William J. McCuen Jr., West Chester, Pennsylvania; John P. Niggeman, Jr., Malvern, Pennsylvania; James W. Noyes, Media, Pennsylvania; Susan F. O'Donnell, Chester Springs, Pennsylvania; Lawrence M. O'Donnell, Chester Springs, Pennsylvania; Steve P. Pahides, Media, Pennsylvania; Stephen H. Palmer, Media, Pennsylvania; John L. Smith, Jr., Malvern, Pennsylvania; Walter M. Strine, Jr., Media, Pennsylvania; William B. Strine, Media, Pennsylvania; to acquire 100 percent of the voting shares of Freedom Valley Bank, West Chester, Pennsylvania.

B. Federal Reserve Bank of Atlanta (Robert E. Heck, Vice President) 104 Marietta Street, NW., Atlanta, Georgia 30303:

1. *James E. Blackburn,* Vicksburg, Mississippi; to acquire an additional .80 percent (for a total of 12.17 percent) of the voting shares of Merchants Capital Corporation, Vicksburg, Mississippi, and thereby indirectly acquire Merchants National Bank, Vicksburg, Mississippi.

2. *Howell N. Gage, Jr.,* Vicksburg, Mississippi; to acquire an additional .69 percent (for a total of 10.04 percent) of the voting shares of Merchants Capital Corporation, Vicksburg, Mississippi, and thereby indirectly acquire Merchants National Bank, Vicksburg, Mississippi.

C. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *First State Bank of Covington, Tennessee employee Stock Ownership Trust,* Covington, Tennessee, and James O. Edmonds, Covington, Tennessee, Jack C. Sanford, Covington, Tennessee; and Theodore B. Sloan, Covington, Tennessee, as trustees, to acquire up to 24.64 percent of the voting shares of FSB, Inc., Covington, Tennessee, and thereby indirectly acquire First State Bank of Covington, Covington, Tennessee.

D. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *Liberty State Bank Employee Stock Ownership Plan,* St. Paul, Minnesota; to acquire 2.15 percent of the voting shares of Liberty Bancshares, Inc., St. Paul, Minnesota, and thereby indirectly acquire Liberty State Bank, St. Paul, Minnesota.

E. Federal Reserve Bank of Kansas City (Thomas M. Hoenig, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Marvin N. Christensen,* Waubun, Minnesota; to acquire 100 percent of the voting shares of Columbine Valley Bank & Trust Company, Littleton, Colorado.

2. *John E. Kirkpatrick,* Oklahoma City, Oklahoma; Christina K. Keesee, Oklahoma City, Oklahoma, and James K. Hotchkiss, Chicago, Illinois; to acquire 19.6 percent of the voting shares of Banks of MidAmerica, Inc., Oklahoma City, Oklahoma, and thereby indirectly acquire Liberty National Bank & Trust Company, Oklahoma City, Oklahoma, and First National Bank & Trust Company of Tulsa, Tulsa, Oklahoma.

F. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. *Jack W. Schuler,* Lake Bluff, Illinois; to acquire 9.91 percent of the voting shares of USA Bancshares, Inc., Dallas, Texas, and thereby indirectly acquire The First National Bank of Anna, Anna, Texas, Howe State Bank, Howe, Texas, and Plano East National Bank, Plano, Texas.

2. *Jerry C. Smith,* Azle, Texas; to acquire 3.61 percent of the voting shares of Azle Bancorp. Azle, Texas, and thereby indirectly acquire Azle State Bank, Azle, Texas.

G. Federal Reserve Bank of San Francisco (Harry W. Green, Vice President) 101 Market Street, San Francisco, California 94105:

1. *Terry W. Giles,* Santa Ana, California; to acquire 100 percent of the voting shares of Merchant House, Santa Ana, California, and PNB Financial Group, Santa Ana, California, and thereby indirectly acquire Pacific National Bank, Newport Beach, California.

Board of Governors of the Federal Reserve System, December 6, 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89-28946 Filed 12-11-89; 8:45 am]

BILLING CODE 6210-01-M

Colonial Banc Corp., et al.; Applications to Engage de novo in Permissible Nonbanking Activities

The companies listed in this notice have filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 3, 1990.

A. **Federal Reserve Bank of Cleveland** (John J. Wixted, Jr., Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. *Colonial Banc Corp.*, Eaton, Ohio; to engage *de novo* through its subsidiary, Financial Services, Inc., Eaton, Ohio, in retail tax preparation services pursuant to section 225.25(b)(21) of the Board's Regulation Y.

B. **Federal Reserve Bank of Richmond** (Lloyd W. Bostain, Jr., Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. *CB&T Financial Corp.*, Fairmont, West Virginia; to engage *de novo* through its subsidiary CB&T Investor Services, Inc., Fairmont, West Virginia, in the business of effecting transactions in securities for the accounts of others and in connection therewith to engage in all activities and to take all action which are lawful for a corporation organized under the laws of the State of West Viginia whether expressed or implied permitted by statute or otherwise including but not limited to performaing all act coverned generally by the denomination broker, dealer, or broker-dealer pursuant to § 225.25(b)(15) of the Board's Regulations Y.

Board of Governors of the Federal Reserve System, December 6,1989.

Jennifer J. Johnnson,

Associate Secretary of the Board.

[FR Doc. 89-28947 Filed 12-11-89; 8:45 am]

[FR Doc. 89-28947 Filed 12-11-89; 8:45 am]
BILLING CODE 6210-01-M

First Virginia Banks, Inc., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than December 29, 1989.

A. **Federal Reserve Bank of Richmond** (Lloyd W. Bostian, Jr., Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. *First Virginia Banks, Inc.*, Falls Church, Virginia; to acquire 100 percent of the voting shares of Clifton Trust Bank, Cockeysville, Maryland.

B. **Federal Reserve Bank of Atlanta** (Robert E. Heck, Vice President) 100 Marietta Street, NW., Atlanta, Georgia 30303:

1. *Community National Bancorporation*, Ashburn, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of Community National Bank, Ashburn, Georgia, a *de novo* bank.

2. *First National Financial Corporation*, Albany, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of First National Bank of South Georgia, Albany, Georgia, a *de novo* bank.

C. **Federal Reserve Bank of St. Louis** (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *Union Planters Corporation*, Memphis, Tennessee; to acquire 100 percent of the voting shares of North Arkansas Bancshares, Inc., Jonesboro, Arkansas, and thereby indirectly acquire The Bank of Rector, Rector, Arkansas; Searcy County Bank, Marshall, Arkansas; First State Bank of Newport, Newport, Arkansas; Security National Bank, Sidney, Arkansas; Peoples National Bank, Mammoth Spring, Arkansas; and Mercantile Bank, Jonesboro, Arkansas.

D. **Federal Reserve Bank of Minneapolis** (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *Border Bancshares, Inc.*, Greenbush, Minnesota; to become a bank holding company by acquiring 84.83 percent of the voting shares of Badger State Bank, Badger, Minnesota.

Board of Governors of the Federal Reserve System, December 6, 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89-28948 Filed 12-11-89; 8:45 am]

BILLING CODE 6210-01-M

First Citizens Banc Corp., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the

application has been accepted for proceeding, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than December 29, 1989.

A. **Federal Reserve Bank of Cleveland** (John J. Wixted, Jr., Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. *First Citizens Banc Corp.,* Sandusky, Ohio; to acquire 100 percent of the voting shares of The Castalia Banking Company, Sandusky, Ohio.

B. **Federal Reserve Bank of Richmond** (Lloyd W. Bostian, Jr., Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. *Bancshares 2000, Inc.,* McLean, Virginia; to acquire 100 percent of the voting shares of Jefferson Bank and Trust Company, Greenbelt, Maryland.

C. **Federal Reserve Bank of Chicago,** (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Great River Bancshares, Inc.,* Quincy, Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of The Hill-Dodge Banking Company, Warsaw, Illinois.

2. *Durand Bancorp, Inc.,* Durand Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of Durand State Bank, Durand, Illinois.

D. **Federal Reserve Bank of St. Louis,** (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *Planters & Merchants Bancshares, Inc.,* Gillett, Arkansas; to become a bank holding company by acquiring Planters & Merchants Bank, Gillett, Arkansas.

Board of Governors of the Federal Reserve System, December 6, 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89-28949 Filed 12-11-89; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cadco, Inc.; Withdrawal of Approval of NADA's

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of three new animal drug applications (NADA's) held by Cadco, Inc. One NADA provides for use of a tylosin Type A article for making Type C swine, beef cattle, and chicken feeds, the second for use of a tylosin-sulfamethazine Type A article for making Type C swine feeds, and the third for use of a hygromycin B Type A article for making Type C swine feeds. The firm requested the withdrawal of approval of the NADA's.

EFFECTIVE DATE: December 22, 1989.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4093.

SUPPLEMENTARY INFORMATION: Cadco, Inc., P.O. Box 3599, 10100 Douglas Ave., Des Moines, IA 50322, is the sponsor of the following NADA's:

NADA 91-783, originally approved by letter of December 12, 1972, for use of a tylosin Type A medicated article to make Type C medicated swine, beef cattle, and chicken feeds;

NADA 99-561, originally approved February 9, 1976 (41 FR 5632), for use of a tylosin-sulfamethazine Type A medicated article to make Type C medicated swine feeds;

NADA 109-635, originally approved April 10, 1981 (46 FR 21364), for use of a hygromycin B Type A medicated article to make Type C medicated swine feeds.

By letter of February 29, 1988, the sponsor requested the withdrawal of approval of NADA's 91-783 and 99-561 because it manufactures and markets these medicated articles only at levels which no longer require approved NADA's. By letter of February 4, 1988, the sponsor requested the withdrawal of approval of NADA 109-635 because it is no longer manufacturing or distributing the product.

Therefore, under section 512(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(e)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 Withdrawal of approval of applications (21 CFR 514.115), notice is given that approval of NADA's 91-783, 99-561, and 109-635 and all supplements thereto is hereby withdrawn, effective December 22, 1989.

In a final rule published elsewhere in this issue of the **Federal Register,** FDA is amending 21 CFR 558.274 (a)(2) and (c)(1), 21 CFR 558.625(b)(4), and 21 CFR 558.630(b)(10) to reflect withdrawal of the approvals.

Dated: December 6, 1989.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 89-28958 Filed 12-11-89; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 89D-0420]

Langostinos—Frozen, Cooked—Adulteration by Bacteriological Contamination; Compliance Policy Guide; Revocation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of Compliance Policy Guide (CPG) 7108.09 "Langostinos—Frozen, Cooked—Adulteration by Bacteriological Contamination" dated October 1, 1980.

FOR FURTHER INFORMATION CONTACT: Mischelle B. Ledet, Division of Compliance Policy (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1500.

SUPPLEMENTARY INFORMATION: CPG 7108.09 provided guidance to FDA field offices regarding the initiation, without the need for further scientific review by the agency's Center for Food Safety and Applied Nutrition (CFSAN), of regulatory action involving frozen, cooked langostinos contaminated with certain microorganisms at specified levels. Based on a recent review of data, some of the microbiological criteria referenced in the CPG will require revision.

In order to avoid the initiation of regulatory actions based on outdated criteria, FDA has revoked CPG 7108.09. FDA field offices will make recommendations for regulatory actions involving langostinos adulterated by bacterial contamination to CFSAN.

Dated: December 4, 1989.

Alan L. Hoeting,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 89-28898 Filed 12-11-89; 8:45 am]

BILLING CODE 4160-01-M

Consumer Participation; Open Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following district consumer exchange meeting: BOSTON DISTRICT OFFICE, chaired by Edward J. McDonnell, District Director. The topic to be discussed is food labeling.

DATES: Thursday, January 4, 1990, 10 a.m. to 11:30 a.m.

ADDRESSES: Food and Drug Administration, One Montvale Ave., Stoneham, MA 02180.

FOR FURTHER INFORMATION CONTACT: Paula Fairfield, Consumer Affairs Officer, Food and Drug Administration, One Montvale Ave., Stoneham, MA 02180, 617-279-1479.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's district offices, and to contribute to the agency's policymaking decisions on vital issues.

Dated: December 6, 1989.

Alan L. Hoeting,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 89-28960 Filed 12-11-89; 8:45 am]

BILLING CODE 4160-01-M

Public Health Service

Privacy Act of 1974; New System of Records

AGENCY: Public Health Service, HHS.

ACTION: Notification of a new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act, the Public Health Service (PHS) is publishing a notice of a new system of records 09-15-0055, "Organ Procurement and Transplantation Network (OPTN) Data System." Routine uses for this new system also are proposed.

DATE: PHS invites interested parties to submit comments on the proposed routine uses on or before January 11, 1990. PHS has sent a Report of a New System of Records to Congress and the Office of Management and Budget (OMB) on November 30, 1989. The new system of records will be effective 60 days from the date submitted to OMB, unless PHS receives comments which would result in a contrary determination.

ADDRESS: Please address comments to the HRSA Privacy Act Coordinator, Department of Health and Human Services, Parklawn Building, Room 14A-20, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-3760. This is not a toll-free number. Comments received will be available for public inspection at the above address during normal business hours 8:30 a.m.-5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Mr. Remy Aronoff, Chief, Operations and Analysis Branch, Division of Organ Transplantation, Bureau of Maternal and Child Health and Resources Development, Parklawn Building, Room 9-A-22, 5600 Fisher Lane, Rockville, Maryland 20857, telephone (301) 443-7577. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: The Bureau of Maternal and Child Health and Resources Development (BMCHRD), Health Resources and Services Administration (HRSA), proposes to establish a new system of records for the purpose of: (1) Matching donor organs with recipients; (2) monitoring compliance of member organizations with membership requirements of the Organ Procurement and Transplantation Network (OPTN); (3) reviewing and reporting periodically on the status of organ donation and transplantation in the United States; and (4) assisting the Health Care Financing Administration (HCFA) in evaluating its financial support of organ transplantation.

A. The Department of Health and Human Services (HHS) through a contract with the United Network for Organ Sharing (UNOS) will establish a data bank to collect and disseminate demographic and medical information concerning: (1) Organ donors; (2) transplant candidates; and (3) transplant recipients.

The data bank will be maintained by: United Network for Organ Sharing, Suite 500, 1100 Boulders Parkway, P.O. Box 13770, Richmond, Virginia 23225, (804) 330-8500.

The contractor will be required to maintain Privacy Act safeguards with respect to this records system.

Definitions in this system notice:

The term "donor" includes any person from whom an organ or organs has been taken for the purpose of transplantation.

The term "recipient" includes any person in whom an organ has been transplanted, or a person who is a candidate for organ transplantation.

The term "organ" includes kidneys, livers, pancreas, hearts, heart/lungs and lungs.

The term "transplant center" includes any hospital that transplants kidneys, livers, pancreas, hearts, heart/lungs, or lungs.

B. The Privacy Act permits disclosure of information without the consent of the subject individual for "routine uses," that is, disclosure for a purpose compatible with the purpose for which the data is collected. Accordingly, routine uses for information in this system of records have been established.

The first routine use will permit HRSA, through the contractor, to disclose records regarding organ donors, organ transplant candidates, and organ transplant recipients to transplant centers, histocompatibility laboratories, and organ procurement organizations. These records consist of Social Security numbers, other patient identification information, and pertinent medical information.

The second routine use provides for disclosure to the Department of Justice should the Department become a defendant in litigation to enable the Department to present an effective defense.

The third routine use is proposed to allow subject individuals to obtain assistance from their representative in Congress, should they so desire.

C. Safeguards have been established to insure that no unauthorized personnel have access to this information. The safeguards in the notice have been prepared to reflect the minimum safeguards which HRSA and the contractor will maintain. Safeguards will be periodically reviewed by the Project Officer, ADP System Security Officer, and the Contractor to assure the confidentiality and security of the data is strictly enforced.

This notice is written in the present rather than the future tense to avoid the expenditure of public funds to republish the notice after the system has become effective.

Dated: December 5, 1989.

Wilford J. Forbush,

Deputy Assistant Secretary for Health Operations and Director, Office of Management.

09-15-0055

SYSTEM NAME:

Organ Procurement and Transplantation Network (OPTN) Data System, HHS/HRSA/BMCHRD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

United Network for Organ Sharing (UNOS), Suite 500, 1100 Boulders Parkway, P.O. Box 13770, Richmond, Virginia 23225.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Persons from whom organs have been obtained for transplantation, persons who are candidates for organ transplantation, and persons who have been recipients of transplanted organs.

CATEGORIES OF RECORDS IN THE SYSTEM:

Donor registration and histocompatibility forms, transplant recipient registration and histocompatibility forms, and transplant recipient follow-up forms. Data items include: Name, Social Security number (voluntary), identifiers assigned by OPTN contractors, hospital and hospital provider number, city and State, race/ethnicity, date and time of organ recovery and transplantation, name of transplant center, histocompatibility status, patient condition before and after transplantation, immunosuppressive medication, and cause of death (if appropriate).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 274 requires that the Secretary, by contract, provide for the establishement and operation of an OPTN, and 42 U.S.C. 274a requires that the Secretary, by grant or contract, develop and maintain a Scientific Registry of the recipient of organ transplants.

PURPOSE(S):

The purpose of the system is to: (1) Match donor organs with recipients; (2) monitor compliance of member organizations with membership requirements of the OPTN; (3) review and report periodically on the status of organ donation and transplantation in the United States; and (4) assist the Health Care Financing Administration (HCFA) in evaluating their financial support of organ transplantation.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OR USERS AND THE PURPOSES OF SUCH USES:

1. The Health Resources and Services Administration, through its contractor, may disclose records regarding organ donors, organ transplant candidates, and organ transplant recipients to transplant centers, histocompatibility laboratories, and organ procurement organizations. These records consist of Social Security numbers, other patient identification information and pertinent medical information.

2. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to effect directly the operation of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Department of Justice has agreed to represent such employee, for example, in defending a claim against the Public Health Service in connection with such individual, disclosure may be made to the Department of Justice to enable the Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

3. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in file folders, magnetic tapes, and disc packs.

RETRIEVABILITY:

The following three identifier levels will be used:

(1) Name; (2) Social Security number (if available), and (3) transplant center and date of transplant.

SAFEGUARDS:

1. Authorized Users: Access is limited to authorized Bureau of Maternal and Child Health and Resources Development and contract personnel responsible for administering the program. Authorized personnel include the System Manager and Project Officer, and the HRSA Automated Information System (AIS) Systems Security Officer; and the contractor's employees and officials, computer personnel, and program managers who have responsibilities for implementing the program. Both HRSA and the contractor shall maintain current lists of authorized users.

2. Physical Safeguards: Magnetic tapes, disc packs, computer equipment, and hard copy files are stored in areas where fire and life safety codes are strictly enforced. All automated and nonautomated documents are protected on a 24-hour basis in locked storage areas. Security guards perform random checks on the physical security of the records storage area. The contractor is required to maintain offsite a complete copy of the system and all necessary files to run the computer organ donor-recipient match and update software.

3. Procedural Safeguards: A password is required to access the terminal and a data set name controls the release of data to only authorized users. All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. All authorized users must sign a nondisclosure statement.

Access to records is limited to those staff members trained in accordance with the Privacy Act and Automated Data Processing (ADP) security procedures. The contractor is required to assure that the confidentiality safeguards of these records will be employed and that it complies with all provisions of the Privacy Act. All individuals who have access to these records must have the appropriate ADP security clearances. Privacy Act and ADP system security requirements are included in the contract. The BMCHRD Project Officer and the System Manager oversee compliance with these requirements. The HRSA authorized users will make site visits to the contractor's facilities to assure security and Privacy Act compliance.

RETENTION AND DISPOSAL:

Each record shall be retained for 25 years beyond the known death of the organ recipient.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Operations and Analysis Branch, Division of Organ Transplantation, Bureau of Maternal and Child Health and Resources Development, Room 9-A-31, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

NOTIFICATION PROCEDURES:

1. Request by mail: To determine if a record about you exists, write to the contractor operating the bank (see

SYSTEM LOCATION). The request should contain the name and address of the individual; the Social Security number if the individual chooses to provide it; the name of his/her transplant center, a written statement that the requester is the person he/she claims to be and that he/she understands that the request or acquisition of records pertaining to another individual under false pretenses is a criminal offense subject to a $5,000 fine.

2. Request in person: The individual must meet all the requirements stated above for a request by mail, providing the information in written form. The individual should recognize that in order to maintain confidentiality, and thus the accuracy of data released through repeated internal verification, securing the information by request in person will be time consuming.

3. Request by telephone: Since positive identification of the caller cannot be established, telephone requests are not honored.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requestors should also provide a reasonable description of the record being sought. Requestors also may request an accounting of disclosures that have been made of their records, if any.

A parent or guardian who requests notification of, or access to, a minor's/incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the minor/incompetent person as well as his/her own identity.

CONTESTING RECORD PROCEDURES:

Contact the official at the address specified under notification procedure above and reasonably identify the record, specify the information being contested, and the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Organ procurement organizations, histocompatibility laboratories, and organ transplant centers.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE PRIVACY ACT:

None.

[FR Doc. 89-28955 Filed 12-11-89; 8:45 am]
BILLING CODE 4160-15-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID-050-00-4212; IDI-20595]

Suspension of Competitive Sale of Public Lands in Blaine County, ID

AGENCY: Bureau of Land Management, Interior.

ACTION: Sale Suspension Notice—The public land sale scheduled to be held at the BLM Shoshone District Office in Shoshone, Idaho at 10:00 a.m., Friday, December 15, 1989, is hereby suspended until further notice.

SUMMARY: A Notice of Realty Action for the subject sale was published in the **Federal Register**, Vol. 54, No. 202, on Friday, October 20, 1989, page 43144. Based on issues raised in a protest to the sale, a decision has been made to suspend the sale until these issues are resolved.

SUPPLEMENTARY INFORMATION: Contact the Monument Resource Area Manager or the Staff Realty Specialist at: BLM Shoshone District Office, 400 West F Street, P.O. Box 2-B, Shoshone, ID 83352, or telephone at (208) 886-2206.

John H. Idso,

Associate District Manager.

[FR Doc. 89-29002 Filed 12-11-89; 8:45 am]
BILLING CODE 4310-66-M

[MTM78518; MT-20-00-4212-13]

Realty Action—Exchange; Montana

AGENCY: Bureau of Land Management, Miles City District Office, Interior.

ACTION: Notice of Realty Action MTM-78518. Exchange of public lands in Big Horn County, Montana, for private land in Powder River and Big Horn Counties, Montana.

SUMMARY: The following described lands have been determined to be suitable for disposal by exchange under Section 206 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1716.

Principal Meridian, Montana

T. 8 S., R. 43 E.,
Sec. 17, N½SW¼;
Sec. 25, S½N½;
Sec. 26, SE¼NE¼;
Sec. 28, NW¼NE¼; SW¼NW¼, NW¼SW¼;
Sec. 29, N½NE¼, SE¼NE¼;
Sec. 33, SW¼NE¼.
T. 8 S., R. 44 E.,
Sec. 19, Lots 5, and 8;
Sec. 30, Lots 19, and 20;
Sec. 31, Lots 5, 6, 15, and 16;
T. 9 S., R. 44 E.,
Sec. 2, NE¼SE¼;
Sec. 6, Lots 1, 2, and 8 to 18, Incl, W½SE¼;
Sec. 7, Lots 15, 16, 19, and 20, S½SE¼;
Sec. 8, SW¼;
Sec. 9, S½SE¼;
Sec. 18, NE¼NE¼.

Aggregating 1878.12 acres of public land

The United States will exchange these lands with Charles F. Conley and L. C. Fowler to acquire the following described lands from the proponents:

Principal Meridan, Montana

T. 9 S., R. 44 E.,
Sec. 11, W½SW¼;
Sec. 13, W½E½, W½;
Sec. 14, W½SE¼;
Sec. 15, N½, SE¼;
Sec. 22, N½NE¼;
Sec. 23, N½N½;
Sec. 24, NW¼NW¼.

The United States will also acquire an exclusive road easement, 60 feet by 8814.18 feet crossing the following private lands:

Principal Meridian, Montana

T. 9 S., R. 44 E.,
Sec. 12, S½NE¼, E½SW¼, NW¼SE¼.
T. 9 S., R. 45 E.,
Sec. 7, Lot 1, Lot 2, NE¼NW¼.

Aggregating 12.14 acres of private land.

DATES: For a period of 45 days from the date of this notice, interested parties may submit comments to the Bureau of Land Management at the address shown below. Any adverse comments will be evaluated by the BLM Montana State Director who may sustain, vacate or modify this realty action. In the absence of any objections, this realty action will become the final determination of the Department of the Interior.

FOR FURTHER INFORMATION CONTACT: Information related to the exchange, including the environmental assessment and land report is available for review at the Miles City District, Powder River Resource Area Office, Miles City Plaza, Miles City, Montana 59301.

SUPPLEMENTARY INFORMATION: The publication of this notice segregates the public lands described above from settlement, sale, location, and entry under the public land laws, including the mining laws, but not from exchange pursuant to section 206 of the Federal Land Policy and Management Act of 1976 for a period of 2 years from the date of first publication. The exchange will be made subject to:

1. A reservation to the United States of a right-of-way for ditches or canals in accordance with 43 U.S.C. 945.

2. The reservation to the United States of all minerals.

3. All valid existing rights for the following rights-of-way of record:

Sheridan-Johnson REA, MTM–29576, and Big Horn County, MTM–61090.

4. Value equalization by cash payment of $800.00 will be paid to Charles F. Conley by the United States of America.

5. The following reservation in the patents: "By purchase (exchange) of this land, the owner, pursuant to Section 714 of the Surface Mining Control and Reclamation Act, 30 U.S.C. 1304, gives "surface owner" consent to the United States and its lessees to enter and commence surface mining operations to extract the United States reserved coal.

6. The two-year notifications to grazing lessees were received October 3, 1989, and October 11, 1989, in accordance with 43 CFR 4110.4–2(b).

This exchange is consistent with Bureau of Land Management policies and the Powder River RMP/EIS and has been discussed with state and local officials. The estimated intended time of the exchange is March 1990.

The public interest will be served by completion of this exchange because it will enable the Bureau of Land Management to acquire lands with high public values, and will increase management efficiency of public lands in the area.

Dated: December 5, 1989.

Janet L. Edmonds,

Acting District Manager.

[FR Doc. 89–28987 Filed 12–11–89; 8:45 am]

BILLING CODE 4310–ON–M

[NV–930–00–4214–11; Nev–045161, Nev–051663]

Proposed Continuation of Withdrawals; Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration proposes that the withdrawals comprising 283 acres for two air navigation sites be continued for an additional 20 years. The lands will remain closed to surface entry and mining. The lands will be opened to mineral leasing.

DATE: Comments should be received by (90 days from publication date).

ADDRESS: Comments should be sent to: Chief, Branch of Lands and Minerals Operations, Bureau of Land Management, P.O. Box 12000, Reno, Nevada 89520.

FOR FURTHER INFORMATION CONTACT: Vienna Wolder, Nevada State Office, 702–328–6326.

The Federal Aviation Administration proposes that the existing land withdrawals made by Public Land Orders 1905 and 2142 be modified and continued for a period of 20 years pursuant to 204 of the Federal Land Policy and Management Act of 1976, 90 Stat. 2751, 43 U.S.C. 1714. The land is described as follows:

Mount Diablo Meridian

T. 3 N., R. 43 E.,
Sec. 19, SE¼NE¼, NE¼SE¼;
Sec. 20, SW¼NW¼, NW¼SW¼.
T. 2 N., R. 44 E.,
Sec. 15, NW¼.

The area described aggregates 283 acres in Nye County.

The withdrawals were established for air navigation site facilities and are used for that purpose. The withdrawals segregate the land from operation of the public land laws generally, including the mining and mining leasing laws. A change is proposed to reduce the segregative effect of the withdrawals by opening the lands to application under the mineral leasing laws. Mineral leases will not be approved without the concurrence of the Federal Aviation Administration.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments in connection with the proposed continuation of the withdrawals may present their views in writing to the Chief, Branch of Lands and Minerals Operations, in the Nevada State Office. The authorized officer of the Bureau of Land Management will undertake such investigations as are necessary to determine the existing and potential demand for the land and its resources. A report will also be prepared for consideration by the Secretary of the Interior, the President, and Congress, who will determine whether or not the withdrawals will be continued and if so, for how long. The final determination on the continuation of the withdrawals will be published in the Federal Register. The existing withdrawals will continue until such final determination is made.

Edward F. Spang,

State Director, Nevada.

[FR Doc. 89–28988 Filed 12–11–89; 8:45 am]

BILLING CODE 4310–HC–M

Office of Surface Mining Reclamation and Enforcement

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). Copies of the proposed collection of information and related form may be obained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the proposal should be made directly to the bureau clearance officer and to the Office of Management and Budget, Paperwork Reduction Project (1029–0047), Washington, DC 20503, telephone 202–395–7340.

Title: Permanent Program Performance Standards—Surface Mining Activities, 30 CFR part 816.

OMB approval number: 1029–0047.

Abstract: Section 515 of the Surface Mining Control and Reclamation Act of 1977 provides that permittees conducting surface coal mining operations shall meet all applicable performance standards of the Act. The information collected is used by the regulatory authority in monitoring and inspecting surface coal mining activities to ensure that they are conducted in compliance with the requirements of the Act.

Bureau form number: None.

Frequency: On occasion, quarterly, and annually.

Description of respondents: Surface coal mining operators.

Estimated Completion Time: 1 hour.

Annual Responses: 786,156.

Annual Burden Hours: 666,058.

Bureau clearance officer: Andrew F. DeVito 202–343–5954.

Dated: November 14, 1989.

Annetta L. Cheek,

Chief, Regulatory Development and Issues Management.

[FR Doc. 89–28962 Filed 12–11–89; 8:45 am]

BILLING CODE 4310–05–M

Request for Determination of Valid Existing Rights Within the Monongahela National Forest

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of request for determination and invitation for interested persons to participate.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) has received a request for a determination that Walter D. Helmick has valid existing rights (VER) to surface mine coal on Federal lands within the Monongahela National Forest in Pocahontas County, West Virginia. By this notice, OSM is inviting interested persons to participate in the proceeding

and to submit relevant factual material on the matter. OSM intends to develop a complete Administrative Record, and will render a final agency decision on whether Walter D. Helmick has VER.

DATES: OSM will accept written materials on this request for a VER determination until 5 p.m. local time January 26, 1990.

ADDRESSES: Hand deliver or mail written materials to Carl C. Close, Assistant Director, Eastern Field Operations at the address listed below. Documents contained in the Administrative Record are available for public review at the locations listed below during normal business hours, Monday through Friday, excluding holidays.

Office of Surface Mining Reclamation and Enforcement, Eastern Field Operations, Room 246, Ten Parkway Center, Pittsburgh, PA 15220, Telephone: (412) 937-2897.

Office of Surface Mining Reclamation and Enforcement, Charleston Field Office, 603 Moris Street, Charleston, WV 25301, Telephone: (304) 347-7158.

SUPPLEMENTARY INFORMATION: Section 522(e) of SMCRA prohibits surface coal mining operations in certain areas, subject to VER and except for those operations which existed on August 3, 1977. Under section 522(e)(2), the prohibition is applied to any Federal lands within the boundaries of any national forest unless the Secretary of the Interior finds that there are no significant recreational, timber, economic or other values that may be incompatible with such surface coal mining operations and the surface operation and impacts are incident to an underground coal mine. National forest land west of the 100th meridian that does not have significant forest cover as determined by the Secretary of Agriculture may be surface coal mined.

The term "VER" is not defined in SMCRA. On September 14, 1983 (48 FR 41312-41356), OSM adopted a regulatory definition of VER at 30 CFR 761.5 which defined VER as those rights, which if affected by the prohibitions in section 522(e), would entitle the owner to payment of just compensation under the fifth and fourteenth amendments to the United States Constitution, the so-called "takings" test.

On March 22, 1985, the United States District Court for the District of Columbia held that the promulgation of the VER definition in 30 CFR 761.5 violated the Administrative Procedure Act and remanded the definition to the Secretary of the Interior ((*In Re: Permanent Surface Mining Regulation Litigation II*, No. 79-1144).

In the November 20, 1986 **Federal Register** (51 FR 41952), OSM suspended the Federal definition of VER insofar as it incorporates a takings test. OSM announced that during the period of suspension it would make VER determinations on Federal lands within the boundaries of national forests using the VER definition contained in the appropriate State regulatory program.

The term VER is defined in section 2.126 of the West Virginia Surface Mining Reclamation Regulations. Section 2.126 provides that VER exists, except for haulroads, in each case in which a person demonstrates that the limitation provided for in section A-3-22(d) of the West Virginia Surface Coal Mining and Reclamation Act would result in the unconstitutional taking of that person's rights.

By letter dated June 24, 1988, Walter D. Helmick requested that OSM make a determination of VER for his planned surface coal mining operation on Federal lands within the Monongahela National Forest in the Little Levels District of Pocahontas County, West Virginia. Mr. Helmick alleges that he owns mineral rights on two adjacent tracts of land, the surface of which is owned by the United States of America and managed by the United States Forest Service. Tract 574 contains 1,045.3 acres and is situated seven miles west of Hillsboro, West Virginia on the waters of Hills Creek and the waters of Robins Run, a tributary of Spring Creek. The second tract, known as the Killingsworth Tract, contains 179 acres and is situated on the headwaters of Spruce Run, a tributary of the Greenbrier River. Both properties are located on Briery Knob.

In order to establish that the requester has VER for surface coal mining on the property in question, OSM must first determine that the requester has demonstrated all necessary rights to mine the coal. OSM particularly invites interested persons to provide factual information as to whether the requester has the property right to mine by the proposed method, and other factual information concerning whether the requester has VER under the applicable standards.

OSM will make a final decision on Walter D. Helmick's VER request as soon as it is practicable following completion of the Administrative Record. If OSM determines that Walter D. Helmick has VER, the West Virginia Department of Energy may issue a permit to Mr. Helmick authorizing the surface mining of coal on the two tracts in question. If it is determined that Mr. Helmick does not have VER, no permit can be issued.

Dated: November 29, 1989.

Carl C. Close,

Assistant Director, Eastern Field Operations.

[FR Doc. 89-28971 Filed 12-11-89; 8:45 am]

BILLING CODE 4310-05-M

National Park Service

National Register of Historic Places: Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before December 2, 1989. Pursuant to § 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be fowarded to the National Register, National Park Service, P.O. Box 37127, Washington, DC 20013-7127. Written comments should be submitted by December 27, 1989.

Carol D. Shull,

Chief of Registration, National Register.

FLORIDA

Brevard County

Pritchard House (Titusville MPS), 424 S. Washington Ave., Titusville, 89002167

Robbins, Judge George, House (Titusville MPS), 703 Indian River Ave., Titusville, 89002168

Spell House (Titusville MPS), 1200 Riverside Dr., Titusville, 89002166

Titusville Commercial District (Titusville MPS), Roughly bounded by Julia St., Hopkins Ave., Main St., and Indian River Ave., Titusville, 89002164

Wager House (Titusville MPS), 631 Indian River Ave., Titusville, 89002165

Hillsborough County

House at 131 West Davis Boulevard (Mediterranean Revival Style Buildings of Davis Islands MPS), 131 W. Davis Blvd., Tampa, 89002161

KANSAS

Anderson County

Spencer's Crossing Bridge (Metal Truss Bridges in Kansas 1861-1939 MPS), Over Pottawatomie Creek, NW of Greeley, Greeley vicinity, 89002177

Barton County

Walnut Creek Bridge (Metal Truss Bridges in Kansas 1861-1939 MPS), Over Walnut Creek, NW of Heizer, Heizer vicinity, 89002178

Bourbon County

Long Shoals Bridge (Metal Truss Bridges in Kansas 1861-1939 MPS), Over Little Osaga River, E of Fulton, Fulton vicinity, 89002182

Chautauqua County

Otter Creek Bridge (Metal Truss Bridges in Kansas 1861-1939 MPS), FSA 95 over Otter

Creek, 3.0 mi. N of Cedar Vale, Cedar Vale vicinity, 89002189

Cloud County

County Line Bowstring (Metal Truss Bridges in Kansas 1861–1939 MPS), Over West Creek, NW of Hollis, Hollis vicinity, 89002192

Pott's Ford Bridge (Metal Truss Bridges in Kansas 1861–1939 MPS), Over Solomon River, SE of Glasco, Glasco vicinity, 89002173

Republican River Pegran Truss (Metal Truss Bridges in Kansas 1861–1939 MPS), Rt. 795 over the Republican River, Concordia vicinity, 89002190

Crawford County

Little Walnut Creek Bowstring (Metal Truss Bridges in Kansas 1861–1939 MPS), Over Little Walnut Creek, NE of Walnut, Walnut vicinity, 89002174

Dickinson County

Asylum Bridge (Metal Truss Bridges in Kansas 1861—1939 MPS), First St. over Marais des Cygnes, Osawatomie vicinity, 89002187

Doniphan County

Doniphan County Waddell (Metal Truss Bridges in Kansas 1861—1939 MPS), FAS 28, 1.7 mi. NE of Doniphan, Doniphan vicinity, 89002185

Ford County

West Sappa Creek Lattice (Metal Truss Bridges in Kansas 1861—1939 MPS), NW of Morton over West Sappa Creek, Norton vicinity, 89002191

Grant County

Jack Creek Kingpost (Metal Truss Bridges in Kansas 1861—1939 MPS), SE of Long Island, Long Island vicinity, 89002188

Jefferson County

Jefferson Old Town Bowstring Truss (Metal Truss Bridges in Kansas 1861—1939 MPS), Off US 59, Oskaloosa vicinity, 89002186

Meriden Rock Creek Bridge (Metal Truss Bridges in Kansas 1861—1939 MPS), KS 4 at jct. with FAS 1328, NE of Meriden, Meriden vicinity, 89002183

Miami County

Carey's Ford Bridge (Metal Truss Bridges in Kansas 1861—1939 MPS), Over Marais des Cygnes River, E of Osawatomie, Osawatomie vicinity, 89002179

Washington County Kingpost (Metal Truss Bridges in Kansas 1861—1939 MPS), SE of Barnes, Barnes vicinity, 89002184

Montgomery County

Independence Bowstring (Metal Truss Bridges in Kansas 1861—1939 MPS), Over the Verdigris River, M of jct. of Burns and Myrtle Sts., Independence, 89002180

Onion Creek Bridge (Metal Truss Bridges in Kansas 1861—1939 MPS), Over Onion Creek, S. of Coffeyville, Coffeyville vicinity, 89002172

Morris County

Four Mile Creek Lattice (Metal Truss Bridges in Kansas 1861—1939 MPS), Over Four Mile Creek, SE of Wilsey, Wilsey vicinity, 89002181

Republic County

East Riley Creek Bridge (Metal Truss Bridges in Kansas 1861—1939 MPS), Over East Riley Creek, S of Belleville, Belleville vicinity, 89002176

Riley Creek Bridge (Metal Truss Bridges in Kansas 1861—1939 MPS), Over Riley Creek, S of Belleville, Belleville vicinity, 89002175

MASSACHUSETTS

Suffolk County

St. Joseph's Roman Catholic Church Complex, Bounded by Circuit, Regent, Hulbert, and Fenwick Sts., Boston, 89002169

MONTANA

Custer County

East Main Street Residential Historic District, 1600—2315 E. Main St., Miles City, 89002171

Wibaux County

Wibaux Commercial Historic District, Roughly bounded by W. Orgain Ave., Wibaux, E. First Ave. S., and E, Wibaux, 89002170

NEBRASKA

Arthur County

First Arthur County Courthouse and Jail (County Courthouses of Nebraska MPS), Marshall St. between Fir and Elm Sts., Arthur, 89002241

Box Butte County

Box Butte County Courthouse (County Courthouse of Nebraska MPS), Box Butte Ave. between E. 5th and 6th Sts., Alliance, 89002212

Burt County

Burt County Courthouse (County Courthouses of Nebraska MPS), 13th St. between M and N Sts., Tekamah, 89002223

Cass County

Cass County Courthouse (County Courthouses of Nebraska MPS), Main St. between 3rd and 4th Sts., Plattsmouth, 89002248

Cedar County

Cedar County Courthouse (County Courthouses of Nebraska MPS), Broadway Ave. between Centre and Franklin Sts., Hartington, 89002214

Chase County

Chase County Courthouse (County Courthouses of Nebraska MPS), Broadway between 9th and 10th Sts., Imperial, 89002222

Cherry County

Cherry County Courthouse (County Courthouses of Nebraska MPS), 4th and Main Sts., Valentine, 89002229

Clay County

Clay County Courthouse (County Courthouses of Nebraska MPS), Fairfield St. between Alexander and Brown Aves., Clay Center, 89002240

Custer County

First Custer County Courthouse (County Courthouses of Nebraska MPS), Pacific St. and Cameron Ave., Callaway, 89002213

Dawson County

Dawson County Courthouse (County Courthouses of Nebraska MPS), Washington St. between 7th and 8th Sts., Lexington, 89002236

Deuel County

Deuel County Courthouse (County Courthouses of Nebraska MPS), 718 3rd St., Chappell, 89002239

Dixon County

Dixon County Courthouse (County Courthouses of Nebraska MPS), 3rd and Iowa Sts., Ponca, 89002247

Dodge County

Dodge County Courthouse (County Courthouses of Nebraska MPS), 435 N. Park Ave., Fremont, 89002208

Dundy County

Dundy County Courthouse (County Courthouses of Nebraska MPS), W. 7th Ave. and Chief St., Benkelman, 89002237

Gage County

Gage County Courthouse (County Courthouses of Nebraska MPS), 612 Grant St., Beatrice, 89002226

Garden County

Garden County Courthouse (County Courthouses of Nebraska MPS), F and Main Sts., Oshkosh, 89002231

Greeley County

Greeley County Courthouse (County Courthouses of Nebraska MPS), Kildare St., Greeley, 89002228

Hooker County

Hooker County Courthouse (County Courthouses of Nebraska MPS), Cleveland Ave. between Railroad and 1st Sts., Mullen, 89002218

Howard County

Howard County Courthouse (County Courthouses of Nebraska MPS), Indiana St. between 6th and 7th Sts., St. Paul, 89002233

Johnson County

Johnson County Courthouse (County Courthouses of Nebraska MPS), Courthouse Sq., Tecumseh, 89002246

Kearney County

Kearney County Courthouse (County Courthouses of Nebraska MPS), 5th St. between Colorado and Minden Aves., Minden, 89002234

Lincoln County

Lincoln County Courthouse (County Courthouses of Nebraska MPS), Dewey St. between 3rd and 4th Sts., North Platte, 89002224

Merrick County

Merrick County Courthouse (County Courthouses of Nebraska MPS), 18th St. between 15th and 16th Aves., Central City, 89002211

Morrill County

Morrill County Courthouse (County Courthouses of Nebraska MPS), M St. between 5th and 6th Sts., Bridgeport, 89002227

Nemaha County

Nemaha County Courthouse (County Courthouses of Nebraska MPS), 1824 N St., Auburn, 89002243

Nuckolls County

Nuckolls County Courthouse (County Courthouses of Nebraska MPS), 150 S. Main St., Nelson, 89002219

Pawnee County

Pawnee County Courthouse (County Courthouses of Nebraska MPS), 625 6th St., Pawnee City, 89002232

Phelps County

Phelps County Courthouse (County Courthouses of Nebraska MPS), 5th Ave. between East and West Aves., Holdrege, 89002242

Platte County

Platte County Courthouse (County Courthouses of Nebraska MPS), 2610 14th St., Columbus, 89002217

Polk County

Polk County Courthouse (County Courthouses of Nebraska MPS), Courthouse Sq., Osceola, 89002238

Saunders County

Saunders County Courthouse (County Courthouses of Nebraska MPS), Chestnut between 4th and 5th Sts., Wahoo, 89002220

Scotts Bluff County

Scotts Bluff County Courthouse (County Courthouses of Nebraska MPS), 10th and Q Sts., Gering, 89002230

Seward County

Seward County Courthouse (County Courthouses of Nebraska MPS), Seward between 5th and 6th Sts., Seward, 89002245

Sheridan County

Sheridan County Courthouse (County Courthouses of Nebraska MPS), 2nd and Sprague Sts., Rushville, 89002216

Sherman County

Sherman County Courthouse (County Courthouses of Nebraska MPS), 630 O St., Loup City, 89002225

Thurston County

First Thurston County Courthouse (County Courthouses of Nebraska MPS), 400–412 Main St., Pender, 89002210

Thurston County Courthouse (County Courthouses of Nebraska MPS), Main St. between 5th and 6th Sts., Pender, 89002209

Valley County

Valley County Courthouse (County Courthouses of Nebraska MPS), 16th St. between L and M Sts., Ord, 89002235

Washington County

Washington County Courthouse (County Courthouses of Nebraska MPS), 16th St. between Colfax and South Sts., Blair, 89002221

Wheeler County

Wheeler County Courthouse, Former (County Courthouses of Nebraska MPS), Maine St. between 2nd and 3rd Sts., Bartlett, 89002215

NEW JERSEY

Mercer County

Penns Neck Baptist Church, U.S. 1 at Princeton—Hightstown Rd., Penns Neck, 89002160

Middlesex County

Kingston Village Historic District, Roughly NJ 27 from Raymond Rd. to Delaware & Raritan Canal, Church st., Laurel Ave., Heathcote Brook Rd., & Academy St., Kingston, 89002163

Monmouth County

Wurts, George, Summer Home, 306 Eighth Ave., Asbury Park, 89002162

OKLAHOMA

Washington County

Civic Center, Johnstone Ave. between 6th St. and Adams Blvd., Bartlesville, 89002122

[FR Doc. 89–28939 Filed 12–11–89; 8:45 am]

BILLING CODE 4310-70-M

INTERSTATE COMMERCE COMMISSION

[Docket No. AB–290 (Sub-No. 78X)]

Southern Railway Co.—Abandonment Exemption—In Henry County, VA

Applicant has filed a notice of exemption under 49 CFR 1152 subpart F—Exempt Abandonments to abandon its 6.1-mile line of railroad between mileposts 30.0–DW and 36.1–DW, at or near Axton, Henry County, VA.

Applicant has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) any overhead traffic on the line can be rerouted over other lines; and (3) no formal complaint filed by a user of rail service on the line (or a State or local government entity acting on the behalf of such user) regarding cessation of service over the line either is pending with the Commission or with any U.S. District Court or has been decided in favor of the complainant within the 2-year period. The appropriate State agency has been notified in writing at least 10 days prior to the filing of this notice.

As a condition to use of this exemption, any employee affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10505(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance has been received, this exemption will be effective on January 11, 1990 (unless stayed pending reconsideration). Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an offer of financial assistance under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking statements under 49 CFR 1152.29 must be filed by December 22, 1989.[3] Petitions for reconsideration or requests for public use conditions under 49 CFR 1152.28 must be filed by January 3, 1990, with: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any petition filed with the Commission should be sent to applicant's representative: Roger A. Petersen, Norfolk Southern Corporation, Three Commercial Place, Norfolk, VA 23510.

If the notice of exemption contains false or misleading information, use of the exemption is *ab initio*.

Applicant has filed an environmental report which addresses environmental or energy impacts, if any, from this abandonment.

The Section of Energy and Environment (SEE) will prepare an environmental assessment (EA). SEE will issue the EA by December 15, 1989. Interested persons may obtain a copy of the EA from SEE by writing to it (Room 3219, Interstate Commerce Commission, Washington, DC 20423) or by calling Elaine Kaiser, Chief, SEE at (202) 275–7684. Comments on environmental and energy concerns must be filed within 15

[1] A stay will be routinely issued by the Commission in those proceedings where an informed decision on environmental issues (whether raised by a party or by the Secretary of Energy and Environment in its independent investigation) cannot be made prior to the effective date of the notice of exception. *See Exemption of Out-of-Service Rail Lines*, 5 I.C.C.2d 377 (1989). Any entity seeking a stay involving environmental concerns is encouraged to file its request as soon as possible in order to permit this Commission to review and act on the request before the effective date of this exemption.

[2] *See Exempt. of Rail Abandonment—Offers of Finan. Assist.*, 4 I.C.C.2d 164 (1987).

[3] The Commission will accept a late-filed trail use statement so long as it retains jurisdiction to do so.

days after the EA becomes available to the public.

Environmental, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Decided: December 6, 1989.

By the Commission, Jane F. Mackall, Director, Office of Proceedings.

Noreta R. McGee,

Secretary.

[FR Doc. 89-28990 Filed 12-11-89; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-23, 172]

Associated Materials, Inc.; Alside Division Cuyahoga Falls, OH; Negative Determination Regarding Application for Reconsideration

By an application dated October 16, 1989, the United Steelworkers requested administrative reconsideration of the subject petition for trade adjustment assistance. The denial notice was signed on September 19, 1989 and published in the Federal Register on October 3, 1989 (54 FR 40755).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previousy considered; or

(3) If, in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The union claims that imported vinyl siding has increased its market share at the expense of metal siding and indicates that Alside intends to import products that were formerly made at Cuyahoga Falls.

Investigation findings show that Alside does not import metal siding (aluminum and steel) nor does it intend to import such products. All future needs for metal siding will be met by another company with plants in Chicago and New Jersey. Although vinyl siding was not made at Cuyahoga Falls, this product will continue to be made at other plants of the subject firm. The findings further show that the number of housing starts decreased in 1987 compared to 1986 and in 1988 compared to 1987 and is forecasted to decrease even further in 1989 compared to 1988.

With respect to raw materials, within the meaning of the Trade Act of 1974, only increased imports of articles like or directly competitive with the articles produced by the workers' firm can be considered. Accordingly, raw materials used in the production of a finished article cannot be considered as finished articles (metal siding). This issue was addressed in *United Shoe Workers of America, AFL-CIO* v. *Bedell,* 506 F2d 174, (D.C. Cir. 1974). The court held that imported finished women's shoes were not like or directly competitive with shoe components—shoe counters.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, DC, this 30th day of November 1989.

Robert O. Deslongchamps,

Director, Office of Legislation and Actuarial Services, UIS.

[FR Doc. 89-28978 Filed 12-11-89; 8:45 am]

BILLING CODE 4310-30-M

[TA-W-23,230]

Harnischfeger Corp.; Cedar Rapids, IA; Negative Determination Regarding Application for Reconsideration

By an application dated November 1, 1989 Local # 1316 of the United Auto Workers (UAW) requested administrative reconsideration of the subject petition for trade adjustment assistance. The denial notice was signed on October 3, 1989 and published in the Federal Register on October 31, 1989 (54 FR 45812).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If, in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The UAW requests that the Department re-instate its earlier certification for the Clear Rapids workers TA-W-17,694. It is also claimed that the Department's negative decision contradicts information on the data collection form submitted by the company.

First, Departmental certifications run for two years unless terminated earlier and the worker group cannot be recertified unless it files a new petition. Two denials have been issued by the Department for the Cedar Rapids worker group since the Department's last certification (TA-W-17,694) which expired on November 20, 1988. Workers at Cedar Rapids were denied eligibility on March 22, 1989 (TA-W-22,451) because no production workers were separated after the expiration of TA-W-17,694. Workers were also denied under (TA-W-23,230) because company imports declined in 1988 compared to 1987 and in the first seven months of 1989 compared to the same period in 1988.

Although the Cedar Rapids plant was sold to another domestic firm on April 30, 1988, the production of cranes continued until July 1989 under an agreement with the new owner. Sales and production of cranes increased in 1988 compared to 1987 and in the first seven months of 1989 compared to the same period in 1988. The sale of the Cedar Rapids plant and the transfer of its production to another domestic firm would not form a basis for certification.

Also, the allegation that the Federal Government forced Harnischfeger to sell its Cedar Rapids plant would not form a basis for certification. In order for a worker group to be certified eligible to apply for adjustment assistance, it must meet all three of the Group Eligibility Requirements of the Trade Act of 1974—a signficiant decline in employment; an absolute decline in production and/or sales and an increase in imports of articles like or directly competitive with those produced by the workers' firm which "contributed importantly" to worker separations.

The data collection form contains no information which would support a worker group certification. Also, personal assurances, in themselves, would not support a certification.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, DC, this 29th day of November 1989.

Dated:

Robert O. Deslongchamps,

Director, Office of Legislation and Actuarial Services, UIS.

[FR Doc. 89-28979 Filed 12-11-89; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-23,229]

Honeywell, Inc. Colorado Springs, Co; Negative Determination Regarding Application for Reconsideration

By an application dated October 20, 1989, the petitioners requested administrative reconsideration of the subject petition for trade adjustment assistance. The denial notice was signed on October 3, 1989 and published in the **Federal Register** on October 31, 1989 (54 FR 45812).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances;.

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If, in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The petitioners claim that Honeywell lost production and sales to at least two foreign customers which had semi-conductor component work performed at foreign locations. It is also claimed that packaging facilities in Mexico and Taiwan had an adverse employment effect at Colorado Springs. The petitioners also claim that there was an adverse employment effect when one of Honeywell's customers went out of business, supposedly because of foreign competition.

The Department's denial was based on the fact that the contributed importantly test of the Group Eligibility Requirements of the Trade Act was not met. The Department's survey showed that the major customers who represented a majority of the subject firm's sales decline in 1988 and in the first eight months of 1989 did not import semi-conductors. Also, the findings show a large share of Honeywell's Colorado Springs' semi-conductor production went internally to other Honeywell plants. Workers at Colorado Springs producing components for other company plants can be certified if their separation was caused importantly by a reduced demand for their production from affiliated production facilities whose workers independently meet the statutory criteria for certification. These conditions were not met for workers of Honeywell's Colorado Springs plant since none of Honeywell's other plants had workers certified for adjustment assistance.

Foreign customers shifting a part of their purchases to foreign manufacturers would not form a basis for certification. Only increased U.S. imports adversely affecting employment, production or sales would form such a basis.

The fact that a domestic customer went out of business supposedly because of foreign competition would not form a basis for certification. That customer purchased semi-conductors from Honeywell as components for its super-conductors. However, under the Trade Act of 1974, only increased imports of articles like or directly competitive with the articles produced by the workers' firm can be considered. Semi-conductors are not like or directly competitive with super-computers. The issue of components and finished articles was addressed in *United Shoe Workers of America, AFL-CIO* v. *Bedell*, 506 F2d 174, (D.C. Cir. 1974). The court held that imported finished women's shoes were not like or directly competitive with shoe components—shoe counters. Similarly, semi-conductors are not like or directly competitive with super-computers.

Lastly, investigation findings show that there were no layoffs during the period applicable to the petition as a result of overseas packaging. The Mexican facility packaged items never packed at Colorado Springs. The Taiwan facility was brought in as an outside contractor because the Colorado Springs facility ran out of packaging capacity.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, DC, this 30th day of November 1989.

Robert O. Deslongchamps,

Director, Office of Legislation and Actuarial Services, UIS.

[FR Doc. 89-28980 Filed 12-11-89; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-23, 299]

Miami Extruders, Miami, FL; Determinations Regarding Eligibility to Apply for Worker Adjustment Assistance; Correction

This notice corrects the petition number from TA-W-23,347 to TA-W-23,299 on the negative determination issued on October 31, 1989 for workers of Miami Extruders, Miami, Florida and published in the **Federal Register** on November 15, 1989 on page 47587 of FR Document 89-26806.

Under Negative Determinations, in column 3 line 51 on page 47587 the petition number is corrected to read "TA-W-23, 299" instead of TA-W-23, 347.

Signed at Washington, DC, this 30th day of November 1989.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 89-28981 Filed 12-11-89; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-23, 347]

Pony Industries, Inc., Miami Extruders Division, Miami, FL; Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated in response to a worker petition filed on behalf of workers of Miami Extruders Division of Pony Industries, Incorporated, Miami, Florida.

A negative determination applicable to the petitioning group of workers was issued on October 31, 1989 (TA-W-23, 299). No new information is evident which would result in a reversal of the Department's previous determination. Consequently, further investigation in this case would serve no purpose; and the investigation has been terminated.

Signed at Washington, DC, this 30th day of November 1989.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 89-28982 Filed 12-11-89; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-23, 398]

Revelations Shoe Corp., Exeter, PA; Certification Regarding Eligibility To Apply for Worker Adjustment Assistance; Correction

This notice corrects the impact date from September 7, 1988 to June 2, 1989 on the subject certification published on

November 28, 1989 in the **Federal Register** on page 48954 of FR Document 89-27871.

Under Affirmative Determinations, in column 3 line 8 on page 48954 the impact date is corrected to read "June 2, 1989" instead of September 7, 1988.

Signed at Washington, DC, this 30th day of November 1989.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 89-28983 Filed 12-11-89; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-21, 145; TA-W-21, 145A; TA-W-21, 145B]

Transit America, Inc.; Philadelphia, PA, Chicago, IL, New York, NY; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on November 18, 1988 applicable to all workers of Transit America, Inc., Philadelphia, Pennsylvania.

Based on new information from the company, several workers were retained for warranty work and retrofit programs on railcars in Chicago, Illinois and New York, New York. The amended notice applicable to TA-W-21, 145 is hereby issued as follows:

"All workers of Transit America, Incorporated, Philadelphia, Pennsylvania, Chicago, Illinois and New York, New York who became totally or partially separated from employment on or after September 19, 1988 are eligible to apply for adjustment assistance under section 222 of the Trade Act of 1974.

Signed at Washington, DC, this 1st day of December 1989.

Barbara Ann Farmer,

Director, Office of Program Management, UIS.

[FR Doc. 89-28984 Filed 12-11-89; 8:45 am]

BILLING CODE 4510-30-M

Occupational Safety and Health Administration

Oregon State Standards; Notice of Approval

1. *Background.* Part 1953 of title 29, Code of Federal Regulations, prescribes procedures under section 18 of the Occupational Safety and Health Act of 1970 (hereinafter called the Act) by which the Regional Administrator for Occupational Safety and Health (hereinafter called Regional Administrator) under a delegation of authority from the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter called the Assistant Secretary) (29 CFR 1953.4) will review and approve standards promulgated pursuant to a state plan which has been approved in accordance with section 18(c) of the Act and 29 CFR part 1902. On December 28, 1972, notice was published in the **Federal Register** (37 FR 28628) of the approval of the Oregon plan and the adoption of Subpart D to Part 1952 containing the decision. The Oregon plan provides for adoption of Federal standards as State standards by reference.

In response to Federal standards changes, the state has submitted by letter dated May 3, 1989 from John A. Pompei, Administrator, to James W. Lake, Regional Administrator, and incorporated as part of the plan, state standard amendments comparable to: 29 CFR part 1926, Subpart Q—Concrete and Masonry Construction Safety Standards, Final Rule, as published in the **Federal Register** (53 FR 22643) on June 16, 1988; 29 CFR 1926.550(g). Subsequently, by letter dated September 13, 1989 from John Pompei, Administrator, to James W. Lake, Regional Administrator, the same amendments were resubmitted as permanent standards. The state's temporary rules pertaining to Concrete and Masonry Construction were contained in OAR 437, Division 3. They were adopted by reference on an emergency basis on March 31, 1989 and became effective May 1, 1989 pursuant to ORS 654.025(2), ORS 656.726(3), and ORS 183.335, as ordered and transmitted under Oregon APD Administrative Order 5-1989. Concurrently, state rules contained in Division 83, Construction, were repealed by the same Administrative Order. Subsequently, the state adopted by reference and effective July 7, 1989, permanent rules, pursuant to ORS 654.025(2), ORS 656.726(3), and ORS 183.335, as ordered and transmitted under Oregon APD Administrative Order 8-1989.

On April 18, 1989, the state mailed the Notice of Emergency Adoption of Rules and the Proposed Permanent Amendment of Rules to those on the Department of Insurance and Finance mailing list, established pursuant to OAR 436-01-000 and to those on the Department's distribution list as their interest appeared. A public hearing was not held for the emergency adoption of the state's rules. On April 26, 1989 and May 5, 1989, the state mailed the Notice of the Proposed Permanent Amendment of Rules to those on the Department of Insurance and Finance mailing list as their interest appeared. The state's notifications failed to elicit a request for public hearing.

In response to federal standards changes, the state has submitted by letter dated November 29, 1988 from John A. Pompei, Administrator, to James W. Lake, Regional Administrator, and incorporated as part of the plan, a state standard amendment comparable to 29 CFR 1910.1047, Occupational Exposure to Ethylene Oxide, Final Rule, as published in the **Federal Register** 53 FR 11437 on April 6, 1988. The state's rules pertaining to Ethylene Oxide, contained in OAR 437-02-360(26), were adopted by reference and became effective on November 17, 1988, pursuant to ORS 654.025(2), ORS 656.726(3), and ORS 183.335, as ordered and transmitted under Oregon APD Administrative Order 18-1988. Concurrently, equivalent state rules contained in Division 156, which pertained to Ethylene Oxide, were repealed by the same Administrative Order. On October 5, 1988, the state mailed the Notice of Proposed Rules to those on the Department of Insurance and Finance mailing list, established pursuant to OAR 436-01-000 and to those on the Department's distribution list as their interest appeared. No requests for a public hearing were received.

In response to federal standards changes, the state has submitted by letter dated September 15, 1989 from John A. Pompei, Administrator, to James W. Lake, Regional Administrator, and incorporated as part of the plan, state standard amendments comparable to: 29 CFR 1926.800, Underground Construction, Final Rule, as published in the **Federal Register** (54 FR 23824) on June 2, 1989. The state's rules pertaining to Underground Construction are contained in OAR 437, Division 3. They were adopted by reference and effective September 13, 1989, pursuant to ORS 654.025(2), 656.756(3), and ORS 183.335, as ordered and transmitted under Oregon APD Administrative Order 15-1989. The state's rules replace the Emergency Temporary Standards previously approved in the **Federal Register** at 54 FR 38300 dated September 15, 1989. On August 10, 1989, the state mailed the Notice of the Proposed Permanent Amendment of Rules to those on the Department of Insurance and Finance mailing list as their interest appeared. The state's notifications failed to elicit a request for public hearing.

2. *Decision.* Having reviewed the state's submissions in comparison with the federal standards, it has been determined that the state's standards

are identical to the federal stai OSHA, therefore, approves these standards.

3. *Location of supplement for inspection and copying.* A copy of the standards supplement, along with the approved plan, may be inspected and copied during normal business hours at the following locations: Office of the Regional Administrator, Occupational Safety and Health Administration, Room 6003, Federal Office Building, 909 First Avenue, Seattle, Washington 98174; Department of Insurance and Finance, Labor and Industries Building, Salem, Oregon 97310; and the Office of State Programs, Occupational Safety and Health Administration, Room N-3476, 200 Constitution Ave NW., Washington DC 20210.

4. *Public participation.* Under 29 CFR 1953.2(c), the Assistant Secretary may prescribe alternative procedures to expedite the review process or for other good cause which may be consistent with applicable laws. The Assistant Secretary finds that good cause exists for not publishing the supplement to the Oregon State plan as a proposed change and making the Regional Administrator's approval effective upon publication for the following reasons:

1. The standard amendments are identical to the federal standards which were promulgated in accordance with federal law including meeting requirements for public participation.

2. The standard amendments were adopted in accordance with the procedural requirements of state law and further participation would be unnecessary.

This decision is effective December 12, 1989.

Authority: Sec. 18, Pub. L. 91-596, 84 STAT. 6108 (29 U.S.C. 667).

Signed at Seattle, Washington this 29th day of September, 1989.

James W. Lake,

Regional Administrator.

[FR Doc. 89-28985 Filed 12-11-89; 8:45 am]

BILLING CODE 4510-26-M

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Records Schedules; Availability and Request for Comments

AGENCY: Office of Records Administration, NARA.

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Records schedules identify records of sufficient value to warrant preservation in the National Archives of the United States. Schedules also authorize agencies after a specified period to dispose of records lacking administrative, legal, research, or other value. Notice is published for records schedules that (1) propose the destruction of records not previously authorized for disposal, or (2) reduce the retention period for records already authorized for disposal. NARA invites public comments of such schedules, as required by 44 USC 3303a(a).

DATE: Requests for copies must be received in writing on or before January 26, 1990. Once the appraisal of the records is completed, NARA will send a copy of the schedule. The requester will be given 30 days to submit comments.

ADDRESS: Address requests for single copies of schedules identified in this notice to the Records Appraisal and Disposition Division (NIR), National Archives and Records Administration, Washington, DC 20408. Requesters must cite the control number assigned to each schedule when requesting a copy. The control number appears in parentheses immediately after the name of the requesting agency.

SUPPLEMENTARY INFORMATION: Each year U.S. Government agencies create billions of records on paper, film, magnetic tape, and other media. In order to control this accumulation, agency records managers prepare records schedules specifying when the agency no longer needs the records and what happens to the records after this period. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. These comprehensive schedules provide for the eventual transfer to the National Archives of historically valuable records and authorize the disposal of all other records. Most schedules, however, cover records of only one office or program or a few series of records, and many are updates of previously approved schedules. Such schedules also may include records that are designated for permanent retention.

Destruction of records requires the approval of the Archivist of the United States. This approval is granted after a thorough study of the records that takes into account their administrative use by the agency of origin, the rights and interests of the Government and of private persons directly affected by the Government's activities, and historical or other value.

This public notice identifies the Federal agencies and their subdivisions requesting disposition authority, includes the control number assigned to each schedule, and briefly describes the records proposed for disposal. The records schedule contains additional information about the records and their disposition. Further information about the disposition process will be furnished to each requester.

Schedules Pending:

1. Department of the Air Force (N1-AFU-90-9). Routine personnel records relating to Air National Guard Employees.

2. Defense Logistics Agency (N1-361-89-2). Routine records relating to the Defense National Stockpile Center.

3. Department of Commerce, Office of the Secretary (N1-40-89-1). Invitation and appointments records.

4. Department of Commerce, National Oceanic and Atmospheric Administration (N1-370-87-1). Records relating to the creation and administration of the Monitor Marine Sanctuary.

5. Department of State, Bureau of Public Affairs (N1-59-89-29). Miscellaneous routine and facilitative records.

6. Tennessee Valley Authority, Office of the Inspector General (N1-142-89-5). Background records created and used in the drafting of policy directives and semiannual reports to Congress.

7. Tennessee Valley Authority, Purchasing Function (N1-142-89-15). Routine procurement files to be retained for a period other than specified by the General Records Schedules.

8. Tennessee Valley Authority, Power Function (N1-142-89-23). Solar Pond Project test data and photographic print enlargements (transparencies taken of the project have been appraised as having sufficient archival value to warrant permanent retention by the National Archives).

9. Tennessee Valley Authority, Human Resources (N1-142-90-1). Records documenting nuclear safety for activities other than power generation.

Dated: December 6, 1989.

Don W. Wilson,

Archivist of the United States.

[FR Doc. 89-28989 Filed 12-11-89; 8:45 am]

BILLING CODE 7515-01-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 89-84]

NASA Advisory Council (NAC), Aeronautics Advisory Committee (AAC); Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, as amended, the National Aeronautics and Space Administration announces a forthcoming meeting of the NASA Advisory Council, Aeronautics Advisory Committee, Ad Hoc Review Team on Advanced Cockpit Technology.

DATES: January 8, 1990, 8:30 a.m. to 5 p.m.; January 9, 1990, 8:30 a.m. to 5 p.m.; and January 10, 1990, 8 a.m. to 12 noon.

ADDRESSES: National Aeronautics and Space Administration, Langley Research Center, Building 1218, Room 107, Hampton, VA 23365.

FOR FURTHER INFORMATION CONTACT: Mr. Ray Hood, Office of Aeronautics and Space Technology, National Aeronautics and Space Administration, Washington, DC 20546, 202/453-2745.

SUPPLEMENTARY INFORMATION: The NAC Aeronautics Advisory Committee (AAC) was established to provide overall guidance to the Office of Aeronautics and Space Technology (OAST) on aeronautics research and technology activities. Special ad hoc review teams are formed to address specific topics. The Ad Hoc Review Team on Advanced Cockpit Technology, chaired by Dr. John K. Lauber, is comprised of eight members.

The meeting will be closed to the public from 8:30 a.m. to 5 p.m. on January 9 for discussion of matters which are likely to disclose trade secrets and commercial or financial information obtained from a person, and are privileged or confidential. Since this discussion will be concerned with matters listed in 5 U.S.C. 552b(c)(4), it has been determined that the meeting be closed to the public for this period of time. The remainder of the meeting will be open to the public up to the seating capacity of the room (approximately 20 persons including the team members and other participants).

Type of Meeting: Open—except for a closed session as noted in the agenda below.

Agenda:

January 8, 1990
8:30 a.m.—Opening Remarks.
9 a.m.—Current Langley Research Center Cockpit Technology Thrusts.
11 a.m.—Facility Tour.
1 p.m.—Future Cockpit Technology Research.
2 p.m.—Facility Tour.
3 p.m.—Group Discussion.
5 p.m.—Adjourn.

January 9, 1990
8:30 a.m.—Closed Session.
5 p.m.—Adjourn.

January 10, 1990
8 a.m.—Interim Report Preparation.
12 noon—Adjourn.

Dated: December 4, 1989.

John W. Gaff,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 89-28943 Filed 12-11-89; 8:45 am]

BILLING CODE 7510-01-M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards Subcommittee on Containment Systems; Postponed

The ACRS Subcommittee meeting on Containment Systems scheduled for December 12, 1989 has been postponed to January 10, 1990, Room P-110, 7920 Norfolk Avenue, Bethesda, MD. The notice of this meeting was previously published in the **Federal Register** on Tuesday, December 5, 1989 (54 FR 50294).

Dated: December 6, 1989.

Sam Duraiswamy,

Acting Chief, Project Review Branch No. 2.

[FR Doc. 89-28969 Filed 12-11-89; 8:45 am]

BILLING CODE 7590-01-M

NRC Committee To Review the Severe Accident Risks Report; Meeting

The NRC Committee to Review the Severe Accident Risks Report (NUREG-1150) will hold its third meeting on January 18 and 19, 1990 at the Hyatt Regency Hotel, 1 Bethesda Metro Center, Bethesda, Maryland. Notice of the establishment of this Committee was published in the **Federal Register** on June 21, 1989. [54 FR 26124].

The purpose of this Special Committee is to provide the NRC with a technical peer review of the adequacy of the methods, insights, analyses and conclusions set forth in the April 1989 draft of NUREG-1150 and, in addition, to provide answers to particular questions posed by the Commission and set forth in the referenced **Federal Register** notice.

The entire meeting will be open to the public. Any member of the public wishing to file a written statement with the Committee may send the statement to Mr. Charles B. Bartlett, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

The meeting participants will be the Committee members and the NRC and Contractor staff.

The following topics will be discussed:

(1) An in-depth review of the seismic inputs to the study including the two different seismic hazards distributions used and the effects of the use of these two distributions traced through the analysis.

(2) A review of the significant differences (and rationale) between the first and second drafts of NUREG-1150 particularly with respect to the probabilities and characteristics of the modes of early containment failures.

(3) A detailed discussion of the high pressure melt ejection scenario including:

—The conclusions of the individual experts with respect to probabilities
—The data base used to evaluate the major determining features of the early melt scenario
—the method of factoring in key experimental results into the analysis

(4) A discussion of how the probability of early containment failure and related risk estimates could be affected by the inclusion of pressure vessel failure in the analysis.

(5) A review of the modeling uncertainties in Human Reliability Analysis and the significance of the results of the ISPRA benchmark exercise.

(6) An explanation of how the value of $2X10^{-2}$ for failure to initiate the Standby Liquid Control was derived from the BNL analysis of the Peachbottom ATWS sequence, the uncertainty distribution that was used and its derivation.

(7) A review and discussion of the major issues associated with each reactor analyzed as revealed by analysis of dominate accident sequences.

Further information regarding this meeting can be obtained by calling Mr. Charles B. Bartlett (telephone 301-492-3604).

Dated: December 6, 1989.

John C. Hoyle,

Advisory Committee Management Officer.

[FR Doc. 89-28950 Filed 12-11-89; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-293, et al.*]

Boston Edison Co., et al.*; (Pilgrim Nuclear Power Station, et al.)*; Issuance of Director's Decision Under 10 CFR 2.206

Notice is hereby given that the Director, Office of Nuclear Reactor Regulation (NRR), has issued a Director's Decision concerning a Petition dated March 8, 1989, filed by Ms. Anna Harlowe, Issues Coordinator, on behalf of the Ecology Center of Southern California. The Petition asked the Director, NRR, to take action to relieve what the Petitioner alleged to be undue risks to the public health and safety posed by the containment design of boiling water reactors (BWRs), as revealed by various NRC staff members' statements, published studies, and by the 1975 General Electric "Reed Report." The specific relief requested was to order all BWR licensees to "fix" or close all BWR reactors. Ms. Harlowe gave as grounds for the Petition that (1) in 1972, a member of the NRC staff recommended that GE-designed reactors be banned in the United States; (2) in 1975, GE engineers generated the "Reed Report" that detailed dozens of safety and economic problems with GE-designed reactors and recommended that GE stop selling those reactors; (3) in 1986, an NRC official admitted that 24 GE reactors with Mark I containments had a 90 percent chance of failure in a nuclear accident; (4) in 1987, an NRC task force confirmed that Mark I containments were virtually certain to fail in an accident; (5) according to NRC safety studies, Mark II reactors have many possible scenarios for early containment failures; and (6) Mark II designs, on which the Reed Report focused, have dozens of safety and economic problems and have suffered massive cost overruns during construction as a result of design problems.

On June 5, 1989, the Director, NRR, acknowledged receipt of the Petition. He informed Ms. Harlowe that (1) Petition would be treated under 10 CFR 2.206 of the Commission's regulations, and (2) appropriate action would be taken within a reasonable time.

The Director has now determined that Ms. Harlowe's requests should be denied for the reasons set forth in the "Director's Decision Pursuant to 10 CFR 2.206" (DD-89-9). The Decision is available for inspection and copying in the Commission's Public Document Room, Gelman Building, 2120 L Street NW., Washington, DC 20555, and at the Local Public Document Rooms near the facilities listed below. The addresses and hours of operations for the local public document rooms may be obtained by calling the following toll-free number: 1-800-638-8081.

A copy of the Decision has been filed with the Secretary of the Commission for the Commission's review in accordance with 10 CFR 2.206(c). As provided in 10 CFR 2.206(c), the Decision will become the final action of the Commission twenty-five (25) days after issuance unless the Commission on its own motion institutes review of the Decision within that time.

Dated at Rockville, Maryland, this 4th of December 1989.

For the Nuclear Regulatory Commission.

Thomas E. Murley,

Director, Office of Nuclear Reactor Regulation.

*Carolina Power & Light Co. (Brunswick Steam Electric Plant, Units 1 and 2, Docket Nos. 50-324 and 50-325)
Cleveland Electric Illuminating Co., et al. (Perry Nuclear Power Plant, Unit 1, Docket No. 50-440)
Commonwealth Edison Co. (Dresden Nuclear Power Station, Units 2 and 3, Docket Nos. 50-237 and 50-249), (Quad Cities Station, Units 1 and 2, Docket Nos. 50-254 and 50-265), (LaSalle County Station, Units 1 and 2, Docket Nos. 50-373 and 50-374)
Consumers Power Co. (Big Rock Point Nuclear Plant, Docket No. 50-155) Detroit Edison Co. (Enrico Fermi Atomic Power Plant, Unit 2, Docket No. 50-341)
General Public Utilities (Oyster Creek Nuclear Power Plant, Docket No. 50-219)
Georgia Power Co. (Edwin I. Hatch Nuclear Plant, Units 1 and 2, Docket Nos. 50-321 and 50-366)
Gulf States Utilities Co. (River Bend Station, Docket No. 50-458)
Illinois Power Co. (Clinton Power Station, Docket No. 50-461)
Iowa Electric Light & Power Co. (Duane Arnold Energy Center, Docket No. 50-331)
Long Island Lighting Co. (Shoreham Nuclear Power Station, Docket No. 50-322)
Mississippi Power & Light Co. (Grand Gulf Nuclear Station, Docket No. 50-416)
Nebraska Public Power District (Cooper Nuclear Station, Docket No. 50-298)
Niagara Mohawk Power Corp. (Nine Mile Point Nuclear Station, Units 1 and 2, Docket Nos. 50-220 and 50-410)
Northeast Utilities (Millstone Nuclear Power Station, Docket No. 50-245)
Northern States Power Co. (Monticello Nuclear Generating Plant, Docket No. 50-263
Pennsylvania Power & Light Co. (Susquehanna Steam Electric Station, Units 1 and 2, Docket Nos. 50-387 and 50-388)
Philadelphia Electric Co. (Peach Bottom Atomic Power Station, Units 2 and 3, Docket Nos. 50-277 and 50-278), (Limerick Generating Station, Unit 1, Docket No. 50-352)
Power Authority of the State of New York (James A. Fitzpatrick Nuclear Power Plant, Docket No. 50-333)
Public Service Electric & Gas Co. (Hope Creek Nuclear Station, Docket No. 50-354)
Tennessee Valley Authority (Browns Ferry Nuclear Power Station, Units 1, 2, and 3, Docket Nos. 50-259, 50-260, and 50-296)
Vermont Yankee Nuclear Power Corp. (Vermont Yankee Nuclear Power Station, Docket No. 50-271)
Washington Public Power Supply System (WNP Unit 2, Docket No. 50-397)

[FR Doc. 89-28967 Filed 12-11-89; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-397]

Washington Public Power Supply System; Withdrawal of Application for Amendment to Facility Operating License NPF-21

The United States Nuclear Regulatory Commission (the Commission) has granted the request of the Washington Public Power Supply System (the licensee) to withdraw its March 24, 1989 application to amend the WNP-2 Operating License. The proposed amendment would have revised the License to defer to the end of the fifth refueling outage the implementation of the requirements of Regulatory Guide 1.97, Revision 2 for flux monitoring to "prior to startup following the fifth refueling outage" (Spring 1990). The Commission issued a Notice of Consideration of Issuance of Amendment in the **Federal Register** on April 19, 1989 (54 FR 1580) as corrected in the **Federal Register** on May 16, 1989 (54 FR 21142). By letter dated June 15, 1989 the licensee stated that the March 24, 1989 application for amendment was not needed.

Consequently, the licensee requested that the March 24, 1989 application for amendment be withdrawn.

For further details with respect to this action, see (1) the application for amendment dated March 24, 1989 and (2) the licensee's letter of June 15, 1989 requesting withdrawal of the application. Both of the above documents are available for public inspection at the Commission's Public Document Room, 2120 L Street, NW., Washington, DC and at the Richland City Library, Swift and Northgate Streets, Richland, Washington 99352.

Dated at Rockville, Maryland, this 4th day of December, 1989.

For the Nuclear Regulatory Commission.

Robert B. Samworth,

Project Manager, Project Directorate V, Division of Reactor Projects—III, IV, V and Special Projects.

[FR Doc. 89-28966 Filed 12-11-89; 8:45 am]

BILLING CODE 7590-01-M

OFFICE OF PERSONNEL MANAGEMENT

Establishment of the Director's Task Force on Executive and Management Development

AGENCY: Office of Personnel Management.

ACTION: Notice.

Establishment of a Task Force: This notice is published in accordance with section 9(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463) and advises of the establishment of the Director's Task Force on Executive and Management Development. The Director of the Office of Personnel Management has determined that establishment of this Task Force is in the public interest.

Designation: Director's Task Force on Executive and Management Development.

Purpose: The purpose of the Task Force is to provide an opportunity for a wide spectrum of knowledgable parties to have significant involvement in discussions on, and development of recommendations to improve, the current Federal executive and management development policies and programs for the Director's consideration.

FOR FURTHER INFORMATION CONTACT: The Director of Policy, OPM, is the sponsor of this Task Force. For additional information, contact Ms. Dona Wolf, Director of Policy, Office of the Director, OMP on (202) 632–6106.

Office of Personnel Management.

Dated: December 1, 1989.

Constance Berry Newman,

Director.

[FR Doc. 89–28900 Filed 12–11–89; 8:45 am]

BILLING CODE 6325–01–M

Director's Task Force on Executive and Management Development; Meetings

AGENCY: Office of Personnel Management.

ACTION: Notice of open meetings.

SUMMARY: OPM is holding open meetings concerning possible changes to the Federal policies and programs related to executive and management development. According to provisions of section 10 of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given that meetings of the Director's Task Force on Executive and Management Development will be held on:

DATES: January 10, 1990, 10 a.m. to 12 noon, Office of Personnel Management, Room 1350, 1900 E Street, NW., Washington, DC.

January 24, 1990, 10 a.m. to 12 noon, Office of Personnel Management, Room 1350, 1900 E Street, NW., Washington, DC.

February 7, 1990, 10 a.m. to 12 noon, Office of Personnel Management, Room 1350, 1900 E Street, NW., Washington, DC.

February 14, 1990, 10 a.m. to 12 noon, Office of Personnel Management, Room 1350, 1900 E Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dona Wolf, Director of Policy, Office of the Director, Room 5305, Office of Personnel Management, 1900 E Street, NW., Washington, DC 20415, (202) 632–6106.

SUPPLEMENTARY INFORMATION: Due to time restrictions, public comment will be limited to five minutes for each person or organization who wishes to testify. Written testimony will be accepted until five calendar days after the final meeting. Those wishing to testify before the Task Force must be registered in advance and must submit eight copies of their testimony to Dona Wolf, at the above address, at least seven days before the requested day of testimony. Thirty minutes will be provided for public input at the end of each meeting.

Office of Personnel Management.

Constance Berry Newman,

Director.

[FR Doc. 89–28899 Filed 12–11–89; 8:45 am]

BILLING CODE 6325–01–M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. 34–27497; File No. 4–281]

Joint Industry Plan; Notice of Filing of an Amendment to the Consolidated Quotation Plan to Introduce a New, Consolidated Form of Vendor/Computer Input User Agreement

The participants in the Consolidated Quotation ("CQ") plan on October 16, 1989, submitted an amendment to the CQ plan created pursuant to Rule 11Aa3–1(b)(2) and Rule 11Aa3–2(b) under the Securities Exchange Act of 1934 ("Act").[1]

[1] The participants in the restated CTA plan are the American Stock Exchange ("Amex"), Boston Stock Exchange, Cincinnati Stock Exchange, Midwest Stock Exchange, National Association of Securities Dealers, New York Exchange ("NYSE"), Pacific Stock Exchange, and Philadelphia Stock Exchange.

I. Description of the Amendment

The purpose of the amendment is to implement a new, consolidated form of the vendor/computer input user agreements, which restates and consolidates into one form (the "Consolidated Form") the existing vendor agreements to: (1) Reduce paperwork; simplify and accelerate application processing; facilitate the administration of vendor and computer input agreements; and eliminate duplicative effort; and (2) improve the content of existing vendor agreements and addenda by eliminating provisions redundant of other protections afforded by the Consolidated Form or of statutory and common law protections and by substituting generic requirements for detailed specifications and proscriptions; and by reworking the language in general to make the agreement easier to read and understand.

A. Approach of the Consolidated Form

Section VIII of the plan requires the plan participants to enter into contracts with each vendor and computer input user ("Contracting Party" or "Contracting Parties") to govern the receipt of access to, and use of, last sale or quotation information, as appropriate. Since the adoption of the plan, the participants have fulfilled that obligation by evolving two series of agreement forms: one series for (1) the receipt of last sale and quotation information over the high speed line, (2) the receipt of Network A last sale information over the low speed line and (3) the use of Network A last sale and quotation information; the other for (1) the receipt of Network B last sale information over the low speed line and (2) the use of Network B last sale and quotation information. Contracting Parties receive and use last sale and quotation information for the purposes described in section VIII of the plan pursuant to those agreements ("Existing Vendor Agreements").

Historically, the NYSE and the Amex have specifically tailored each Existing Vendor Agreement to meet the specific services and requirements of each Contracting Party. The evolutionary nature of those agreements, and the need to tailor them on a case-by-case basis, were in large part a function of the ever-changing technologies in the market data community. In creating the Consolidated Form, the participants have taken a different approach.

The objectives of the new approach are: (1) to enable each Contracting Party to satisfy the plan's contract

requirements by entering into only one agreement with the participants for all purposes of the plan and (2) to develop one standard form of agreement that applies for all Contracting Parties, no matter what technologies or means of receipt may be used. As a result, the participants have attempted to create a contract form that addresses all foreseeable contract variables associated with the many aspects of the receipt and use of market data, even though one or more of the Consolidated Form's provisions may not apply in the context of a particular Contracting Party. The participants have used several devices in developing this universal form:

(1) *Exhibit A*—Existing Vendor Agreements already require the Contracting Party to describe the manner in which it receives, uses and safeguards market data in Exhibit A. The Consolidated Form will place greater emphasis on the content of Exhibit A. Contracting Parties will have to include more information and more detailed descriptions so that vendor-specific information will no longer have to be incorporated into the body of the agreement.

(2) *Exhibit B*—The participants recognize that the Consolidated Form cannot anticipate the many new technologies and other developments that are likely to surface. In addition, in the interest of keeping the Consolidated Form to a manageable length, the participants have determined to omit from the body of the Consolidated Form provisions governing certain infrequent uses of market data (*e.g.*, provisions governing public desplays and participant-supplied equipment). Exhibit B affords the participants flexibility by incorporating those unforeseen or less frequently-used provisions into the Consolidated Form on a case-by-case basis.

(3) *Genericization*—The universal nature of the Consolidated Form requires it to take a much more generic approach to the rights and obligations of the Contracting Party. Examples include:

(a) Existing Vendor Agreements allow a wide assortment of third parties to assist Contracting Parties in their receipt and use of market data (*e.g.*, "facilities proprietors," "cablecasters," "switch service suppliers," and "installation contractors"). The Consolidated Form adopts the umbrella concept of a "Service Facilitator" to generically govern the obligations of Contracting Parties in respect of those third parties.

(b) The Consolidated Form moves to Exhibit A all vendor-specific information, such as the services a vendor will provide or the means by which a vendor will receive access to market data (*e.g.*, directly versus indirectly; high speed line versus low speed line). As a result, the body of the Consolidated Form contains only generic references to the manner in which a vendor receives and uses market data.

(c) The Consolidted Form omits specification of the period after which a last sale price becomes a delayed last sale price.

(d) The Consolidated Form governs the receipt and use of multiple types of information. Like its predecessor forms in use over the past few years, the Consolidated Form governs last sale and quotation information disseminated pursuant to the plan, as well as market information furnished by the NYSE and Amex outside of the plan.

(e) The Consolidated Form applies to all types of vendor services: professional subscriber services, nonprofessional subscriber services, limited access services, and, for last sale information, delayed data services. It also applies in a generic way to all other foreseeable permitted uses of market data by a Contracting Party. The information provided in Exhibit A dictates which of the Consolidated Form's provisions governing those services and uses apply in respect of a particular vendor.

B. Administrative Changes

The Consolidated Form also incorporates administrative changes from Existing Vendor Agreements. The use of a generic form necessitates many of these changes. Other changes result from the participants' evaluation of their administrative experiences under Existing Vendor Agreements. The changes include:

(1) *The NYSE as Contract Administrator*—To facilitate the use of a generic form with wide application, to reduce the burden associated with administering market data contracts and to eliminate duplicative efforts, the plans delegate to the NYSE authority to administer contracts on behalf of the Network B participants. Thus, the NYSE will act for the Network B participants in executing the Consolidated Form on behalf of the Network B participants. The delegation of authority is solely ministerial and primarily permits the NYSE to approve one or more uses of market data relating to Network B eligible securities where the NYSE has already approved identical uses of market data relating to Network A eligible securities. In all other respects, Amex continues in its present role as the Network B administrator. The amendments conform the plan to reflect this delegation of authority.

(2) *Recapture of Costs Associated with Non-Compliance*—The Consolidated Form imposes a series of financial consequences relating to the unauthorized or unreported provision or use of market data designed to end subsidy of non-complying recipients by those who comply. The consequences include:

(a) If a Contracting Party makes an unauthorized or unreported provision or use of market data, it must pay any charge payable in respect of that provision or use. In addition, if a professional subscriber, a nonprofessional subscriber and/or any other person receives market data in the chain of dissemination that commenced with the Contracting Party's illicit provision or use, the Contracting Party must pay any charge payable in respect of any unauthorized or unreported provision or use of market data by such subscriber or other person. This provision recasts and replaces a provision found in Existing Vendor Agreements that requires the Contracting Party to indemnify the participants for losses resulting from reporting failures.

(b) The Contracting Party must pay an administrative fee equal to ten percent of the charges described in the preceding paragraph to cover the participants' investigation, processing and collection costs.

(c) The Contracting Party must pay interest on any charge not remitted in a timely manner. The interest rate will be the lesser of (1) one and one-half perccent per month and (2) the maximum rate permitted by law. Existing Vendor Agreements already impose this charge, subject to a maximum for any one year equal to one million dollars, adjusted for inflation since 1983.

The Consolidated Form changes that maximum amount. For each professional subscriber receiving market data as a nonprofessional, the vendor need pay no more than the applicable professional subscriber fees payable for the two preceding years plus the associated administrative and interest charges described above.

(3) *Audit Requirement*—Existing Vendor Agreements require the vendor to provide an audited list of nonprofessional subscribers annually, or more frequently if the participants so request. The Consolidated Form eliminates the mandatory annual audit, but otherwise expands the scope of the audit requirement. Upon request, the Contracting Party must provide an

audited list or report containing such information as the participants may request, whether the request concerns nonprofessional subscribers, professional subscribers or other services.

(4) *Service Facilitators*—The Consolidated Form introduces the term Service Facilitator to replace the assortment of third parties that Existing Vendor Agreements permit to assist the Contracting Party in its receipt or use of market data. The Existing Vendor Agreements impose a variety of obligations on the Contracting Party in respect of those third parties and often require the third party to undertake to comply with the applicable terms and conditions of the agreement. To make the Consolidated Form more generic, the participants have determined to adopt a uniform approach to govern all Service Facilitators.

(a) First, the NYSE, as the contract administrator, must determine whether the third party plays the subsidiary role of a Service Facilitator or has more substantive responsibilities in the data dissemination process (*e.g.*, a partner or joint venturer). If the latter, the NYSE may require the third party to enter into the Consolidated Form, independently of the Contracting Party.

(b) If the NYSE determines a third party to be a Service Facilitator, the Service Facilitator need not undertake in writing to comply with the applicable terms and conditions imposed by the Consolidated Form. Instead, the Consolidated Form requires the Contracting Party to guarantee Service Facilitator's compliance. In addition, the NYSE will require the Contracting Party to cause Exhibit A to adequately describe the Service Facilitator and its functions.

(5) *Access to Records*—Existing Vendor Agreements grant participants the right to have access to, and to audit, the Vendor's nonprofessional subscriber records. In order to improve the participants' ability to monitor compliance, the Consolidated Form expands that right of access to include all relevant records of a Contracting Party.

(6) *Reasonableness Standard*—The Consolidated Form, unlike Existing Vendor Agreements, includes a provision that requires the participants to act in a reasonable manner when acting under the Consolidated Form. While the participants have always acted in a reasonable manner under their agreements, they intend for the explicit reasonableness standard to offer added comfort to Contracting Parties.

C. Deleted Provisions

The Consolidated Form omits a number of provisions found in Existing Vendor Agreements. The omitted provisions include:

(1) *Display Requirements*—The restated CQ plan requires Existing Vendor Agreements to contain the following provisions:

(a) For vendors of last sale information interrogation services, the agreement must require that the interrogation devices have the ability to display the most recent last sale price relating to an eligible security.

(b) For vendors retransmitting a ticker display, the agreement must require the vendor to retransmit all last sale prices without deletions and to refrain from retransmitting unless the participants have first approved the retransmission format.

(c) For quotation information vendors, the agreement must require the vendor to display quotation information in a comprehensive, nondiscriminatory manner that complies with the Act and the rules and regulations thereunder.

(d) For quotation information vendors whose services include devices not capable of displaying quotation size and of indicating that bids and offers are not firm, the agreement must require the vendor to cause such devices to have both capabilities.

(e) The vendor's transmissions must comply with all display rules under the Act and the rules and regulations thereunder.

(f) The vendor's retransmitted ticker display devices must comply with all the NYSE requirements for content, format and timeliness.

Because the Consolidated Form and the plans are, by their terms, subject to the Act and the rules thereunder, and because the relevant provisions of the Act and the rules thereunder are enforceable in and of themselves, the practicipants have omitted the above-listed display requirements from the Consolidated Form as either redundant or no longer necessary. To conform to the plan accordingly, the amendments delete from the plan the requirements described above.

(2) *Regulation of Transmissions*—The Consolidated Form omits a provision requiring the Contracting Party to connect and use transmission equipment and to effect transmissions in accordance with the regulations of the participants, common carriers and relevant public authorities. Instead, the Consolidated Form relies upon the requirement that the equipment be arranged and protected so as to preclude unauthorized access. The participants feel that they can omit the provisions because the rules of public authorities are enforceable without reference to the Consolidated Form.

(3) *Regulation of Vendor's Transmission Facility*—The Consolidated Form omits the several provisions relating to the Contracting Party's facilities. The omitted provisions include:

(a) The Contracting Party may only locate its service equipment and software at premises specifically identified in Exhibit A.

(b) The Contracting Party must control those premises and access to them.

(c) The Contracting Party must prohibit all but specifically identified persons from having access to market data at its premises.

(d) The Contracting Party must comply with and enforce the participants' regulations designed to prevent improper access to market data at its premises.

In some instances, equipment components may be located at so many locations, or may be moved from one location to another at such frequent intervals, that Exhibit A identification of those locations is administratively burdensome and generally unnecessary. Instead, the participants feel that other elements of the Consolidated Form adequately protect against abuses at transmission facilities and computer sites. In particular, the participants will rely on the following:

(a) Exhibit A must describe the transmission facilities and computer sites in detail.

(b) The Consolidated Form contains proscriptions against unauthorized access to market data. (See paragraph 13(a) of the Consolidated Form.)

(4) *Device Requirements*—The Consolidated Form omits a provision prohibiting the vendor from attaching any display device to service equipment and software unless Exhibit A describes the device in detail. Because the participants already require Exhibit A to describe all service equipment, the prohibition is redundant.

(5) *Vendor Modification of Nonprofessional Subscriber Agreements*—The Consolidated Form omits a prohibition against the vendor modifying, or vitiating the terms of, any nonprofessional subscriber's application and agreement. The Consolidated Form requires the vendor to have nonprofessional subscribers sign the appropriate application and agreement(s) or an alternate form approved by the NYSE. The omitted provision would be redundant.

(6) *Competing Data Use*—The Consolidated Form omits a provision specifying that the participants may provide market data to all other parties, including competitors of the Contracting Party. Because the Consolidated Form does not provide for any "exclusive" arrangement, no implication arises that would necessitate that participants reserve the right to provide market data to others. Moreover, the Act makes clear that the participants must provide data to all who seek it and meet the terms of the provision.

(7) *Employee Authority to Act*—The Consolidated Form omits a provision clarifying that an officer, or a person designated by an officer, is authorized to act on behalf of the NYSE or the Amex. By operation of law, an officer would have the authority to act, or to delegate another person to act, on behalf of the NYSE or the Amex for market data contract purposes, even without a specific provision.

D. Provisional Use of Consolidated Form

The participants began provisional use of the Consolidated Form in mid-1988. Since then, the participants have required all new Contracting Parties to enter into it rather than into the Existing Vendor Agreements. Copies of the Consolidated Form executed prior to its final approval contain in Exhibit B a provision specifying that it may be superseded by the ultimate form of agreement.

Since that time, the participants have solicited comments and suggestions from Contacting Parties. In particular, they helped to create, and have participated in, a vendor committee formed by the Information Industry Association's Financial Information Services Division (the "Committee") for the purpose of examining the Consolidated Form. Representatives of the participants and a cross section of the vendor community comprised the Committee. It provided a forum for discussing the concepts underlying the Consolidated From and an opportunity for vendors to offer input. The participants explained the operation and rationale for provisions that vendors questioned and agreed to make several changes to address vendor concerns.

The Consolidated Form as filed contains modifications from the version that the participants have been using provisionally. Those modifications reflect many of the Committee's comments and suggestions as well as a number of other comments and suggestions raised by vendors and securities firms that were not on the Committee.

On August 9, 1989, the participants distributed copies of the Consolidated Form as filed to each member of the Committee. An accompanying letter explained the changes and explained why, in some instances, the participants declined to incorporate vendor comments into the Consolidated Form.

The participants have required, and will hereafter require, a Contracting Party that receives and/or uses market data pursuant to an Existing Vendor Agreement to execute the Consolidated Form in the form filed.

Further, the participants have required, and will hereafter require, a Contracting Party that receives and/or uses market data pursuant to an Existing Vendor Agreement to execute the Consolidated Form (a) if and when it modifies the manner in which it receives or uses last sale or quotation information in a manner that would otherwise require it to execute a supplement or addendum to its Existing Vendor Agreements or (b) in lieu of an assignment of an Existing Vendor Agreement (as when a vendor merges into another corporation). By its terms, the Consolidated Form supersedes a predecessor Existing Vendor Agreement if the Consolidated Form's Exhibit A covers the service(s) that are the subject of the Existing Vendor Agreement. The participants may also ask other current Contracting Parties to execute the Consolidated Form in other instances, such as when doing so would serve administrative efficiency.

II. Implementation of The Amendment

Under section IV(c) of the CQ plan, each of the plan's participants must execute a written amendment to the plan before the amendments can become effective. Each amendment is so executed.

III. Request for Comment

Interested persons are invited to submit written comments on the amendments. Persons submitting comments should file six copies with the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW., Washington DC 20549. Copies of the submissions and related items, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, NW., Washington, DC. All communications should refer to File No. 4-281 and should be submitted by January 2, 1990.

For the commission, by the Division of Market Regulation, pursuant to delegated authority. 17 CFR 200.30-3(a)(27)

Dated: December 4, 1989.

Jonathan G. Katz,

Secretary.

[FR Doc. 89-28921 Filed 12-11-89; 8:45 am]

BILLING CODE 8010-01-M

[Rel. No. 34-27508; File No. SR-CBOE-89-22]

Self-Regulatory Organization; Chicago Board Options Exchange, Inc.; Order Approving and Granting Accelerated Approval to Proposed Rule Change Relating to Audit Trail Submissions

On October 26, 1989, the Chicago Board Options Exchange, Inc. ("CBOE" or "Exchange") submitted to the Securities and Exchange Commission ("SEC" or "Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") [1] and Rule 19b-4 thereunder,[2] a proposed rule change to establish a summary fine system for failure to perform certain audit trail reporting duties.

The proposed rule change was published for comment in Securities Exchange Act Release No. 27417 (November 2, 1989), 54 FR 47001. No comments were received on the proposed rule change.[3]

The proposed rule change establishes a summary fine procedure for a market maker's or floor broker's failure to perform certain reporting duties which are currently required under CBOE Rule 6.51. The fines, intended to ensure accurate audit trail submissions, are for (1) failure to report accurate transaction times, and (2) failure to submit trade information to the Standard & Poor's 100 index option ("OEX") reporter. The purpose of the proposed summary fine procedures is to enable the Exchange to penalize members who are deficient in meeting their reporting duties. The overall objective is to deter such conduct and thereby ensure establishment of the necessary audit trail information.

The proposed rule codifies the informal standards that market makers and floor brokers currently are held to pursuant to CBOE Rule 6.51. In particular, the proposal creates two summary fine schedules, one addressing the submission of inaccurate trade

[1] 15 U.S.C. 78s(b)(1) (1982).

[2] 17 CFR 240.19b-4 (1989).

[3] The proposal was amended on November 27, 1989 to: (1) change the test by which transactions are judged to be reported in a timely manner; (2) make the fees associated with filing appeals to fines refundable, if, in fact, the fine is eliminated upon appeal; and (3) clarify that suspensions of the fine system can be extended under appropriate circumstances.

reports and the other addressing the failure to submit trade information to OEX price reporters. With regard to inaccurate trade reports, the proposal provides that a transaction time submitted by a market maker or floor broker is considered inaccurate if not within five minutes of the time submitted by the contra-party to the transaction or the time disseminated by the Exchange's price reporter.[4] Otherwise, with certain specified exceptions, trades will be deemed to be inaccurately reported. Fines for inaccurate trade reports will be assessed monthly based on the number of violations occurring within that month.[5] With regard to OEX transaction reporting, the proposal provides for a fine on CBOE members if they sell OEX contracts and fail to submit required trade information to the OEX price reporter.[6]

In addition, the Exchange proposes to establish several safeguards designed to protect its members from the imposition of improper fines. First, members can request a verification by the Exchange of a fine.[7] Upon receipt of a request, which will be required to deal solely with factual issues or the application of the Rule, Exchange employees will verify the accuracy of the fine and determine whether the fine should be upheld, modified, or eliminated.[8] The Exchange's determination on a request for verification will not be appealable, however, the underlying fine will be.

Second, CBOE members will be able to appeal a fine, provided the protest is filed within thirty days of receipt of the fine or notice of determination on a request for verification of the fine. The review will be based on written evidence unless the member requests a hearing.[9] Appeals will be heard before a Protest Committee comprised of disinterested members of either the CBOE's Equity Floor Procedure Committee or its Index Floor Procedure Committee.[10]

Third, a decision of a Protest Committee may be appealed pursuant to Chapter XIX of CBOE Rules.

Fourth, under unusual circumstances which have affected or will affect the ability of a significant number of market makers and floor brokers to submit accurate transaction times or report OEX trades, the Exchange may suspend temporarily the application of the proposed reporting requirements.

The CBOE believes that a summary fine approach is the most efficient method to encourage better performance of the reporting duties on a floorwide basis. Using objective criteria and computer generated reports, the Exchange believes it will have the ability to impose immediately fines on all market makers and floor brokers who are failing to meet specified levels of compliance. The Exchange does not believe that following its normal disciplinary procedures would be practical because the numerous transaction reporting cases spawned by the proposed Rule would clog the regular disciplinary process, which is geared toward handling more serious rule violations. Moreover, the Exchange believes the imposition of summary fines will yield much speedier results. At the same time, however, the CBOE notes that the conduct of the member involved may be reviewed under normal disciplinary procedures and that members have the right to seek a review of fines imposed.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange. In particular, the Commission finds that the proposed rule change is consistent with sections 6(b) (1), (5), (6) and (7) and section 17A(a)(1)(A) of the Act.

The proposed rule change, for the most part, merely codifies the audit trail standards currently applicable to CBOE members and places in violations of these standards under a summary fine procedure. The Commission agrees with the CBOE that the summary fine schedule will serve as a deterrent to Exchange members from reporting transactions in an untimely manner, thereby further enhancing the CBOE's ability to create necessary and reliable audit trail information. Accordingly, the Commission finds that the proposed rule change is consistent with section 6(b)(1) of the Act because it will result in the production of more robust audit trail information that will enable the CBOE to better enforce compliance by its members with the federal securities laws and CBOE Rules. The Commission believes that the CBOE's increased surveillance capabilities will, in turn, prevent fraudulent and manipulative practices, promote just and equitable principles of trade, and protect investors and the public interest, consistent with section 6(b)(5) of the Act. Moreover, the Commission finds that the proposal is consistent with section 17A(a)(1)(A) of the Act because it is designed to promote the prompt and accurate clearance and settlement of securities transactions.

The Commission notes that the summary fine procedures are not altering the standards for adequate transaction reporting, but rather are establishing triggers for use of the summary procedures. The CBOE still could use its regular disciplinary procedures in instances when the summary procedures are not involved or when it determines that harsher sanctions than the schedule of summary fines are warranted.[11]

The Commission does not believe that the imposition of fines in a summary fashion for violations of the Rule will compromise the rights of CBOE members to a fair disciplinary proceeding. The CBOE's summary fine procedures are substantially the same as summary fine procedures of several

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[4] In its original filing, the CBOE proposed to evaluate the timeliness of reporting OEX transactions by using a ten-minute window standard. Amendment No. 1 to the filing, however, reduced the standard to five minutes, as this is currently the goal for OEX transactions.

[5] Specifically, members will be assessed a $100 fine if their trades are reported inaccurately 30–40% of the time, $250 if 40–50% of the time, and $500 if 50% of the time. In addition, the fine schedule provides for higher fines in the event of repeat violations. Specifically, if a member receives two fines within a nine-month period, then any subsequent fine imposed in that nine-month period will be equal to the appropriate fine according to the fee schedule plus the amount of the most recent fine. Finally, the fine schedule will only be imposed on those market makers or floor brokers who execute at least five transactions on each of at least ten different trading days during the applicable month.

[6] Specifically, for CBOE members who execute at least 25 OEX sale transactions during a particular month, a fine of $1,000 will be imposed if at least 50% of their short OEX trades are not reported to the OEX price reporter. Unlike the fine schedule for inaccurate transaction reports, however, the proposal does not provide for increased fines in the event of repeat violations. Because buyers of OEX contracts are not required to submit trade reports to price reporters under CBOE Rule 6.51, the fine schedule only applies to sellers of OEX contracts.

[7] Under the proposal, the CBOE is required to provide a period of at least fifteen days in which members can seek verification of their fines.

[8] During the verification process, the Exchange will not be required to take extraordinary steps or spend an unreasonable amount of time in investigating the request and Exchange staff will have the authority to request the member to submit documentary evidence in support of its claim.

[9] For appeals based on written evidence, members will be required to pay a $100 fee. For appeals involving a hearing, a $300 fee will be charged. In either case, however, the fees will be refunded if the fine is eliminated upon appeal.

[10] The appropriate floor procedure committee will be determined by the majority of transactions (*i.e.*, OEX or non-OEX) giving rise to the fine.

[11] For example, the trigger of 50% non-reporting of OEX trade information only relates to the use of summary fine procedures. The CBOE could still use its regular disciplinary procedures to sanction a member that failed to report information for 49% (or even 5%) of its OEX trades, or decide to use regular disciplinary procedures (and thus harsher sanctions) for a member that failed to report trade information for 51% of its OEX trades.

other exchanges.[12] As with the procedures of the other exchanges, the CBOE's summary fine procedures permit the person charged to contest the fine and seek a full hearing on the charges in accordance with established procedures. In addition, the proposal provides for exceptions to the accuracy test in the event that the contra-side to a transaction or the price reporter does not report the trade accurately. Accordingly, the Commission finds that the proposed rule change is consistent with sections 6(b)(6) and (7) of the Act because it provides for appropriate discipline for failure to report transactions accurately, while at the same time providing a fair procedure for imposing such discipline. The Commission also approves the CBOE's plan to report quarterly the sanctions imposed pursuant to the proposed rule change.[13]

The Commission finds good cause for granting accelerated approval of the proposed rule change. First, the filing codifies existing audit trail standards currently in place, including the summary fines. CBOE members have been receiving notices from the CBOE for several months of the amount of fines they would have paid, based on their inaccurate transaction reports, if the fine schedules had been in place. Second, the proposed rule change had a full comment period, and no comments were received. Third, the acceleration is only for two days, and will put in place more quickly summary fine procedures designed to enhance the CBOE's compliance program.[14]

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[15] that the proposed rule change (SR–CBOE–89–22) is approved.

[12] *See e.g.,* Securities Exchange Act Release No. 21688 (January 25, 1985), 50 FR 5025 (order approving New York Stock Exchange ("NYSE") summary fine procedures).

[13] The CBOE's plan is similar to plans adopted by other exchanges pursuant to Rule 19d–1 under the Act and approved by the Commission. Rule 19d–1(c)(2) under the Act allows national securities exchanges to adopt minor rule violation plans for the summary discipline and abbreviated reporting of minor rule violations by exchange members. *See e.g.,* Securities Exchange Act Release No. 22415 (September 17, 1985), 50 FR 38600 (order approving NYSE minor disciplinary rule violation reporting plan).

[14] The Commission also believes tha there is good cause for accelerating approval of Amendment No. 1 to the proposed rule change. The amendment makes only minor changes to the proposed rule change. To the extent that the amendment switches the standard for the accurate reporting of OEX trades, it merely is returning the standard to its current level.

[15] 15 U.S.C. 78s(b) (1982).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[16]

Dated: December 6, 1989.

Jonathan G. Katz,

Secretary.

[FR Doc. 89–28920 Filed 12–11–89; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. 34–27501; File No. SR–NASD–89–30]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Order Approving Proposed Rule Change Relating to Amendments to the Examination Specifications and Study Outline for the Financial and Operations Principal ("Series 27") Qualification Examination

The National Association of Securities Dealers, Inc. ("NASD") submitted on July 12, 1989, to the Securities and Exchange Commission ("Commission") a proposed rule change pursuant to Section 19(b) of the Securities Exchange Act of 1934 ("Act") [1] and Rule 19b–4 thereunder.[2] The proposal amends the examination specifications and study outline for the Financial and Operations Principal ("Series 27") qualification examination. The NASD periodically reviews the content of the examination to determine whether amendments are necessary or appropriate in view of changes pertaining to the subject matter covered by the examination.

Notice of the proposed rule change together with the terms of substance of the proposal was provided by the issuance of a Commission release (Securities Exchange Act Release No. 27111, August 9, 1989) and by publication in the **Federal Register** (54 FR 33793, August 16, 1989).

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the NASD and, in particular, the requirements of section 15A [3] and the rules and regulations thereunder.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the above-mentioned proposed rule change be, and hereby is, approved, effective January 1, 1990.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[4]

[16] 17 CFR 200.30–3(a)(12) (1989).

[1] 15 U.S.C. 78s(b)(1) (1982).

[2] 17 CFR 240.19b–4 (1989).

[3] 15 U.S.C. 78*o*–3 (1982).

[4] 17 CFR 200.30–3(a)(12) (1989).

Dated: December 5, 1989.

Jonathan G. Katz,

Secretary.

[FR Doc. 89–28919 Filed 12–11–89; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–27502; File No. SR–NASD–89–45]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Proposed Rule Change Relating to Expedited Remedial Proceedings Under the Code of Procedure

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on October 5, 1989, the National Association of Securities Dealers, Inc. ("NASD") filed with the Securities and Exchange Commission ("Commission" or "SEC") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the NASD. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change would amend the NASD Code of Procedure to add a new procedure by which the NASD could take appropriate remedial actions against an NASD member or an associated person if the member or person had engaged and there was a reasonable likelihood that the member or person would again engage in securities law violations.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the NASD included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NASD has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The NASD has proposed this rule change because it has been confronted

on several occasions with instances of members and persons that have violated various Commission and NASD rules and regulations and, when advised to cease such activities, have evidenced an intent to continue and have continued the violative conduct. The NASD, under the present Code of Procedure, has no expeditious method specifically designed to handle such situations.

The proposed amendment would permit the NASD to suspend or condition the membership of a broker-dealer, or suspend or condition a person's association with a broker-dealer if the broker-dealer or person has engaged, and there is a reasonable likelihood the broker-dealer or person will again engage or continue to engage, in acts or practices inconsistent with just and equitable principles of trade. The amendment provides the NASD with a wide range of actions it could take against a member or associated person for ongoing violations, including suspension or imposition of limitations or conditions on the firm's membership or the person's registration. This range of permissible actions would allow the NASD to tailor the action taken to meet the seriousness of the situation. The firm or person that is the subject of such a proceeding would have the right to a hearing prior to the NASD taking any action.

Under the proposed amendment, the NASD Executive Committee would be able to authorize the initiation of such a proceeding only after a finding by that Committee that the proceeding was needed to protect the public interest. In arriving at this decision, the Executive Committee would consider the egregious nature of this conduct and the likelihood of continuing violations. The NASD would notify the member and/or associated person of the time and place of the hearing. The matter would be considered by a District or Market Surveillance Committee hearing panel consisting of at least three Committee persons, and this panel would render its decision within five business days of the hearing.

Any party aggrieved by the decision, or the Executive Committee, could ask that this decision be reviewed by a committee of the Board of Governors ("Board"). Any such request would not operate as a stay of the District or Market Surveillance Committee's decision. Upon any application for review, a hearing before a Hearing Committee of the Board would be held within five business days. Any decision rendered by the Board Hearing Committee would be a final action of the NASD and could be appealed to the SEC. All decisions rendered would be in writing, and any member or person would have the right to appear in person, submit any relevant evidence, and be represented by counsel.

The proposed rule change is consistent with section 15A(b)(6) of the Act which mandates that the rules of a national securities association be designed to promote just and equitable principles of trade and to remove impediments to, and perfect the mechanisms of, a free and open market, because the NASD believes that it must have a procedure to expeditiously handle situations where NASD members or their associated persons have been violating and continue to violate NASD and SEC rules and regulations. The NASD also believes that sections 15A(g)(3) (A) and (B) of the Act authorize the NASD to take such action and that the proposed procedure meets the due process and hearing requirement of section 15A(h)(1) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The NASD does not believe that the proposed amendment imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The proposed rule change was published for comment in NASD Notice to Members 89-40 in May 1989. As a result of this Notice, the NASD received 5 comment letters.[1] Of these, 1 commentator generally favored the proposed amendment, one generally favored the proposal with amendment, 3 were opposed. Those commentators opposed to the proposal raised the following major concerns:

1. There is no time limit for the issuance of the Board's decision thus subjecting the member to the potential of an indefinite duration of the sanctions imposed since the initial hearing panel's decision is not stayed on appeal to the Board;

2. It is unclear who would be responsible for determining if and when the conditions imposed had been fulfilled to eliminate the supervision or restrictions; and

3. It is unclear what standard would be used to determine the kind of misconduct which would cause the initiation of such a proceeding.

[1] The Notice of Members, a list of the commentators, and the comment letters are attached as Exhibits 2 and 3 of the rule filing.

The commentator that was in favor of the proposal subject to amendment believed that the procedure should only be used in situations involving "fraud or manipulation." The Board of Governors did not believe that such a limitation was appropriate in that such action under this section could be appropriate in situations involving serious and ongoing violations of securities rules and regulations which, while not involving fraud or manipulation could pose a serious threat to public customers or other members.

In response to the comments which expressed concern over the absence of a time limit to issue the decision of a matter appealed to the Board, the NASD has added language to Section 5 of the rule which would provide that a written decision shall be issued by the Board hearing panel within 5 business days of the date of the hearing. In response to comments concerning what standard would be used to determine the kind of misconduct which would cause the initiation of such a proceeding, the proposal was amended to provide that the Executive Committee would take into consideration the egregious nature of the violations and the likelihood that they would continue. The proposal was also amended so that any decision conditioning or suspending a member or person associated with it shall not remain in effect longer than six months. With respect to the comment concerning which body would determine whether the member had met any conditions that had been imposed, this matter would be reviewed by the District staff in the District where the alleged misconduct had occurred. This situation would be handled in a manner similar to that in which the District staff reviews compliance with restrictions placed in proceedings under Article III, Section 38 of the Rules of Fair Practice.

One commentator asked who would consider this matter if a hearing were not held. Sections 2 and 4 of the proposed Article state a three person hearing panel will be appointed at the District level and if applicable at the Board level. These three person panels will render the decision in these matters regardless of whether a hearing is held. The same commentator asked what made these hearing panels "special". The panels will be appointed in the same manner as any hearing panels are under the NASD By-Laws and Code of Procedure. It was determined, however, to delete the word "special" as the term did not have any particular meaning and it could cause confusion.

III. Date of Effectiveness of the Proposed Rule Change and Timing For Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the NASD consents, the Commission will:

A. By order approve such proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to the file number in the caption above and should be submitted by January 2, 1990.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30-3(a)(12).

Dated: December 5, 1989.

Jonathan G. Katz,

Secretary.

[FR Doc. 89-28922 Filed 12-11-89; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-27507; Filed No. SR-PHLX-89-54]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Philadelphia Stock Exchange, Inc. Relating to Narrowing Quotation Spreads for Low-Priced Equity Options

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on November 27, 1989 the Philadelphia Stock Exchange, Inc. ("PHIX" or "Exchange") filed with the Securities Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Rule 1014(c)(i) to narrow the maximum bid-ask differential applicable to certain equity options traded on the Exchange. The following is the text of the proposed amendment (italics indicate additions; brackets indicate deletions).

Obligations and Restrictions Applicable to Specialists and Registered Options Traders

Rule 1014 (a)—(c) No change.

(c)(i) Options on [Stocks] *Equities.* (A) Bidding and/or offering so as to create differences of no more than ⅛ [¼] of $1 between the bid and offer for each option contract for which the prevailing bid is less than ½ *of* $1, *no more than ¼ of $1 where the prevailing bid is ½ of $2 or more but less than $2* no more than ⅜ of $1 where the prevailing bid is [$1] *$2* or more but less than $5, no more than ½ of $1 where the prevailing bid is $5 or more but less than $10, or more than ¾ of $1 where the prevailing bid is $10 or more but less than $20, and no more than $1 where the prevailing bid is $20 or more provided that the Exchange may establish differences other than the above for one more series or classes of options.

(c)(B)—(e)(iii) No change.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statments concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statements of the Purpose of, and Statutory Basis for the Proposed Rule Change

The purpose of the proposed rule change is to narrow maximum quotation spread parameters for low-priced equity options. Current Exchange rules provide for a maximum quote spread of ¼ of $1 when the prevailing bid in the options series is less than $1, ⅜ of $1 when the bid is between $1 and $5, and wider spreads for bids $5 and more. The proposal would require no greater than ⅛ of $1 spreads for bids under ½ of $1, no greater than ¼ of $1 spreads for bids ½ of $1 up to but under $2, and no greater than ⅜ of $1 for bids $2 up to $5. No further changes would be made to current spread parameters. The PHLX believes that the proposal reflects the Exchange's continued commitment to making quality markets in the products it trades.

The Exchange believes the proposed rule change is consistent with the requirements of the Act in that it may be expected to promote the maintenance of fair and orderly markets and in particular Section 6(b)(5) of the Act which provides in pertinent part that the rules of the Exchange be designed to promote just and equitable principles of trade and to protect the investing public.

B. Self-Regulatory Organization's Statement on Burden on Competition

The PHLX does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of the publication of this ntoice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or,

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments.

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments,

all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted within January 2, 1990.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[1]

Jonathan G. Katz,

Secretary.

Dated: December 6, 1989.

[FR Doc. 89-28923 Filed 12-11-89; 8:45 am]

BILLING CODE 8010-01-M

[File 84-1370; Exchange Act Release No. 27514]

AAA Transfer Corp.; Order Cancelling Registration Pursuant to Section 17A(c)(4)(B) of the Securities Exchange Act of 1934

AAA Transfer Corporation ("AAA Transfer"), hereinafter referred to as the registrant, being registered as a transfer agent pursuant to section 17A(c) of the Securities Exchange Act of 1934; and

The Commission finding that the registrant has ceased doing business as a transfer agent;

Accordingly, *it is ordered,* pursuant to section 17A(c)(4)(B) of the Securities Exchange Act of 1934, that the registration of said registrant be, and the same hereby is, cancelled.

By the Commission.

Jonathan G. Katz,

Secretary.

[FR Doc. 89-28986 Filed 12-11-89; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Air Traffic Procedures Advisory Committee Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Air Traffic Procedures Advisory Committee meeting.

SUMMARY: The FAA is issuing this notice to advise the public that a meeting of the Federal Aviation Administration Air Traffic Procedures Advisory Committee (ATPAC) will be held to review present air traffic control procedures and practices for standardization, clarification, and upgrading of terminology and procedures.

DATES: The meeting will be held from January 22, at 1 p.m., through January 25, 1990, at 5 p.m.

ADDRESS: The meeting will be held at the MGM Desert Inn Hotel, 3145 Las Vegas Boulevard South, Las Vegas, Nevada.

FOR FURTHER INFORMATION CONTACT: Mr. John Mayrhofer, Executive Director, ATPAC, Air Traffic Operations Service, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267-3725.

SUPPLEMENTAL INFORMATION: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463; 5 U.S.C. App. 1), notice is hereby given of a meeting of the ATPAC to be held from January 22, at 1 p.m., through January 25, 1990, at 5 p.m., at the MGM Desert Inn Hotel, 3145 Las Vegas Boulevard South, Las Vegas, Nevada. The agenda for this meeting is as follows: a continuation of the Committee's review of present air traffic control procedures and practices for standardization, clarification, and upgrading of terminology and procedures. It will also include:

1. Approval of minutes.
2. Discussion of agenda items.
3. Discussion of urgent priority items.
4. Report from Executive Director.
5. Old Business.
6. New Business.
7. Discussion and agreement of location and dates for subsequent meetings.

Attendance is open to the interested public but limited to the space available. With the approval of the Chairperson, members of the public may present oral statements at the meeting. Persons desiring to attend and persons desiring to present oral statements should notify the person listed above not later than January 19, 1990. The next quarterly meeting of the FAA ATPAC is planned to be held from April 9 through April 12, 1990, in Washington, DC. Any member of the public may present a written statement to the Committee at any time.

Issued in Washington, DC, on December 6, 1989.

John Mayrhofer,

Executive Director, ATPAC.

[FR Doc. 89-28940 Filed 12-11-89; 8:45 am]

BILLING CODE 4910-13-M

Federal Highway Administration

[FHWA Docket No. 89-18]

RIN 2125-AC39

Handicapped Parking Regulatory Negotiation Advisory Committee

AGENCY: Federal Highway Administration (FHWA), National Highway Transportation Safety Administration (NHTSA), DOT.

ACTION: Notice of correction of meeting days.

SUMMARY: This notice corrects the meeting days previously published in the **Federal Register** November 30, 1989, 54 FR 49387, FR Doc. 89-28090 for public meetings to be held in Washington, DC. The dates given for the meetings on January 10, 11, and 12 of 1990 are correct, but the days of the week are changed to read as follows:

"Wednesday, January 10, 1990, 1:00 p.m. to 5:00 p.m., Thursday, January 11, 1990, and Friday, January 12, 1990 9:00 a.m. to 5:00 p.m."

Authority: 23 U.S.C. 315; 49 CFR 1.48.

Issued on: December 6, 1989.

Larry L. Thompson,

Chief Counsel, Federal Highway Administration.

[FR Doc. 89-28927 Filed 12-11-89; 8:45 am]

BILLING CODE 4910-22-M

Maritime Administration

[Docket No. S-856]

Ocean Technical Services, Inc.; Application for a Waiver of Section 804 of the Merchant Marine Act, 1936, As Amended To Permit the Acquisition of an Interest in, Operate, or Charter of Foreign-Flag Tankers

By application of November 29, 1989, Ocean Technical Services, Inc. (Applicant), requested permission, under the provisions of section 804 of the Act, to acquire an interest in, operate or charter foreign-flag tankers for operation in the foreign commerce. Section 804 approval is required because the Applicant is affiliated with Ocean Carriers, Inc.; Ocean Chemical Carriers, Inc.; and Ocean Chemical Transport, Inc., which companies hold Operating-Differential Subsidy Agreements

[1] 17 CFR 200.30-3(a)(12) (1989).

(ODSA), Contracts MA/MSB-167, MA/MSB-440, and MA/MSB-442, respectively.

The Applicant specifically requested that a waiver pursuant to section 804(b) of the Act be granted for up to nine foreign-flag tankers for the carriage of crude oil and its products and/or petrochemicals. The waiver is to remain in effect until April 2, 1996, May 26, 2001, and September 19, 2001, the termination dates of the respective ODSAs. Such a waiver, in the Applicant's view, may be granted under special circumstances, and for good cause shown, as enumerated in its instant application.

In support of its instant application, the Applicant points out that the Maritime Administrator (Administrator) has already approved similar applications for the Mormac Maritime Group (Mormac) in Docket S-831 and the Keystone Shipping Company (Keystone) in Docket S-841. The Applicant states that its current situation is identical to that of Mormac and Keystone. Also, it is currently impossible for companies like the Applicant to compete with foreign-flag operators in the worldwide market with U.S.-flag vessels. Such competition, the Applicant contends, would be possible only if the Federal government obligates sufficient funding to expand the operating-differential subsidy (ODS) program to new entrants. The Applicant, however, believes that increased funding for the ODS program is not likely in the foreseeable future due to the budgetary constraints facing the Federal government. Consequently, its options are limited to acquiring an interest in, operating, or chartering foreign-flag vessels if it is to compete in the worldwide tanker market.

In addition, in Dockets S-831 and S-841, the Administrator has determined that granting of a blanket section 804(b) waiver for Mormac and Keystone until the termination of their respective ODSAs would not create a substantial adverse competitive impact on U.S.-flag operators. Such assessment, the Applicant contends, continues to hold true. Furthermore, its entry as the charterer or operator of foreign-flag tankers would do nothing to create an adverse impact on U.S.-flag operators. Moreover, the Applicant adds, its operations would, at best, compete only with foreign-flag operations of Mormac and Keystone, and, in its view, such a competition is not prohibited under section 804.

Finally, the Applicant asserts that granting the requested waiver would serve to promote the U.S. merchant marine. In this connection, it goes on to say that it shares administrative costs with its affiliated companies. Additionally, as has been noted by Mormac in its prior application for a section 804 waiver, the ability to spread out indirect administrative costs strengthens the position of both the Applicant and its affiliated companies that are providing U.S.-flag service. Such an improved financial situation would strengthen existing U.S. operations and preserve jobs for U.S. seamen, advises the Applicant.

This application may be inspected in the Office of the Secretary, Maritime Administration. Any person, firm, or corporation having any interest in such application within the meaning of section 804 of the Act and desiring to submit comments concerning the application, must file written comments in triplicate with the Secretary, Maritime Administration, Room 7300, Nassif Building, 400 Seventh Street SW., Washington, DC 20590. Comments must be received no later than 5:00 p.m. on December 27, 1989.

This notice is published as a matter of discretion and publication should in no way be considered a favorable or unfavorable decision on the application, as filed or as may be amended. The Maritime Administration will consider any comments submitted and take such action with respect thereto as may be deemed appropriate.

(Catalog of Federal Domestic Assistance Program No. 20.804 (Operating-Differential Subsidies)).

By order of the Maritime Administration.

Dated: December 7, 1989.

James E. Saari,

Secretary.

[FR Doc. 89-28972 Filed 12-11-89; 8:45 am]

BILLING CODE 9410-81-M

National Highway Traffic Safety Administration

Rulemaking, Research and Enforcement Programs; Meeting

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice.

SUMMARY: This notice announces a public meeting at which NHTSA will answer questions from the public and the automobile industry regarding the agency's rulemaking, research and enforcement programs.

DATE: The agency's regular, quarterly public meeting relating to the agency's rulemaking, research, and enforcement programs will be held on January 18, 1990, beginning at 10:30 a.m. Questions relating to the agency's rulemaking, research, and enforcement programs, must be submitted in writing by January 8, 1990. If sufficient time is available, questions received after the January 8, date may be answered at the meeting. The individual, group or company submitting a question(s) does not have to be present for the question(s) to be answered. A consolidated list of the questions submitted by January 8, 1990, and the issues to be discussed will be mailed to interested persons on January 12, 1990, and will be available at the meeting.

ADDRESS: Questions for the January 18 meeting relating to the agency's rulemaking, research, and enforcement programs should be submitted to Barry Felrice, Associate Administrator for Rulemaking, Room 5401, 400 Seventh Street, SW., Washington, DC 20590. The public meeting will be held in Room 2230, Department of Transportation Headquarters Building, 400 Seventh Street, SW., Washington, DC 20590.

SUPPLEMENTARY INFORMATION: NHTSA will hold its regular, quarterly meeting to answer questions from the public and industry regarding the agency's rulemaking, research, and enforcement programs on January 18, 1990. The meeting will begin at 10:30 a.m., and will be held in Room 2230, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590. The purpose of the meeting is to focus on those phases of NHTSA activities which are technical, interpretative or procedural in nature. A transcript of the meeting will be available for public inspection in the NHTSA Technical Reference Section in Washington, DC, within four weeks after the meeting. Copies of the transcript will then be available at twenty-five cents for the first page and five cents for each additional page (length has varied from 100 to 150 pages) upon request to NHTSA Technical Reference Section, Room 5108, 400 Seventh Street, SW., Washington, DC 20590.

Issued on December 6, 1989.

Barry Felrice,

Associate Administrator for Rulemaking.

[FR Doc. 89-28926 Filed 12-11-89; 8:45 am]

BILLING CODE 4910-59-M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

Dated: December 6, 1989.

The Department of Treasury has submitted the following public information collection requirement(s) to

OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2224, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Internal Revenue Service

OMB Number: 1545–0990.
Form Number: 8610.
Type of Review: Extension.
Title: Annual Low-Income Housing Credit Agencies Report.
Description: Form 8610 is used as a transmittal form for Forms 8609, Low-Income Housing Credit Allocation Certification. Form 8610 is completed by state and local housing credit agencies.
Respondents: State or local governments.
Estimated Number of Respondents: 300.
Estimated Burden Hours Per Response:
Recording: 2 hours, 23 minutes
Learning about the law or the form: 27 minutes
Preparing and sending the form to IRS: 27 minutes
Frequency of Response: Annually.
Estimated Total Reporting Burden: 972 hours.
OMB Number: 1545–0023.
Form Number: 720.
Type of Review: Revision.
Title: Quarterly Federal Excise Tax Return.
Description: Form 720 is used to report excise taxes due from retailers and manufacturers on the sale or manufacture of various articles, to report taxes on facilities and services, and taxes on certain products and commodities (gasoline and vaccines, etc.). It enables IRS to monitor excise tax liability for various categories on a single form and to collect the tax quarterly in compliance with the law and regulations (Internal Revenue Code section 6011).
Respondents: Individuals or households, Businesses or other for-profit, Small businesses or organizations.
Estimated Number of Respondents: 92,500.
Estimated Burden Hours Per Response:
Recording: 6 hours, 28 minutes
Learning about the law or the form: 3 hours, 22 minutes
Preparing and sending the form to IRS: 12 hours, 1 minute
Frequency of Response: Quarterly.
Estimated Total Reporting Burden: 8,084,500 hours.
Clearance Officer: Garrick Shear (202) 535–4297, Internal Revenue Service, Room 5571, 1111 Connecticut Avenue, NW., Washington, DC 20224.
OMB Reviewer: Milo Sunderhauf (202) 395–6880, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503.

Irving W. Wilson, Jr.,
Departmental Reports, Management Officer.
[FR Doc. 89–28928 Filed 12–11–89; 8:45 am]
BILLING CODE 4810–25–M

Customs Service

[T.D. 89–105]

Extension of Analyses for Which SGS Control Services Inc., an Accredited Customs Laboratory, Have Been Accredited To Perform

AGENCY: U.S. Customs Service, Treasury.

ACTION: Notice of additional analyses for which SGS Control Services, Inc., a Customs accredited commercial laboratory, have been accredited to perform.

SUMMARY: SGS Control Services, Inc., of Carteret, New Jersey, a Customs accredited commercial laboratory under § 151.13 of the Customs Regulations (19 CFR 151.13), has been given an extension of their commercial laboratory accreditation to include the following analyses: Reid Vapor Pressure, Saybolt Universal Viscosity, percent by weight sulfur of petroleum products, percent by weight lead in gasoline, xylene isomer content, and percent by weight composition of benzene, toluene and xylene.

SUPPLEMENTARY INFORMATION: Part 151 of the Customs Regulations provides for the acceptance at Customs Districts of laboratory analyses from Customs-accredited commercial laboratories for certain products. SGS Control Services, Inc., which holds Customs accreditation in certain laboratory analyses has applied to Customs to extend its accreditation to the performance of additional analyses. Review of SGS Control Services, Inc., qualifications shows that the extension is warranted and, accordingly, has been granted.

EFFECTIVE DATE: November 30, 1989.

FOR FURTHER INFORMATION CONTACT: Donald A. Cousins, Office of Laboratories and Scientific Services, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, DC 20229 (202–566–2446).

Dated: December 6, 1989.

John B. O'Loughlin,
Director, Office of Laboratories and Scientific Services.
[FR Doc. 89–28996 Filed 12–11–89; 8:45 am]
BILLING CODE 9820–02–M

Application for Recordation of Trade Name: "Comanche Land Imports"

ACTION: Notice of application for recordation of trade name.

SUMMARY: Application has been filed pursuant to § 133.12, Customs Regulations (19 CFR 133.21), for the recordation under section 42 of the Act of July 5, 1946, as amended (15 U.S.C. 1124), of the trade name "COMANCHE LAND IMPORTS", used by George L. Murray, d/b/a Comanche Land Imports, 3819 San Bernardo, Laredo, Texas 78041.

The application states that the trade name is used in connection with original statues which are reproduced in various plants in Mexico and distributed in the United States by Comanche Land Imports. There are no foreign persons or businesses authorized or licensed to use the trade name.

Before final action is taken on the application, consideration will be given to any relevant data, views, or arguments submitted in writing by any person in opposition to the recordation of this trade name. Notice of the action taken on the application for recordation of this trade name will be published in the **Federal Register.**

DATE: Comments must be received on or before February 12, 1990.

ADDRESS: Written comments should be addressed to U.S. Customs Service, Attention: Value, Special Programs and Admissibility Branch, 1301 Constitution Avenue, NW. (Room 2104), Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Bettie Coombs-Spivey, Value, Special Programs and Admissibility Branch, 1301 Constitution Avenue, NW., Washington, DC 20229 (202–566–5765).

Marvin M. Amernick,
Chief, Value, Special Programs and Admissibility Branch.
[FR Doc. 89–28997 Filed 12–11–89; 8:45 am]
BILLING CODE 4820–02–M

UNITED STATES INFORMATION AGENCY

East European Young Leaders Program; Request for Proposals

The International Youth Exchange Staff of the Bureau of Educational and

Cultural Affairs, U.S. Information Agency, announces its intention to fund a series of educational study projects for future leaders from Hungary, Poland, the German Democratic Republic, Bulgaria, and Czechoslovakia in FY 1990 and invites private non-profit organizations to submit written proposals to conduct projects of this type. The number of projects will be subject to the availability of funding. Previous experience indicates that individual grants in the range of $75,000 to $100,000 have generally been favored by Agency grant review panels for these types of projects.

These projects are designed for young people (ages 18 to 30) who have the potential to become the leaders of the future. The project will be a short-term (approximately four weeks) group activity for 10–12 participants identified and selected by USIS posts. The majority of participants will come from Hungary and Poland, but USIS posts in the German Democratic Republic, Bulgaria, and Czechoslovakia may also nominate participants. The project may be for participants from a single country, possibly conducted in the language of the country with the assistance of English language interpreters, or a regional project for participants from two or more East European countries conducted in English.

The purpose of the youth program is interaction and interchange between foreign and American young people. All projects should be an opportunity for the foreign participants to share and present their ideas. Young American counterparts should be included in all aspects of the substantive program and in social and cultural activities. Programs must be balanced and representative of the diversity of American political, social and cultural life. Travel to more than one area of the United States is encouraged. The program should also provide opportunities for homestays and practical, hands-on activities in order for the foreign participants to develop a more profound understanding of the daily life and work of people in the communities visited. Participation in a conference or seminar relating to the project theme may be arranged as part of the program.

Major themes include the following: conservation/protection of the environment, business administration/management, American economic system, community action, American legal/constitutional systems, American political system, university administration, and the media. Programs are authorized under Public Law 87–256, the Mutual Educational and Cultural Exchange Act of 1961, whose "purpose is to increase mutual understanding between the people of the United States and the people of other countries." Programs must be balanced and representative of the diversity of American political, social, and cultural life.

Eligibility

To be eligible for consideration organizations must be incorporated in the U.S., have not-for-profit status as determined by the IRS, and be able to demonstrate expertise in a field relevant to the theme of the project on which they are bidding. Organizations in existence less than four years will only be eligible for grants under $60,000. Experience programming exchange visitors is desirable.

Allowable costs

Grant-funded expenditures will generally be limited to the following categories:
—International travel
—Domestic travel
—Maintenance and per diem
—Orientation and preparation costs; orientation materials
—Cultural enrichment allowance (not to exceed $150 per participant)
—Speaker honoraria, conference or seminar registration fees, rental of meeting facilities. (Speaker honoraria should not exceed $150 per day per speaker.)
—Materials expenses
—Administration—salaries, benefits, other direct and indirect costs

Criteria for Judging Proposals

All proposals will be judged on a competitive basis. The following criteria will be used by USIA to judge proposals:
—Quality of the project activities proposed.
—Cost effectiveness—greatest return for each federal dollar invested; reasonable per capita cost in relation to other proposals submitted; for those proposals which have been most successful in previous competitions, total administrative costs have generally been below thirty percent of the total requested.
—Cost sharing—financial and in-kind support from participating organizations, schools, and communities.
—Organization's qualifications—based both on past track record and on USIA's judgment of the organization's ability to manage the proposed subject and achieve the stated objectives within the time frame indicated.
—Geographic balance of grants and activities.

Review Process

Proposals (original and 12 copies) must be received in USIA no later than January 31, 1990. Proposals are reviewed for legal and budgetary requirements by USIA offices responsible for these functions and for program content and cost-effectiveness by a grant review panel composed of USIA officers. The Associate Director for Educational and Cultural Affairs identifies and approves grant recipients. Final technical authority for grant awards resides with the Agency Contracting Officer. The award of grants will be announced on or about April 30, 1990.

Proposal Format

Organizations must use "Guidelines for Proposals," which may be obtained by writing to: International Youth Exchange Staff, United States Information Agency, 301 4th St. SW.—Rm. 357, Washington, DC 20547.

For more information on this program contact the International Youth Exchange Staff at (202) 485–7299.

Dated: November 29, 1989.

Csaba T. Chikes,

Director, International Youth Exchange Staff.

[FR Doc. 89–28932 Filed 12–11–89; 8:45 am]
BILLING CODE 3155–01–M

Radio Engineering Advisory Committee Meeting

The Radio Engineering Advisory Committee of the United States Information Agency (USIA) will meet in Washington, DC, on Thursday, December 14, 1989, to discuss current operations and future plans of the Voice of America (VOA). The meeting will be held at the Voice of America, 330 Independence Avenue SW., Washington, DC 20547. The meeting will begin at 9 a.m. on December 14 and will continue through 4 p.m. Point of contact for the meeting is Mrs. Helen Giles, telephone (202) 485–8048.

This meeting will include reports from senior members of the VOA management and engineering staff on the progress being made on the overall VOA modernization and enhancement effort. Specific topics of discussion will include the procurement and testing of

high frequency broadcasting antennas, the status of negotiations with other governments and major construction projects, and other technical and regulatory issues relating to VOA modernization.

Dated: November 30, 1989.

Joseph B. Bruns,

Acting Director, VOA.

[FR Doc. 89-28736 Filed 12-11-89; 8:45 am]

BILLING CODE 8230-01-M

Sunshine Act Meetings

Federal Register
Vol. 54, No. 237
Tuesday, December 12, 1989

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act". (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

INTERNATIONAL TRADE COMMISSION

USITC SE-89-41

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: Tuesday, Dec. 19, 1989 at 3:00 p.m.

PLACE: Room 101, 500 E Street, S.W., Washington, DC 20436.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda.
2. Minutes.
3. Ratifications.
4. Petitions and Complaints.
5. Inv. No. 701-TA-301 (P) (Plastic Tubing Corrugators from Canada)—briefing and vote.
6. Inv. No. 731-TA-432 (F) (Drafting Machines from Japan)—briefing and vote.
7. Any items left over from previous agenda.

CONTACT PERSON FOR MORE INFORMATION: Kenneth R. Mason, Secretary, (202) 252-1000.

Kenneth R. Mason,

Secretary.

Dec. 4, 1989.

[FR Doc. 89-29086 Filed 12-8-89; 12:12 pm]

BILLING CODE 7020-02-M

CONSUMER PRODUCT SAFETY COMMISSION

AGENCY: U.S. Consumer Product Safety Commission, Washington, D.C. 20207.

TIME AND DATE: Commission Meeting, Tuesday, December 12, 1989, 3 p.m.

LOCATION: Room 556, Westwood Towers, 5401 Westbard Avenue, Bethesda, Maryland.

STATUS: Open to the Public.

MATTERS TO BE CONSIDERED: Fiscal Year 1991 Budget.*

The staff will brief the Commission and the Commission will then consider issues concerning the CPSC Budget for Fiscal Year 1991.

FOR A RECORDED MESSAGE CONTAINING THE LATEST AGENDA INFORMATION, CALL: 301-492-5709.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sheldon D. Butts, Office of the Secretary, 5401 Westbard Ave., Bethesda, Md. 20207 301-492-6800.

December 8, 1989,

Sheldon D. Butts,

Deputy Secretary

[FR Doc. 89-29100 Filed 12-8-89; 1:23 pm]

BILLING CODE 6355-01-M

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* The Commission by unanimous vote decided that agency business required holding this meeting without the normal seven day advance notice.

Corrections

Federal Register
Vol. 54, No. 237
Tuesday, December 12, 1989

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF COMMERCE

Foreign Trade Zones Board

[Order No. 454]

Resolution and Order Approving With Restrictions, the Application of Greater Kansas City Foreign-Trade Zone, Inc.

Correction

In notice document 89-28347 beginning on page 50257 in the issue of Tuesday, December 5, 1989, make the following corrections:

1. On page 50257, in the second column, under **Resolution and Order,** in the third complete paragraph, in the fourth and fifth lines, the date should read "October 21, 1988".

2. On the same page, in the third column, under **Grant of Authority To Establish a Foreign-Trade Subzone at the Kawasaki Small Engine Plant in Nodaway County, Missouri, Adjacent to the Kansas City Customs Port of Entry,** in the second complete paragraph, in the second and third lines, "15 U.S.C. 400.304" should read "15 CFR 400.304".

3. On the same page, in the same column, in the third line from the end of the column, the date should read "October 21, 1988".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 89N-0490]]

Drug Export; Didronel® (Etidronate Disodium 200 MG Tablets, U.S.P.)

Correction

In notice document 89-27486 beginning on page 48687 in the issue of Friday, November 24, 1989, make the following corrections:

1. On page 48688, in the first column, under **SUPPLEMENTARY INFORMATION,** the 14th and 15th lines are duplicate text and should be removed.

2. On the same page, in the second column, in the third line, "21 U.S.C. 381" should read "21 U.S.C. 382".

BILLING CODE 1505-01-D

federal register

Tuesday
December 12, 1989

Part II

Department of Housing and Urban Development

Office of the Assistant Secretary for Fair Housing and Equal Opportunity

Community Housing Resource Board Program; Funds Availability; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Fair Housing and Equal Opportunity

[Docket No. N-89-2034; FR-2631-N-01]

Community Housing Resource Board Program; Funds Availability

AGENCY: Office of the Assistant Secretary for Fair Housing and Equal Opportunity, HUD.

ACTION: Notice of funds availability.

SUMMARY: This Notice announces the availability of funds for applications for eligible Community Housing Resource Boards (CHRBs). CHRBs must meet certain eligibility criteria, set out in 24 CFR part 120 and in this Notice, in order to qualify for consideration. The program has two categories of funding: (1) First-time funding for CHRBs that have never obtained previous Federal CHRB funding; and (2) refunding for CHRBs that have obtained previous Federal CHRB funding, except as described in this Notice.

DATE: Applications must be received by March 1, 1990.

FOR FURTHER INFORMATION AND A COPY OF THE APPLICATION KIT CONTACT: Karen Williams, Room 5256, Office of Procurement and Contracts, Office of the Assistant Secretary for Administration, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410. Application Kits will be sent only upon written request to the Office of Procurement and Contracts at the above address. Telephone requests for Application Kits will not be accepted.

SUPPLEMENTARY INFORMATION: The collection of information requirements for the CHRB program were submitted to the Office of Management and Budget (OMB) for review under section 3504(h) of the Paperwork Reduction Act of 1980 and were approved under OMB control number 2529-0022, expiration date March 31, 1992.

I. Program Background

Section 808(e) of title VIII of the Civil Rights Act of 1968 (the Act) (42 U.S.C. 3608(e)) requires the Secretary to "cooperate with and render technical assistance to Federal, State, local and other public or private agencies, organizations, and institutions which are formulating or carrying on programs to prevent or eliminate discriminatory housing practices" and to "administer the programs and activities relating to housing and urban development in a manner affirmatively to further the policies of this title." Section 809 of the Act further directs the Secretary to conduct educational and conciliatory activities to further the purposes of the Act, call conferences of persons in the housing industry and others to acquaint them with the provisions of the Act and ways of implementing its provisions, seek their cooperation for programs of voluntary compliance and of enforcement.

In order to achieve the directives cited above, HUD developed the Voluntary Affirmative Marketing Agreement (VAMA) Program. This nationwide program focuses on local efforts to assure nondiscrimination in the sale, rental, and financing of housing and in the provision of services and facilities associated with those activities. The goal of the VAMA program is to assure that individuals of similar income levels in the same housing market have available to them a similar range of choices in housing regardless of their race, color, religion, sex, handicap, familial status, or national origin.

Consistent with its responsibilities under title VIII of the Act, HUD has negotiated voluntary agreements with the National Association of Realtors, the National Association of Real Estate Brokers, the National Association of Real Estate License Law Officials, and the National Association of Home Builders, as well as a model agreement for adoption by local apartment associations. These voluntary agreements, or VAMAs, are intended to promote a broad equal opportunity program designed to assure that housing will be marketed on a nondiscriminatory basis. Signatories to a VAMA agree to conduct certain programs and activities to acquaint communities with equal housing opportunity, to establish office procedures ensuring that there is no denial of equal professional service, and to make available materials that explain the commitment of signatories to the goal of fair housing. The VAMAs, approved by national housing industry associations, are implemented by local member firms of those associations. The model agreement approved by the National Association of Real Estate License Law Officials is implemented by the individual State agencies concerned with real estate licensing.

HUD's commitment under the VAMAs is to provide technical assistance to local housing industry groups that are signatories to the agreements. This assistance is provided through CHRBs, which were established by HUD to assist the local housing industry groups in implementing VAMA commitments. CHRBs are composed of volunteer representatives of community organizations dedicated to equal housing opportunity.

In 1981, Congress appropriated funds to assist CHRBs in carrying out their responsibility to assess the progress of local housing industry groups in implementing the goals of the VAMAs. From 1982 to 1988, 545 one-year grants, ranging from $15,000 to $25,000, were awarded to 366 local CHRBs. CHRBs have used these funds for a variety of activities that assist the local housing industry groups to achieve the goals of the VAMAs. Although most CHRBs carried on activities that were useful to the local industry group signatories and effective in their local communities in advancing equal housing opportunity, not all CHRBs have monitored the requirements of the VAMAs with equal vigor.

In March 1989, HUD's Inspector General released an audit of the funding component of the CHRB program, which revealed significant deficiencies in: (1) assessment of effectiveness of local VAMAs by CHRBs; (2) accountability for grant funds by CHRBs; and (3) monitoring and training for funded CHRBs by HUD staff.

In an effort to address CHRB problems identified in the audit, HUD will be determining, through the 1989 funding, the most effective and efficient way the CHRBs can achieve their objectives. Therefore, the 1989 funding round will contain various program modifications: (1) Increased grant amounts tied to the grantee's proposed activities; (2) longer time for program implementation; (3) selection of grantees conducted by the Headquarters Office of Fair Housing and Equal Opportunity; (4) bonus selection points for applications with matching sources of funds; and (5) improved accounting and contracting procedures. The level of funding in 1989 will be $950,000.

Beginning immediately, HUD will revamp its funding programs in support of title VIII of the Act with the intention of focusing its efforts toward more effective support of the Fair Housing Amendments Act. HUD does not anticipate that CHRBs or other voluntary organizations will receive further funding until this program revision has been accomplished.

II. Eligible Applicants for Funding

In order to participate in the CHRB program for the first time, an applicant must be a CHRB as described in 24 CFR 120.20 and must otherwise meet the criteria contained in part 120, including having been in existence for at least six months before the publication date of this Notice.

A previously funded applicant must meet the first-time eligibility criteria described above, and must submit evidence that it accomplished at least two of the following activities during the grant year for which it received funding:

(1) Completed two activities, described in the Application Kit, that addressed specifically the objectives of the VAMA to provide information and services that will enable all buyers and renters to have a free housing choice;

(2) Assessed local housing industry group performance under the VAMA; and

(3) Engaged in the identification of local problems and issues that impeded equal housing opportunity.

Since one of the purposes of the VAMA/CHRB program is the promotion of cooperation between the housing industry and the public, CHRBs may not sponsor, conduct, or fund programs of real estate testing.

With respect to previously funded CHRBs, HUD will consider only applicants that have successfully completed previous grant work or corrected any events or conditions that resulted in the termination of a prior CHRB grant for cause. CHRBs funded in fiscal years 1982, 1983, 1984, 1985, 1986, and 1987 are eligible for refunding. CHRBs funded in 1988 are not eligible for funding in 1989. In addition, CHRBs that received grants in prior years must ensure that final payment of grant funds for such years has been approved by the application deadline date, or they may be deemed ineligible to compete for funds under this Notice.

III. Application Requirements

Since one of the purposes of the 1989 funding competition is to determine the most effective and efficient ways CHRBs can achieve their objectives, the grant period for projects funded under this Notice will be 18 months. Grant amounts may vary, depending on the activities proposed.

Training is an essential part of the CHRB program. Therefore, all CHRBs selected for funding must set aside at least five percent of the grant funds for training purposes. HUD will provide further instructions on training requirements during the funding period.

To assure that maximum use of CHRB program funds is realized, grantees must use the majority of the funds for program costs rather than for administrative costs. CHRBs selected for funding that have excessive administrative costs in their budgets will be required to make budget adjustments in compliance with program policy. Moreover, grantees are encouraged to seek funds from other sources for continuing projects.

CHRBs applying for 1989 funding must follow the format and content requirements contained in the Application Kit.

IV. Distribution of Funding

Applicants for first-time funding will be evaluated separately from applicants for refunding to avoid any penalty to less experienced CHRBs. Sixty percent of the funds will be designated for applicants for first-time funding, and 40 percent will be designated for applicants for refunding. Any remaining funds will be used to supplement funding in either category. An applicant must identify the category under which it is applying upon submission of the application.

V. Selection Criteria

Applications will be reviewed, scored, and ranked by selected staff personnel from HUD/FHEO Headquarters and Field Offices. Projects will be ranked on the basis of the following five criteria:

1. The relationship of the proposed project to the goals of the VAMA. The principal purpose of the CHRB is to assess progress under the VAMA, provide technical assistance, and recommend and promote solutions to problems associated with the implementation of the VAMA. Accordingly, all applications must contain a project that seeks to assess the level of local VAMA implementation. Applications that do not contain information related to this project will receive a minimum number of points under this criterion. Conversely, eligible projects that can earn the maximum number of points under this first criterion are those that:

(a) Assess the effectiveness of the VAMA on the local community;

(b) Seek cooperative solutions to problems associated with implementation of the VAMA and provide assistance to the local housing industry group;

(c) Work with local VAMA signatories to develop programs that result in the expansion of minority involvement in the industry;

(d) Require participation with HUD in the annual evaluation of the effectiveness of VAMA implementation and development of follow-up evaluation materials;

(e) Translate fair housing brochures and literature into Chinese, Japanese, Vietnamese, Korean, and Khmer.

The following activities are of a lower priority:

(a) Informing the public regarding the goals of fair housing and the VAMA;

(b) Assessing community fair housing needs and problems or successes;

(c) Expanding public awareness of housing opportunities in the community; and

(d) Seeking expanded use of the HUD Fair Housing Publisher's Notice in major newspapers.

Since the VAMA does not permit CHRBs to sponsor, conduct, or fund programs of real estate testing, projects relating to that activity are not acceptable and will not be funded.

2. The extent to which the proposed project(s) will assist local housing industry groups in achieving the goal of the VAMAs.

3. The commitment of the CHRB members, as indicated by the following:

(a) Regular attendance at meetings (attendance must be verified by copies of meeting minutes);

(b) Demonstrated results of activities (verified by correspondence, news reports, editorials, testimonials, etc.); and

(c) Expected results of activities (demonstrated by analysis of problems and goals).

4. The amount of relevant professional or organizational experience available to the CHRB among its membership, its community contacts and working relationships, or staff to implement the proposed projects.

5. The extent to which the proposed project does not duplicate other community fair housing efforts.

RELATIVE WEIGHTS OF THE SELECTION CRITERIA

Funding criteria	Points
Relationship of projects to VAMA goals	30
Extent to which proposed projects will affect the groups the VAMAs are designed to reach	25
Documentation of Resource Board commitment	15
Experience available to implement projects	20
Extent to which projects do not duplicate other community efforts	10
Total	100

VI. Bonus Points

Applicants may earn up to 10 bonus points to add to the selection criteria points by showing budgets that contain matching sources of funds equal to or exceeding 25 percent of the requested grant amount. The matching sources must consist of cash contributions, as opposed to donated services, labor, or other "in-kind" contributions. Documentation of all contributions must be attached to the budget.

VII. Notification of Applicants

HUD will notify all successful applicants upon selection. Unsuccessful applicants will be notified after the awards have been made. No information will be made available to applicants during the period of HUD review and evaluation, except for notification to those applicants that are declared ineligible or late.

VIII. Other Matters

The collection of information requirements contained in the Application and announced in this Notice were submitted to OMB for review under section 3504(h) of the Paperwork Reduction Act of 1980 and approved under control number 2529–0022, expiration date March 31, 1992. Information on the reporting burden is provided as follows:

Description of burden	Number of respondents	Frequency of response	Hours per response	Burden hours
Applications	110	1	180	19,800

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969. The Finding is available for public inspection between 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk, Office of the General Counsel, Department of Housing and Urban Development, Room 10276, 451 Seventh Street SW., Washington, DC 20410.

The General Counsel, as the Designated Official under Executive Order 12606, *The Family*, has determined that the policies announced in this Notice may have a significant impact on the formation, maintenance, and general well-being of families to the extent that the technical assistance provided to local housing industry groups through the CHRB program encourages efforts by those groups to assure nondiscrimination in the sale, rental, and financing of housing. Providing families with a choice in housing regardless of race, color, religion, sex, handicap, familial status, or national origin supports family values by helping families remain together and by enabling them to live in decent, safe, and sanitary housing.

The General Counsel has determined, as the Designated Official for HUD under section 6(a) of Executive Order 12612, *Federalism*, that the policies contained in this Notice will not have federalism implications and, thus, are not subject to review under the Order. The CHRB program assists local housing industry groups, which are private businesses, in their efforts to encourage voluntary compliance with Title VIII of the Civil Rights Act of 1968.

This program is listed in the catalog of Federal Domestic Assistance under program number 14.403, Community Housing Resource Program.

Dated: September 28, 1989.

Leonora L. Guarraia,

Deputy Assistant Secretary for Enforcement and Compliance.

[FR Doc. 89–28682 Filed 12–11–89; 8:45 am]

BILLING CODE 4210–28–M

federal register

Tuesday
December 12, 1989

Part III

Environmental Protection Agency

Twenty-fifth Report of the Interagency Committee to the Administrator; Receipt of Report and Request for Comments Regarding Priority List of Chemicals; Notice

40 CFR Parts 712 and 716

Preliminary Assessment Information and Health and Safety; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-41032; FRL 3665-4]

Twenty-fifth Report of the Interagency Testing Committee to the Administrator; Receipt of Report and Request for Comments Regarding Priority List of Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Interagency Testing Committee (ITC), established under section 4(e) of the Toxic Substances Control Act (TSCA), transmitted its Twenty-Fifth Report to the Administrator of EPA on November 1, 1989. This report, which revises and updates the Committee's priority list of chemicals, adds 13 chemicals to the list for priority consideration by EPA in promulgation of test rules under section 4(a) of the Act. This list contains five designated chemicals, one intent-to-designate chemical, and seven recommended without designation chemicals. The Twenty-Fifth Report is included with this notice. The designated chemicals are: pentabromodiphenyl ether (CAS No. 32534-81-9), octabromodiphenyl ether (CAS No. 32536-52-0), decabromodiphenyl ether (CAS No. 1163-19-5), hexabromocyclododecane (CAS No. 3194-55-6), and 1,2-bis(2,4,6-tribromophenoxy)ethane (CAS No. 37853-59-1). These chemicals are designated for response within 12 months. Therefore, in response to ITC's designation, EPA will either initiate rulemaking under section 4(a) of TSCA, or publish a **Federal Register** notice explaining the reasons for not initiating such rulemaking within 12 months.

The chemical 4-Vinylcyclohexene (CAS No. 100-40-3), is recommended with intent-to-designate.

The chemicals recommended without intent-to-designate are: 2,4,6-tribromophenol (CAS No. 118-79-6), tetrabromophthalic anhydride (CAS No. 632-79-1), dibromoneopentyl glycol (CAS No. 3296-90-0), Ethylene Bis-(tetrabromophthalimide) (CAS No. 32588-76-4), ethylene bis(5,6-dibromonorbornane-2,3-dicarboximide) (CAS No. 41291-34-3), tribrominated polystyrene (CAS No. 57137-10-7), and ethylene bis(pentabromophenoxide) (CAS No. 61262-53-1).

The ITC has removed one chemical, 1,6-hexamethylene diisocyanate (CAS No. 822-06-0), from the priority list because the EPA published a Notice of Proposed Rulemaking on May 17, 1989 (54 FR 21240).

EPA invites interested persons to submit written comments on the report, and to attend Focus Meetings to help narrow and focus issues raised by the ITC's recommendations. Additionally, EPA is soliciting interest in public participation in the consent agreement process for 4-vinylcyclohexene.

DATES: Written comments should be submitted by January 12, 1990. Written notice interest in being designated an "interested party" to the development of a consent agreement for 4-vinylcyclohexene should be submitted by January 12, 1990. The procedures for negotiations are described in 40 CFR 790.22. All written submissions should bear the identifying docket number (OPTS 41032; FRL 3665-4).

A Focus Meeting will be held on December 13, 1989.

ADDRESS: Send written submissions to: TSCA Public Docket Office (TS-793), Office of Toxic Substances, Environmental Protection Agency, Rm. NE G-004, 401 M St., SW., Washington, DC 20460.

Submissions should bear the document control number (OPTS-41032; FRL 3665-4).

The public record supporting this action, including comments, is available for public inspection in Rm. NE G-004 at the address noted above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Focus Meeting will be held at EPA Headquarters, Rm. 103 NE Mall, 401 M St., SW., Washington, DC. Persons planning to attend the focus Meeting, and/or seeking to be informed of subsequent public meetings on these chemicals, should notify the Environmental Assistance Division at the address listed below. To ensure seating accommodations at the Focus Meetings, persons interested in attending are asked to notify EPA at least one week ahead of the scheduled date.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Rm. E-543B, Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: EPA has received the TSCA Interagency Testing Committee's Report to the Administrator.

I. Background

TSCA (Pub. L. 94-469, 90 Stat. 2003 et seq; 15 U.S.C. 2601 et seq.) authorizes the Administrator of EPA to promulgate regulations under section 4(a) requiring testing of chemical substances and mixtures in order to develop data relevant to determining the risks that such chemical substances and mixtures may present to health and the environment. Section 4(e) of TSCA established an Interagency Testing Committee to make recommendations to the Administrator of EPA on chemical substances and mixtures to be given priority consideration in proposing test rules under section 4(a). Section 4 (e) directs the ITC to revise its list of recommendations at least every 6 months as necessary. The ITC may "designate" up to 50 substances and mixtures at any one time for priority consideration by the Agency. The ITC's Twenty-Fifth Report was received by the administrator on November 1, 1989, and follows this Notice. The Report

adds 13 substances to the TSCA section 4(e) priority list.

II. Written and Oral Comments and Public Meetings

EPA invites interested persons to submit detailed comments on the ITC's new recommendations. The Agency is interested in receiving information concerning additional or ongoing health and safety studies on the subject chemicals as well as information relating to the human and environmental exposure to these chemicals.

A notice is published elsewhere in today's **Federal Register** adding the substances recommended in the ITC's Twenty-Fifth Report to the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR part 716), which requires the reporting of unpublished health and safety studies on the listed chemicals. These chemicals also will be added to the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR part 712) published elsewhere in this issue. The section 8(a) rule requires the reporting of production volume, use, exposure, and release information on the listed chemicals.

Focus Meetings will be held to discuss relevant issues pertaining to these chemicals and to narrow the range of issues/effects which will be the focus of the Agency's subsequent activities in responding to the ITC recommendations. EPA is not planning to hold a separate Focus Meeting on the recommended chemicals because the issues raised on the designated flame retardants should be applicable to the non-designated flame retardants.

The Focus Meetings will be held on December 13, 1989, as follows:

10:00 a.m.

Pentabromodiphenyl ether, octabromodiphenyl ether, decabromodiphenyl ether, tribromophenoxy ethane, hexabromocyclododecane.

1:00 p.m.

vinylcycylohexene.

They will be held at EPA Headquarters, Rm. 103 NE Mall, 401 M St., SW., Washington, DC. These meetings are intended to supplement and expand upon written comments submitted in response to this notice.

Persons wishing to attend these meetings, or subsequent meetings on these chemicals, should call Michael Stahl, Environmental Assistance Division, at the telephone number listed above at least 1 week in advance.

This notice also serves to invite persons interested in participating in or monitoring negotiations for a consent agreement for 4-vinylcyclohexene to notify EPA no later than [insert date 30 days after date of publication in the **Federal Register**]. The Procedures for negotiations are described in 40 CFR 790.22. All Written submissions should bear the identifying docket number (OPTS-41032; FRL 3665-4).

III. Status of List

In addition to adding the 13 recommendations to the priority list, the ITC's Twenty-Fifth Report notes the removal of one chemical, 1,6-hexamethylene diisocyanate, from the list. The current list contains 6 designated substances, 6 chemicals recommended with intent-to-designate, and 20 recommended without designation substances.

Authority: 15 U.S.C. 2603.

Dated: December 1, 1989.

Charles M. Auer,

Acting Director, Existing Chemical Assessment Division.

Twenty-fifth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency

Summary

Section 4 of the Toxic Substances Control Act of 1976 (TSCA, Pub. L. 94-469) provides for the testing of chemicals commerce that may present an unreasonable risk of injury to health and the environment. It also provides for the establishment of a committee (ITC), composed of representatives from eight designated federal agencies, to recommend chemical substances and mixtures (chemicals) to which the Administrator of the U.S. Environmental Protection Agency (EPA) should give priority consideration for the promulgation of testing rules.

Section 4(e)(1)(A) of TSCA directs the Committee to recommend the EPA Administrator chemicals to which the Administrator should give priority consideration for the promulgation of testing rules pursuant to section 4(a). The Committee is required to designate those chemicals, from among its recommendations, which the Administrator should respond within 12 months by either initiating a rulemaking proceeding under section 4(a) or publishing the Administrator's reason for not initiating such a proceeding. At least every 6 months, the Committee makes those revisions the TSCA section 4(e) Priority List that it determines to be necessary and transmits them to the EPA Administrator.

As a result of its deliberations, the Committee is revising the TSCA section 4(e) Priority List by the addition of one chemical and one group of chemicals.

The Priority List is divided into three parts: Part A contains those recommended chemicals and groups designated for priority consideration and response by the EPA Administrator within 12 months. Part B contains chemicals and groups of chemicals recommended with intent-to-designate. This category was established by the Committee in its seventeenth report (50 FR 47603; November 19, 1985) to take advantage of rules promulgating automatic reporting requirements for non-designated ITC recommendations under the section 8(a) Preliminary Assessment rule and the TSCA section 8(d) Health and Safety Data Reporting rule. Information received following recommendation with intent-to-designate may influence the Committee to either designate or not designate the chemicals or groups of chemicals in a subsequent report to the administrator. Part C contains chemicals and groups of chemicals that have been recommended for priority consideration by EPA without being designated for response within 12 months. The changes to the Priority List are presented, together with the types of testing recommended, in the following Table 1:

TABLE 1—ADDITIONS TO THE SECTION 4(e) PRIORITY LIST NOVEMBER 1989

Chemical/Group	Recommended studies
A. Designated for response within 12 months:	
Brominated flame retardants:	
Brominated diphenyl ethers	
Pentabromodiphenyl ether [1] CAS No. 32534-81-9	Chemical Fate: Water solubility; octanol/water partition coefficient; vapor pressure; sediment and soil adsorption; photolysis; aerobic and anaerobic biodegradation. Health Effects: Pharmaco Kinetics; metabolism; neurotoxicity; reproductive and developmental toxicity; chronic toxicity and oncogenicity testing. Ecological Effects: Acute Toxicity to algae; chronic toxicity to fish and aquatic invertebrates and toxicity to benthic organisms.
Octabromodiphenyl ether [2] CAS No. 32536-52-0	Chemical Fate: Water solubility; octanol/water partition coefficient; vapor pressure; sediment and soil adsorption; photolysis; anaerobic biodegradation rate. Aerobic biodegradation if pentabromodiphenyl ether aerobically biodegrades. Health Effects: Pharmacokinetics; metabolism; neurotoxicity; reproductive toxicity; chronic toxicity and oncogenicity testing. Ecological Effects: Acute toxicity to algae; acute chronic toxicity to fish, and aquatic invertebrates and toxicity to benthic organisms only if penta bromodiphenyl ether causes adverse ecological effects.
Decabromodiphenyl ether [3] CAS No. 1163-19-5	Chemical Fate: Water solubility; octanol/water partition coefficient; vapor pressure; sediment and soil adsorption; photolysis; anaerobic biodegradation. Aerobic biodegradation if pentabromodiphenyl ether aerobically biodegrades. Health Effects: Reproductive toxicity. Ecological Effects: Acute and chronic toxicity to fish and aquatic invertebrates and toxicity to benthic organisms only if pentabromodiphenyl ether causes adverse ecological effects.
1,2-Bis(2,4,6-tribromophenoxy)-ethane [4] CAS No. 37853-59-1	Chemical Fate: Vapor pressure; sediment and soil adsorption; photolysis; aerobic and anaerobic biodegradation. Health Effects: Chronic toxicity with emphasis on hepatotoxicity, neurotoxicity and reproductive effects. Ecological Effects: Acute toxicity to algae, fish and aquatic invertebrates; chronic toxicity to fish and aquatic invertebrates and toxicity to benthic organisms based on results of its acute toxicity testing.
Hexabromocyclododecane [5] CAS No. 3194-55-6	Chemical Fate: Vapor pressure; sediment and soil adsorption; anaerobic biodegradation.

TABLE 1—ADDITIONS TO THE SECTION 4(e) PRIORITY LIST NOVEMBER 1989—Continued

Chemical/Group	Recommended studies
	Health Effects: Pharmacokinetics; metabolism, subchronic toxicity. Ecological Effects: Acute toxicity to fish and aquatic invertebrates; chronic toxicity to fish and aquatic invertebrates and toxicity to benthic organisms based on results of its acute toxicity testing.
B. Recommended with Intent-to-Designate:	
4-Vinylcyclohexene [6] CAS No. 100-40-3	Chemical Fate: Aqueous volatilization rate. Health Effects: Pharmacokinetics and oncogenicity by inhalation route of exposure. Ecological Effects: None.
C Recommended Without Being Designated for Response Within 12 Months:	
Brominated flame retardants:	
2,4,6-Tribromophenol [7] CAS No. 118-79-6	Chemical Fate: Chemical properties and persistence. Health Effects: Chronic toxicity, except for dibromoneopentyl glycol. Ecological Effects: Chronic toxicity.
Tetrabromophthalic anhydride [8] CAS No. 632-79-1	Chemical Fate: Chemical properties and persistence. Health Effects: Chronic toxicity, except for dibromoneopentyl glycol. Ecological Effects: Chronic toxicity.
Dibromoneopentyl glycol [9] CAS No. 3296-90-0	Chemical Fate: Chemical properties and persistence. Health Effects: Chronic toxicity, except for dibromoneopentyl glycol. Ecological Effects: Chronic toxicity.
Ethylene bis-(tetrabromophthalimide) [10] CAS No. 32588-76-4	Chemical Fate: Chemical properties and persistence. Health Effects: Chronic toxicity, except for dibromoneopentyl glycol. Ecological Effects: Chronic toxicity.
Ethylene bis(5,6-dibromonorbornane-2,3-dicarboximide) [11] CAS No. 41291-34-3.	Chemical Fate: Chemical properties and persistence. Health Effects: Chronic toxicity, except for dibromoneopentyl glycol. Ecological Effects: Chronic toxicity.
Tribrominated polystyrene [12] CAS No. 57137-10-7	Chemical Fate: Chemical properties and persistence. Health Effects: Chronic toxicity, except for dibromoneopentyl glycol. Ecological Effects: Chronic toxicity.
Ethylene bis(pentabromo phenoxide) [13] CAS No. 61262-53-1 Health Effects: Chronic toxicity, except for dibromoneopentyl glycol.. Ecological Effects Chronic toxicity.	Chemical Fate: Chemical properties and persistence.

Notes: CA Index Names (9CI)
[1] Benzene, 1,1'-oxybis-, pentabromo deriv.
[2] Benzene, 1,1'-oxybis-, octabromo deriv.
[3] Benzene, 1,1'-oxybis[2,3,4,5,6]-pentabromo-
[4] Benzene,1,1'-(1,2-ethanediylbis(oxy)bis)2,4,6-tribromo
[5] Cyclododecane, 1,2,5,6,9,10-hexabromo-
[6] Cyclohexene, 4-ethenyl-
[7] Phenol, 2.4,6-Tribromo-
[8] 1,3-Isobenzofurandione, 4,5,6,7-tetrabromo-
[9] 1,3-Propanediol, 2,2-bis(bromomethyl)-
[10] 1H-Isoindole-1,3(2H)-dione, 2,2'-(1,2-ethanediyl)bis[4,5,6,7-tetrabromo-
[11] 4,7-Methano-1H-isoindole-1,3(2H)-dione, 2,2'-(1,2-ethanediyl)bis[5,6-dibromohexahydro-
[12] Benzene, ethenyl-, tribromo deriv., homopolymer
[13] Benzene, 1,1'-[1,2-ethanediylbis(oxy)]bis[2,3,4,5,6-pentabromo-(1,2-bis (pentabromophenoxy)ethane

TSCA Interagency Testing Committee

Statutory Member Agencies and Their Representatives

Council on Environmental Quality
  John C. Jens, Member
Department of Commerce
  Raimundo Prat, Alternate
Environmental Protection Agency
  Letitia Tahan, Member (see Note 1)
  Vincent Nabholtz, Alternate
National Cancer Institute
  Richard Adamson, Member
  Thomas P. Cameron, Alternate
National Institute of Environmental Health Sciences
  James K. Selkirk, Member and Chairperson
National Institute for Occupational Safety and Health
  Rodger L. Tatken, Alternate
National Science Foundation
  Carter Kimsey, Member (see Note 2)
  Jarvis L. Moyers, Alternate
Occupational Safety and Health Administration
  Loretta Schuman, Member and Vice Chairperson (see Note 3)
  Stephen Mallinger, Alternate

Liaison Agencies and Their Representatives

Agency for Toxic Substances and Disease Registry
  Deborah Barsotti
Consumer Product Safety Commission
  Lakshmi C. Mishra
Department of Agriculture
  Richard M. Parry, Jr.
  Elise A.B. Brown
Department of Defense
  Harry Salem
  Melvin E. Anderson
Department of the Interior
  Clifford P. Rice (see Note 4)
  Barnett A. Rattner
Food and Drug Administration
  Arnold Borsetti
National Library of Medicine
  Vera Hudson
National Toxicology Program
  Dorothy Canter
Committee Staff
  Robert H. Brink, Executive Secretary (see Note 5)
  Norma Williams, ITC Program Specialist
Support Staff
  Alan Carpien—Office of the General Counsel, EPA

Notes:

(1) Appointed on August 17, 1989.
(2) Appointed on September 14, 1989.
(3) Appointed on September 14, 1989.
(4) Appointed on October 2, 1989.
(5) Robert Brink died on July 31, 1989. He served 4 years distinguished and faithful service as the ITC Executive Secretary. The Committee deeply regrets his passing. His dedication and outstanding contributions to the goals of the Committee will long be remembered.

The Committee acknowledges and is grateful for the assistance and support given the ITC by the staff of Syracuse Research Corp. (technical support contractor) and personnel of the EPA Office of Toxic Substances.

Chapter 1—Introduction

1.1 *Background.* The TSCA Interagency Testing Committee (Committee) was established under section 4(e) of the Toxic Substances Control Act of 1976 (TSCA, Pub. L. 94-469). The specific mandate of the Committee is to recommend to the Administrator of the U.S. Environmental

Protection Agency (EPA) chemical substances and mixtures in commerce that should be given priority consideration for the promulgation of testing rules to determine their potential hazard to human health or the environment. TSCA specifies that the Committee's recommendations shall be in the form of a Priority List, which is to be published in the **Federal Register.** The Committee is directed by section 4(e)(1)(A) of TSCA to designate those chemicals on the Priority List to which the EPA Administrator should respond within 12 months by either initiating a rulemaking proceeding under section 4(a) or publishing the Administrator's reason for not initiating such a proceeding. There is no statutory time limit for EPA response regarding chemicals that ITC has recommended but not designated for response within 12 months.

At least every 6 months, the Committee makes those revisions in the section 4(e) Priority List that it determines to be necessary and transmits them to the EPA Administrator.

The Committee is composed of representatives from eight statutory member agencies and eight liaison agencies. The specific representatives and their affiliations are named in the front of this report. The Committee's chemical review procedures and priority recommendations are described in previous reports (Refs. 1 through 8).

1.2 *Committee's previous reports.* Twenty-four previous reports to the EPA Administrator have been issued by the Committee and published in the **Federal Register** (Refs. 1 through 9). Seventy-seven chemicals and 20 groups of chemicals were recommended for priority consideration by the EPA Administrator and designated for response within 12 months. In addition, 12 chemicals and five groups of chemicals were recommended without being designated. Overall, in the 24 reports to the EPA Administrator, the Committee has recommended testing for 89 chemicals and 25 groups of chemicals. A complete list of recommended chemicals may be obtained by contacting: Dr. John D. Walker, ITC Acting Executive Secretary, U.S. Environmental Protection Agency (TS-792), 401 M St. SW., Washington, DC 20460, (202) 382-3820.

1.3 *Committee's activities during this reporting period.* Between April 21, 1989 and October 26, 1989, the Committee reviewed chemicals from nominations by Member Agencies, Liaison Agencies and State Agencies and from its sixth scoring exercise.

The Committee contacted chemical manufacturers and trade associations to request information that would be of value in its deliberations. Most of those contacted provided unpublished information on current production, exposure, uses, and effects of chemicals under study by the Committee.

During this reporting period, the Committee also reviewed available information on 173 chemicals and three groups of over 175 chemicals. One chemical and one group of chemicals were selected for addition to the section 4(e) Priority List; four chemicals were deferred indefinitely. For one group of chemicals the Committee is requesting that EPA propose TSCA section 8(a) and 8(d) rules. The remaining chemicals are still under study.

During this reporting period, the Committee reviewed several for Your Information (FBI), 8(d) and 8(e) documents that are stored on microfiche in the TSCA Public Docket Office, Office of Toxic Substances, Environmental Protection Agency, Room G-004, NE Mall, 401 M St. SW., Washington, DC 20460. These documents are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161 (1-800-336-4700), and from Chemical Information Systems, Inc., 7215 York Road, Baltimore, Maryland 21212 (1-800-CIS-USER). The Committee referenced several of these documents in Chapter 2 of this report and readers are referred to the above address to obtain further information. Beginning with this report, interested parties can also obtain, from the above address, copies of references and information reviews supporting recommendations of chemicals in this report.

The Committee examined testing information on several brominated flame retardants (BFRs) because of concerns related to potential long-term health and ecological effects. Most of the testing was conducted using technical-grade, commercially-available products. The Committee previously designated the following BFRS in the following numbered reports: #2, 1,2-epoxy-3-bromopropane (CAS No. 3132-64-7); #4, 2,4,6-tribromoaniline (CAS No. 147-82-0); #14, 1,2-dibromo-4-(1,2-dibromomethyl) cyclohexane (CAS No. 3322-93-8); #15, pentabromoethylbenzene (CAS No. 85-22-3); and #16, tetrabromobisphenol A (CAS No. 79-94-7). Subsequently, the EPA published **Federal Register** notices in response to these designations.

A few of the BFRs examined by the Committee were listed in the June 22, 1982, Preliminary Assessment Information TSCA section 8(a) final rule (PAIR) which required submission of data quantities of chemicals manufactured, amounts directed to certain classes and uses and the potential exposures and environmental releases associated with the manufacturers' own and immediate customers' processing of the chemicals (47 FR 26992).

A number of the BFRs examined by the Committee were listed in the June 5, 1987, halogenated dibenzo-p-dioxins (HDDs) and dibenzofurans (HDFs) final rule (52 FR 21412). This rule required analytical testing of certain chemicals for HDD/HDF contamination, submission of existing data on contamination of these chemicals with HDDs/HDFs, submission of health and safety studies on HDDs/HDFs and submission of worker allegations of significant adverse reactions to HDDs/HDFs under TSCA sections 4 and 8.

In a February 24, 1988, **Federal Register** notice (53 FR 5466), the Committee requested information on several BFRs.

The Committee is continuing to review information on the chloroalkyl phosphates, recommended with intent-to-designate in the 23rd Report (53 FR 46262), and has not reached a conclusion whether or not to designate one or more of those chemicals.

1.4 *The TSCA section 4(e) Priority List.* Section 4(e)(1)(B) of TSCA directs the Committee to: "* * * make such revisions in the [priority] list as it determines to be necessary and * * * transmit them to the Administrator together with the Committee's reasons for the revisions." Under this authority, the Committees revising the List by adding one chemical, 4-vinylcyclohexene (CAS No. 100-40-3) and one group of chemicals, brominated flame retardants (BFRs). The BFRs include a subgroup of brominated diphenyl ethers [pentabromodiphenyl ether (CAS No. 32534-81-9), octabromodiphenyl ether (CAS No. 32536-52-0), and decabromodiphenyl ether (CAS No. 1163-19-5)], and several other BFRs, including 1,2-bis(2,4,6-tribromophenoxy) ethane (CAS No. 37853-59-1), hexabromocyclododecane (CAS No. 3194-55-6), 2,4,6-tribromophenol (CAS No. 118-79-6), tetrabromophthalic anhydride (CAS No. 632-79-1), dibromoneopentyl glycol (CAS No. 3296-90-0), ethylene bis(tetrabromophthalimide) (CAS No. 32588-76-4), ethylene bis(5,6-dibromonorbornane-2,3-dicarboximide) (CAS No. 41291-34-3), tribrominated polystyrene (CAS No. 57137-10-7), and ethylene bis(pentabromo phenoxide)

(CAS No. 61262–53–1). 1,6-Hexamethylene diisocyanate (CAS No. 822–06–0) was removed from the Priority List because the EPA published a Notice of Proposed Rulemaking on May 17, 1989 (54 FR 21240).

The Priority List is divided in the following Table 2 into three parts; namely, A. Chemicals and Groups of Chemicals Designated for Response Within 12 Months, B. Chemicals and Groups Chemicals Recommended with Intent-to-Designate, and C. Chemicals and Groups of Chemicals Recommended Without Being Designated for Response Within 12 Months. Table 2 follows:

TABLE 2—THE TSCA SECTION 4(e) PRIORITY LIST NOVEMBER 1989

Entry	Date of designation
A. Chemicals and groups of chemicals recommended and designated for response within 12 months:	
Crotonaldehyde	November 1988
Brominated flame retardants	
Brominated diphenyl ethers	
Pentabromodiphenyl ether	November 1989
Octabromodiphenyl ether	November 1989
Decabromodiphenyl ether	November 1989
1,2-Bis(2,4,6-tribromophenoxy)ethane	November 1989
Hexabromocyclododecane	November 1989
B. Chemicals and groups of chemicals recommended with intent-to-designate:	
Chloroalkyl phosphates	
Tris(2-chloroethyl)phosphate	November 1988
Tris(2-chloro-1-propyl)phosphate	November 1988
Tris(1-chloro-2-propyl)phosphate	November 1988
Tris(1,3-dichloro-2-propyl)phosphate	November 1988
Tetrakis(2-chloroethyl)ethylene diphosphate	November 1988
4-Vinylcyclohexene	November 1989
C. Chemicals and groups of chemicals recommended without being designated for response within 12 months:	
C.I. Disperse blue 79	November 1986
N-[5-[bis[2-(acetyloxy)ethyl]amino] -2-[(2-bromo-4,6-dinitrophenyl)azo]- 4-methoxy phenyl]-acetamide	May 1987
N-[5-[bis[2-(acetyloxy)ethyl]amino] -2-[2-chloro-4,6-dinitrophenyl)azo]- 4-methoxy phenyl]-acetamide	May 1987
N-[5-[bis[2-(acetyloxy)ethyl]amino] -2-[(2-chloro-4,6-dinitrophenyl)azo]- 4-ethoxy phenyl]-acetamide	May 1987
Imidazolium quaternary ammonium compounds:	
4,5-dihydro-1-methyl-2-nortallow alkyl-1-(2-tallow amidoethyl), Me sulfates	May 1988
Ethoxylated quaternary ammonium compounds:	
Ethanaminium, 2-amino- N-(2-aminoethyl) -N-(2-hydroxyethyl)-N-methyl-, N,N-ditallow acyl derivs., Me sulfates (salts)	May 1988
Poly(oxy-1,2-ethanediyl),α-[2-[bis(2-aminoethyl)-methylammonio]-ethyl]-ω-hydroxy-, N,N'-dicoco acyl derivs., Me sulfates (salts)	May 1988
Poly(oxy-1,2-ethanediyl),α-[2-[bis(2-aminoethyl)-methylammonio]-ethyl]-ω-hydroxy-, N,N'-bis (hydrogenated tallow acyl) derivs., Me sulfates (salts).	May 1988
Poly(oxy-1,2-ethanediyl),α-[2-[bis(2-aminoethyl)-methylammonio-ethyl]-ω-hydroxy-, N,N'-ditallow acyl derivs., Me sulfates (salts)	May 1988
Poly[oxy(methyl-1,2-ethanediyl)],α-[2-[bis(2-aminoethyl)-methylammonio]-methylethyl] -ω-hydroxy-, N,N'-,ditallow acyl derivs., Me sulfates (salts).	May 1988
Poly(oxy-1,2-ethanediyl),α-[3-[bis(2-aminoethyl)-methylammonio]-2-hydroxypropyl]-ω-hydroxy-, N-coco acyl derivs., Me sulfates (salts)	May 1988
Poly(oxy-1,2-ethanediyl),α-[2-[bis(2-aminoethyl)-methylammonio]-ethyl]-ω-hydroxy-, N,N'-di-C14-18 acyl derivs., Me sulfates, salts)	May 1988
Butyraldehyde	November 1988
2,4,6-Tribromophenol	November 1989
Tetrabromophthalic anhydride	November 1989
Dibromoneopentyl glycol	November 1989
Ethylene bis(tetrabromophthalimide)	November 1989
Ethylene bis(5,6-dibromonorbornane-2,3-dicarboximide)	November 1989
Tribrominated polystyrene	November 1989
Ethylene bis(pentabromo phenoxide)	November 1989

References

(1) Sixteenth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, May 21, 1985, 50 FR 20930–20939. Includes references to Reports 1 through 15 and an annotated list of removals.

(2) Seventeenth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, November 19, 1985, 50 FR 47603–7612.

(3) Eighteenth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, May 19, 1986, 51 FR 18368–18375.

(4) Nineteenth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, November 14, 1986, 51 FR 41417–41432.

(5) Twentieth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, May 20, 1987, 52 FR 19020–19026.

(6) Twenty-first Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, November 20, 1987, 52 FR 44830–44837.

(7) Twenty-second Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, May 20, 1988, 53 FR 18196–18210.

(8) Twenty-third Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, November 16, 1988, 53 FR 46262–46278.

(9) Twenty-fourth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, July 27, 1989, 54 FR 31248–31249.

Chapter 2—Recommendations of the Committee

2.1 *Chemicals recommended for priority consideration by the EPA Administrator.* As provided by section 4(e)(1)(B) of TSCA, the Committee is adding to the section 4(e) Priority List one chemical substance, 4-vinylcyclohexene (VCH) (CAS No. 100–40–3), and one group of chemical substances, the brominated flame retardants (BFRs). The BFRs consist of a subgroup of brominated diphenylethers

(BDPEs) [pentabromodiphenyl ether (PBDPE) (CAS No. 32534–81–9), octabromodiphenyl ether (OBDPE) (CAS No. 32536–52–0), and decabromodiphenyl ether (DBDPE) (CAS No. 1163–19–5)] and several other BFRs, including 1,2-bis(2,4,6-tribromophenoxy) ethane (BTBPE) (CAS No. 37853–59–1), hexabromocyclododecane (HBCD) (CAS No. 3194–55–6), 2,4,6-tribromophenol (TBrP) (CAS No. 118–79–6), 3,4,5-6-tetrabromophthalic anhydride (TBPA) (CAS No. 632–79–1), dibromoneopentyl glycol (DBNG) (CAS No. 3296–90–0), ethylene bis(tetrabromophthalimide) (EBTBPA) (CAS No. 32588–76–4), ethylene bis(5,6-dibromonorbornane 2,3-dicarboximide) (EBDNDC) (CAS No. 41291–34–3), tribrominated polystyrene (TBPS) (CAS No. 57137–10–7) and ethylene bis(pentabromophenoxide) (EBPBP) (CAS No. 61262–53–1). The recommendation of these chemicals is made after considering the factors identified in section 4(e)(1)(A) and other relevant information, such as the chemical testing information deficiencies of Member Agencies.

2.2 *Chemicals designated for response within 12 months*—2.2.a *Brominated flame retardants.* Five BFRs that are produced in substantial quantities and that have been detected in the environment or have potential to cause adverse effects were designated for testing.

2.2.a *Brominated diphenylethers—Summary of recommended studies.* The chemical fate and environmental effects testing recommendations are summarized in the following table 3:

TABLE 3—CHEMICAL FATE AND ENVIRONMENTAL EFFECTS TESTING RECOMMENDED (R), TRIGGERED IF PBDPE IS BIODEGRADED (B), TRIGGERED IF PBDPE IS TOXIC (T) OR NOT RECOMMENDED (N) FOR BDPEs

Test	PBDPE	OBDPE	DBDPE
Chemical Fate:			
Water solubility.	R	R	R
Log octanol/water partition coefficient (log P).	R	R	
Vapor pressure.	R	R	R
Sediment and soil adsorption.	R	R	R
Photolysis	R	R	R
Acrobic biodegradation.	R	B	B
Anaerobic biodegradation.	R	R	R
Environmental Effects:			
Algal bioassay.	R	T	N
Fish acute	R	T	T
Aquatic invertebrate acute.	R	T	T
Fish chronic	R	T	T
Aquatic invertebrate chronic.	R	T	T
Benthic organism toxicity.	R	T	T

The health effects testing recommendations for the BDPEs are listed below.

1. *Pentabromodiphenyl ether.* Pharmacokinetics and metabolism, neurotoxicity, chronic toxicity, reproductive and developmental toxicity and oncogenicity.

2. *Octabromodiphenyl ether.* Pharmacokinetics and metabolism, neurotoxicity, chronic toxicity, reproductive toxicity and oncogenicity.

3. *Decabromodiphenyl ether.* Reproductive toxicity. The physical-chemical properties of the BDPE isomeric mixtures recommended for testing are listed in the following Table 4.

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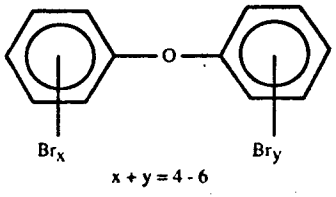
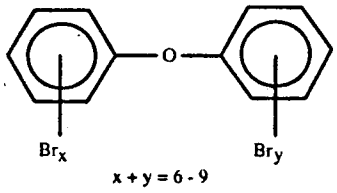
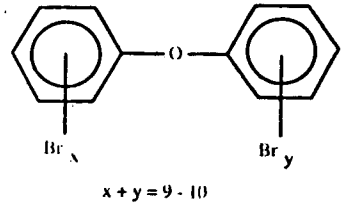
Table 4. Physical-chemical properties of BDPEs recommended for priority testing consideration

Chemical	Pentabromodiphenyl ether	Octabromodiphenyl ether	Decabromodiphenyl ether
CAS No.	32534-81-9	32536-52-0	1163-19-5
Acronym	PBDPE	OBDPE	DBDPE
Synonyms and Trade Names	Pentabromodiphenyl oxide Pentabromophenoxybenzene	Phenyl ether, Octabromo deriv. (8CI) Octabromodiphenyl oxide	Ether, bis (pentabromophenyl) (8CI) Decabromobiphenyl ether Decabromobiphenyl oxide Decabromophenyl ether
Structure			
Molecular Weight	564.72	801.42	959.22
Melting Point (C)	202 (E)[a/]	200-250 (E)	295-310
Solubility in water (mg/L at 20 C)	$9x10^{-7}$ (E)	0.02-0.03[b/]	0.02-0.03[b/]
Log Octanol/Water Partition	7.8 (E)	5.5[b/]	5.24[b/]

[a/] Estimated (E)
[b/] Norris (1974)

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Rationales for Recommendations

I. Exposure Information

A. *Production/use/disposal/exposure.* The BDPEs are all produced in substantial volumes; actual production volumes are confidential business information (CBI). Environmental release and occupational exposure to BDPEs may be anticipated from manufacturing, processing or use in activities associated with filtration, drying, drumming, bagging, compounding or from phase separation or cleaning residues from drums.

PBDPE is recommended for use in acrylonitrile-butadiene-styrene (ABS) resins, flexible polyurethane foams, polyvinyl chloride wired cable insulation, phenolic thermosets and hot-melt adhesives (Ref. 3, Ethyl, 1988). It may also be used as a flame retardant for epoxides, laminates and coatings, and has special application in the preparation of flame retardant wood treatments. When blended with a variety of chlorinated solvents or triethyl phosphate it may be used for dimensional lumber, shakes and shingles (Ref. 6, Great Lakes, 1982).

OBDPE is recommended as a flame retardant for ABS resins nylon, etc. (Ref. 3, Ethyl, 1988 and Ref. 6, Great Lakes, 1982).

DBDPE is a heat-stable additive flame retardant recommended for use in high-impact polystyrene, thermoset and thermoplasticpolyesters, non-drip polypropylene, cross-linked polyethylene and elastomers (Ref. 3, Ethyl, 1988). It is suggested for use in wire and electrical cable insulation of all types. It is also recommended as a flame retardant for epoxy phenolic, polybutyleneterephthalate, and nylon resins (Ref. 6, Great Lakes, 1982).

B. *Evidence for exposure—Environmental exposure.* PBDPE was detected in fish in Sweden (Ref. 1, Anderson and Blomkvist, 1981), and in mussels and river sediment from Japan (Ref. 17, Watanabe, *et al.*, 1986, 1987). It was also detected (as a component of Bromkal 70-5) in marine mammals and birds from Sweden (Ref. 8, Jansson *et al.*, 1987) and in air, soil and sediments near two U.S. production facilities (Ref. 2, DeCarlo, 1979; Ref. 18, Zweidinger *et al.*, 1979). The U.S. EPA Environmental Research Laboratory in Duluth, MN, measured PBDPE in dead Atlantic Bottle Nose dolphins from the U.S. east coast (Ref. 14, USEPA 1989).

DBDPE was detected in air, particulates, soil and sediments in the vicinity of U.S. production facilities (Ref. 2, DeCarlo,1979; Ref. 18, Zweidinger *et al.*, 1979). It was also detected in shell fish and sediments in Japan (Ref. 17, Watnabe, 1987).

DBDPE was one of more than 300 chemicals and chemical categories on an initial list of toxic chemicals (the Toxics Release Inventory) established under section 313 of the Emergency Planning And Community Right-to-Know Act (Pub. L. 99–499, "EPCRA"). Section 313 of EPCRA requires certain facilities that manufacture, process, or otherwise use toxic chemicals to report annually their environmental releases of such chemicals. For DBDPE, 47 exposure and release data forms (Form Rs) were submitted under section 313 of EPCRA during the 1987 reporting year. The reported releases included over 155,000 pounds a year to air (over 120,000 pounds a year from one domestic production facility), over 20,000 pounds a year of water releases and over 16,000 pounds a year of land releases. Since DBDPE is the most highly brominated of the BDPEs, it is anticipated that OBDPE and PBDPE, which should be more volatile and more water soluble, will be released in at least the same percentage of the production volume as DBDPE. The DBDPE release figures only include releases from producers and formulators, not releases from use and disposal of BDPEs.

II. Chemical Fate Information

A. *Transport.* The estimated water solubility and octanol/water partition coefficients (K_{ow}) for PBDPE and the measured water solubility and K_{ow} values for OBDPE and DBDPE relisted in Table 4. Vapor pressures of BDPEs are estimated to below at ambient temperature, i.e., $<10^{-6}$ mm Hg. Based on these estimates and data, BDPEs are likely to partition to sediments and biota.

B. *Persistence.* DBDPE was susceptible to aqueous photolysis, but no rate was reported (Ref. 11, Norris, *et al.*, 1974).

C. *Rationale for chemical fate recommendations.* The Committee recommends testing to obtain measured water solubility and K_{ow} values for PBDPE because there were no data. Water solubility andK_{ow} testing for OBDPE and DBDPE (Table 3) are also recommended because the shake-flask methods used to provide available data may not be appropriate for hydrophobic compounds. The Committee recommends vapor pressure testing for the BDPEs, because there were no data (Table 3). The Committee also recommends sediment and soil adsorption isotherm testing of all BDPEs because there were no data and there is a need to estimate sediment partitioning and soil mobility. The Committee recommends direct and indirect aqueous photolysis because there were no data on photolysis rates and products (Table 3). Rates of aerobic biodegradation may be inversely proportional to the number of bromines on a BDPE. The Committee recommends aerobic biodegradation testing of PBDPE because there were no data and triggering aerobic biodegradation testing of the higher brominated homologs (OBDPE and DBDPE), if PBDPE is biodegraded. The Committee recommends anaerobic biodegradation testing of all BDPEs because there were no data and these chemicals should be susceptible to reductive debromination. Chemical fate testing is recommended because BDPEs have been detected in the environment and there are insufficient data to reasonably determine or predict their environmental persistence.

III. Health Effects Information

A. *Metabolism and pharmacokinetics.* No information was found for OBDPE, or PBDPE.

Decabromodiphenyl ether. In a disposition study using male rats exposed to diets containing 250–50,000 ppm of DBDPE for 9 to 11 days, the feces contained 62- to 100 percent of the ^{14}C-radiolabel (administered on the last day), while the urine contained :0.012 percent (Rex. 13, NTP, 1986). Most of the radio label in the feces was unmetabolized compound, although three unidentified metabolites were detected. All major tissues except the brain contained small but measurable levels of radioactivity. In a single-dose (gavage) disposition study using rats, all tissue samples contained radio label on day 1 following administration, while only the adrenal glands and spleen contained radio label on day 16 (Ref. 11, Norris *et al.*, 1974, 1975). As with the repeated-exposure study, most of the radioactivity (90- >99 percent) was excreted in the feces.

B. *Acute and subchronic (short-term) effects.*

Pentabromodiphenyl ether. The oral LD_{50} values in male and female rats were 7400 and 5800 mg/kg, respectively, with deaths occurring between the second and seventh day post treatment (Ref. 7, Great Lakes Chemical Corp., 1988). Effects included tremors of the forelimb, reduced activity immediately after treatment (4000 mg/kg and above), hepatotoxicity and gastric lesions (all doses). The hepatotoxic effects observed at the lowest dose (2400 mg/kg) persisted for up to 44 days post treatment. In a second acute oral toxicity study, 4 out of 5 rats died when treated by gavage with 5000 mg per kg.

In an inhalation study there were no deaths in male and female rats exposed for 1 hour to PBDPE at concentrations up to 200 mg/L. The only effects were changes in motor activity and irritation observed during the exposure. In a dermal study, PBDPE applied to the abraded skin of rabbits for 24 hours at dose levels up to 2000 mg/kg produced no compound-related systemic toxic effects.

In 28-day studies, male and female rats given diets containing 100, or 1000 ppm of PBDPE showed no gross effects of treatment (Ref. 7, Great Lakes Chemical Corp., 1988). There was an increase in relative and absolute liver weight in males and females in the high-dose group and in females of the low-dose group. Enlargement of the centrilobular and midzonal liver parenchymal cells was reported in the high-dose group, and thyroid hyperplasia was observed in "several" rats at both dose levels. Except for increased bromine levels in the thyroid and liver, no gross or microscopic effects were observed in male and female rats maintained for 30 days on diets which provided PBDPE at doses between 0.01 and 1.0 mg/kg per day. Bromine levels were generally in the normal range following a 6-week recovery period.

In a 90-day study, when rats were given a diet providing doses of PBDPE of 0, 2, or 100 mg/kg/day, absolute and relative liver weight increased in the mid- and high-dose groups and the amount of porphyrins in the liver and urine increased in the high-dose group (Ref. 7, Great Lakes Chemical Corp., 1988). Compound-related microscopic changes characterized as hepatocytomegaly and thyroid hyperplasia were observed in all dose groups. Liver effects were not reversible during the 24-week recovery period; thyroid effects were reversible.

Octabromodiphenyl ether. In acute toxicity studies none of the rats died during the 14-day observation period after a single oral administration of OBDPE at doses between 50 and 5000 mg/kg, or after a 1-hour inhalation exposure at a level of 2 mg/L (Ref. 7, Great Lakes Chemical Corp.,1988). Similarly, none of the rabbits died during the 14-day observation period following a 24-hour dermal application of OBDPE (200 or 2000 mg/kg) to intact or abraded skin. OBDPE was nonirritating to the skin or eyes of rabbits.

Male and female rats given diets containing 100 or 1000 ppm of OBDPE for 28 days showed no gross effects of treatment (Ref. 7, Great Lakes Chemical Corp., 1988). There was a statistically significant increase in relative liver weights in both sexes at both dose levels. Enlargement of the centrilobular and midzonal liver parenchymal cells was reported in both dose groups, and slight to moderate thyroid hyperplasia was observed in rats of the high-dose group. Similar effects on the liver were observed in male and female rats administered diets containing 100, 1000, or 10,000 ppm of OBDPE for 13 weeks. At the two higher levels the effects persisted in a group observed for an additional 6 months post exposure period. Other compound-related effects included kidney and thyroid lesions in the high-dose group; hyperplastic nodules were considered possible compound-related effects in the liver of one mid-dose and two high-dose rats.

In an inhalation study, groups of male and female rats (25/sex) were exposed to 1.2, 12, 120, or 1200 mg/m^3 OBDPE for 8 hours per day for 14 days (Ref. 7, Great Lakes Chemical Corp.1988). Respiratory rate increased during exposure, but returned to normal by the beginning of the next exposure session. Focal or multifocal to diffuse, cytoplasmic enlargements of the hepatocytes as well as focal hepatocellular necrosis and acidophilic degeneration were also observed. These effects were observed in the mid- and high-dose groups; in all dose groups there was correlation between exposure level and the bromine content of the lungs, liver and fat tissues.

Decabromodiphenyl ether. The acute toxicity of DBDPE was low with all rats surviving following single oral doses up to 5000 mg per kg (Ref. 6, Great Lakes, 1982). Following inhalation exposure to DBDPE at 2 or 48.2 mg/L for 1 hour, rats suffered respiratory difficulty and irritation, but were normal by day 13 (Ref. 6, Great Lakes, 1982).

DBDPE fed to male rats at dietary levels of 0.01, 0.1 or 1.0 percent for 30 days resulted in: liver enlargement at the 0.1 and 1.0 percent levels; liver (cytoplasmic enlargement and vacuolation) and kidney (hyaline degenerative cytoplasmic changes) lesions at the 1.0 percent dietary level; and thyroid hyperplasia at the two highest doses (Ref. 12, Norris, 1975). In a 14-day study, no clinical signs or gross pathology were observed in rats or mice maintained on diets containing DBDPE at levels up to 100,000 ppm, while no gross or microscopic pathology were observed in rats and mice maintained for 13 weeks on diets containing DBDPE at levels up to 50,000 ppm (Ref. 13, NTP, 1986).

C. *Genotoxicity.* PBDPE was negative in the Ames/ *Salmonella* test when tested up to the limits of toxicity both with and without metabolic activation (Ref. 7, Great Lakes Chemical Corp., 1988).

OBDPE was negative in the Ames/ *Salmonella* and the *Saccharomyces* assays when tested to the limits of toxicity both with and without metabolic activation. (Ref. 7, Great Lakes Chemical Corp., 1988). Similarly, OBDPE did not increase sister chromatid exchanges in Chinese hamster ovary cells, or the rate of unscheduled DNA synthesis in WI-38 human fibroblast cells, when these tests were conducted in the presence or absence of a metabolic activation system (Ref. 7, Great Lakes Chemical Corp., 1988).

DBDPE was not mutagenic in the Ames/*Salmonella* and the mouse lymphoma L5178Y/TK$^{+/-}$ assay with and without metabolic activation (Ref. 13, NTP, 1986). DBDPE did not cause sister chromatid exchanges or chromosomal aberrations in Chinese hamster ovary cells *in vitro* (Ref. 13, NAP, 1986) or in bone marrow cells following *in viva* administration (30-100 mg/kg/per day for 90 days prior to mating and through lactation) to male and female rats or their offspring (Rex. 12, Norris et al., 1975).

D. *Oncogenicity.* No information was found on PBDPE or OBDPE.

DBDPE has been tested in male and female rats and mice at dose levels of 25,000 and 50,000 ppm. There was some evidence of carcinogenicity in rats, equivocal evidence in male mice and none in female mice (Rex. 13, NAP, 1986). No neoplastic effects were observed in male and female rats given diets which provided doses of DBDPE of 0.01, 0.1, or 1.0 mg/kg/day for 2 years (Ref. 9, Kociba et al., 1975).

E. *Reproductive and developmental effects.* No information was found on PBDPE.

To study developmental effects, OBDPE was administered by gavage to groups of 10 rats at doses of 2.5, 10, 15, 25, or 50 mg/kg on days 6 through 15 of gestation (Ref. 7, Great Lakes Chemical Corp., 1988). Reduced ossification was observed in the fetuses of the high-dose group and was considered to be related to maternal toxicity. There was also a decrease in mean fetal weight and an increase in post-implantation losses in the high-dose group. Increased serum bromide levels were reported in the 25 and 50 mg/kg groups.

DBDPE did not induce developmental toxic effects in offspring of rats administered DBDPE at doses of 10, 100, or 1000 mg/kg/day on days 6 through 15 of gestation (Ref. 11, Norris et al., 1974; Ref. 12, Norris et al., 1975). There was an

increase in subcutaneous edema and delayed ossification in the fetuses of the high-dose group. In a single-generation reproductive toxicity study using doses of 3, 30, or 100 mg/kg for 90 days prior to mating and through lactation, no treatment-related effects of DBDPE to the offspring rats were reported (Ref. 12, 1975, Norris et al.)

F. *Chronic (long-term) effects.* No information was found on PBDPE or OBDPE.

Lesions of the liver, stomach and spleen were observed in a 103–week feeding study in rats and mice administered diets containing 25,000 or 50,000 ppm of DBDPE (Ref. 13, NTP, 1986). These effects were predominately in the high-dose group. After 2 years of feeding DBDPE to rats at 0.01, 0.1 or 1 percent in the diet, no significant long-term effects were noted (Ref. 9, Kociba et al., 1975).

G. *Observations in humans.* No information was found.

H. *Rationale for health effects recommendations.* The Committee recommends pharmacokinetics, neurotoxicity, reproductive and developmental toxicity, chronic toxicity and oncogenicity testing for PBDPE. The Committee also recommends pharmacokinetics, neurotoxicity, reproductive toxicity, chronic toxicity and oncogenicity testing for OBDPE. These health-effects tests are recommended for PBDPE and OBDPE because there were no data and because acute and subchronic studies indicate not only that effects may be only slowly reversible but that the compounds may accumulate with extended exposure. The Committee recommends reproductive toxicity testing for DBDPE because the available data were developed using a single-generation study in which the effects of DBDPE on male rats were not reported and the high dose was too low to produce toxic effects. Health effects testing is recommended because DBDPEs have been detected in the environment and there are insufficient data to reasonably determine or predict their health effects.

IV. Ecological Effects Information

A. *Acute and subchronic (short-term) effects.* DBDPE EC_{50} values for marine and freshwater algae were >1 mg/L, but concentrations tested were 100 times water solubility levels and exposures were too short (3 days) to permit uptake (Ref. 16, Walsh et al., 1987).

B. *Chronic (long-term) effects.* No information was found.

C. *Other ecological effects (biological, behavioral, or ecosystem process).* No information was found.

D. *Bioconcentration and food-chain transport.* PBDPE bioconcentration data submitted under TSCA section 8(d) (EPA document #86-890000045) indicated that after 8 weeks of exposing carp to 105 and 9.7 ug/L PBDPE, the maximum bioconcentration factors (BCF) were 5,380 and 11,700 respectively. For OBDPE, bioconcentration data submitted under the same 8(d) document, using the same test organism and method suggested BCFs of :3.8 for any OBDPE concentration. These data suggest that there may have been less membrane permeation and lower uptake by carp for OBDPE than for PBDPE.

E. *Rationale for ecological effects testing recommendation.* The Committee recommends that an algal bioassay, an aquatic invertebrate acute toxicity test and an extended (14–day) fish acute toxicity test be conducted for PBDPE, because there were no data. The Committee recognizes that membrane permeation may be difficult for large chemicals and is requesting molecular cross-sectional area data for PBDPE, OBDPE and DBDPE. The Committee recommends triggering (T) short-term tests for OBDPE and DBDPE if PBDPE is toxic (Table 3). The Committee recommends that aquatic invertebrate and fish chronic toxicity tests as well as a benthic organism toxicity test be conducted for PBDPE (because there were no data) and that testing of OBDPE and DBDPE be triggered if PBDPE is toxic (Table 3). Based on PBDPE and OBDPE bioconcentration data the Committee is not recommending bioconcentration testing for DBDPE. Ecological effects testing is recommended because BDPEs have been detected in the environment and there are insufficient data to reasonably determine or predict their ecological effects.

2.2.a.2 *1,2-Bis(2,4,6-tribromophenoxy) ethane—Summary of recommended studies.* It is recommended that BTBPE be tested for the following:

1. *Chemical fate.* Vapor pressure; sediment and soil adsorption; photolysis; aerobic and anaerobic biodegradation.

2. *Health effects.* Chronic toxicity with emphasis on hepatotoxicity, neurotoxicity and reproductive effects.

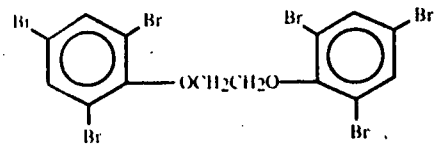
3. *Ecological effects.* Acute toxicity to algae, fish and aquatic invertebrates; chronic toxicity to fish and aquatic invertebrates and toxicity to benthic organisms based on results of its acute toxicity testing.

PHYSICAL AND CHEMICAL INFORMATION

CAS No.: 37853-59-1

Acronym	BTBPE
Synonyms and Trade Names.	Benzene,1,1'-(1,2-ethanediylbis-(oxy)bis)2,4,6 tribromo (9Cl)Bis-1,2-(2,4,6-tribromophenoxy)-ethane1,1'-(1,2-Ethanediylbis(oxy)bis-(2,4,6-tribromobenzene) Fire Master 680 Great Lakes FF680

Structural Formula:



Empirical Formula	$C_{14}H_8Br_6O_2$
Molecular Weight	687.66
Melting Point (°C)	223-225
Solubility in water (mg/L at 20°C).	0.2 (Ref. 4, Great Lakes (1981a)
Log Octanol/Water Partition Coefficient (log P).	3.14 (Ref. 4, Great Lakes (1981a)

I. Exposure Information

A. *Production/use/disposal/exposure.* BTBPE is produced insubstantial volumes; actual production volumes are CBI. BTBPE is used as a flame retardant in ABS polymers and in applications where thermal stability at high processing temperatures is important (Rex. 4, Great Lakes, 1981a). Environmental release may be anticipated from cleaning residues in drums and subsequent release to waste treatment facilities.

B. *Evidence for exposure—Environmental exposure.* BTBPE was detected in air and soil near two U.S. production facilities (Ref. 2, DeCarlo, 1979).

II. Chemical Fate Information

A. *Transport.* Water solubility and Kow data suggest that BTBPE may migrate through soil and desorb from sediment.

B. *Persistence.* BTBPE applied to silica gel and irradiated with UV light was degraded (Ref. 4, Great Lakes, 1981a). Shake-flask biodegradation studies of BTBPE suggested slow degradation, but test concentrations exceeded BTBPE water solubility and recoveries of ^{14}C-BTBPE were <2 percent (Ref. 4, Great Lakes, 1981a).

C. *Rationale for chemical fate recommendations.* The Committee

recommends sediment and soil adsorption isotherm testing and vapor pressure testing at ambient temperature, because there were no data. The Committee recommends direct and indirect photolysis testing because there were no data on photolysis and rates products. The Committee recommends that BTBPE water solubility and vapor pressure data be carefully examined and that an aerobic biodegradation test be designed to adequately measure BTBPE's biodegradation rate. The Committee also recommends anaerobic biodegradation testing because there were no data and because BTBPE should be susceptible to reductive debromination. Chemical fate testing is recommended because BTBPE has been detected in the environment and there are insufficient data to reasonably determine or predict its environmental persistence.

III. Health Effects Information

A. *Metabolism and pharmacokinetics.* Within 4 days of administering radioactive BTBPE to rats, 80 percent and 5 percent of the radioactivity was recovered in the feces and the urine, respectively, indicating likely poor absorption from the gut (Ref. 7, Great Lakes Chemical Corp., 1988).

B. *Acute and Subchronic (Short-Term) Effects.* The acute toxicity of BTBPE was studied by Great Lakes Chemical Corp., (Ref.7, 1988). The oral LD_{50} of BTBPE in male rats, and male and female dogs is >10 g/kg. BTBPE is non-irritating for both abraded and non-abraded skin in rabbits. Acute inhalation, 36.68 mg/L per 4 hours, caused no treatment-related pathology as observed on necropsy at 24 hours post exposure.

Subacute and subchronic toxicity studies also have been reported by Great Lakes Chemical Corp. (Ref. 7, 1988). No compound-related pathology was reported in a 14–day study at the highest concentration tested (10 percent in the diet). Male weaning rats given diets containing 100, or 1000 ppm of BTBPE for 28 days showed no compound-related pathology 6, 12, or 18 days after cessation of treatment. In a 90–day study, albino rats given a diet containing 10 percent BTBPE showed liver changes in most of the animals. The lesions consisted of focal or multifocal enlargement of the hepatocytes located within the centrilobular to midzonal regions of the affected liver lobules. The liver lesion incidence was higher in males than in females. No treatment-related changes were reported in the animals fed diets containing 0.1, or 1.0 percent BTBPE in this study, or in the animals exposed via inhalation to 20 mg BTBPE/L, 4 hours per day, 5 days per week for 21 days in another study.

C. *Genotoxicity.* Negative results were reported in the Ames/*Salmonella* test with or without metabolic activation (Ref. 7, Great Lakes Chemical Corp., 1988).

D. *Oncogenicity.* No information was found.

E. *Reproductive and Developmental Effects.* BTBPE was negative in a teratology study in rats. The doses ranged from 30 mg/kg to 10,000 mg/kg (Ref. 7, Great Lakes Chemical Corp., 1988).

F. *Chronic (long-term) effects.* No information was found.

G. *Observations in humans.* No information was found.

H. *Rationale for health effects recommendations.* The Committee recommends chronic toxicity studies with emphasis on hepatotoxicity, neurotoxicity and reproductive effects because there were no data. Health effects testing is recommended because BTBPE has been detected in the environment and there are insufficient data to reasonably determine or predict its health effects.

IV. Ecological Effects Information

A. *Acute and subchronic (short-term) effects.* BTBPE LC_{50} values for bluegill, rainbow trout and killifish were 1531, 1410 and 230 mg/L, respectively (Ref. 4, Great Lakes, 1981a).

B. *Chronic (long-term) effects.* No information was found.

C. *Other ecological effects (biological, behavioral, or ecosystem process).* No information was found.

D. *Bioconcentration and food-chain transport.* BTBPE bioconcentration data submitted under TSCA section 8(d) (document #86–890000045) indicated that after 8 weeks of exposing carp to 0.27 and 0.026 mg/L BTBPE; the maximum BCFs were 27 and 43, respectively.

E. *Rationale for ecological effects testing recommendation.* The Committee recommends algal and aquatic invertebrate acute toxicity testing because there were no data and fish acute toxicity testing because available LC_{50} values are >1000 times higher than BTBPE's water solubility. The Committee recommends that BTBPE chronic toxicity testing and benthic organism toxicity testing be triggered (T) based on results of its acute toxicity testing. Bioconcentration testing is not recommended because available BCFs are similar to a predicted BCF of 13 (based on a log K_{ow} of 3.14). Ecological effects testing is recommended because BTBPE has been detected in the environment and there are insufficient data to reasonably determine or predict its ecological effects.

2.2.a.3 *Hexabromocyclododecane—Summary of recommended studies.* It is recommended that HBCD be tested for the following:

1. *Chemical fate.* Vapor pressure; sediment and soil adsorption; anaerobic biodegradation.

2. *Health effects.* Pharmacokinetics; metabolism; subchronic toxicity.

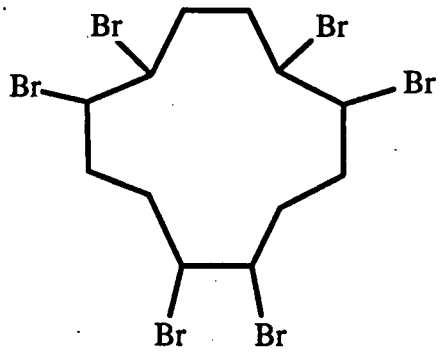
3. *Ecological effects.* Acute toxicity to fish and aquatic invertebrates; chronic toxicity to fish and aquatic invertebrates and toxicity to benthic organism based on results of its acute toxicity testing.

PHYSICAL AND CHEMICAL INFORMATION

CAS No.: 3194–55–60

Acronym	HBCD
Synonyms and Trade Names.	Cyclododecane, 1,2,5,6,9,10-hexabromo-(8CI, 9CI) CD-75P Saytex HBCD

Structural Formula:



Empirical Formula	$C_{12}H_{18}Br_6$
Molecular Weight	641.70
Melting Point (°C)	185-195
Solubility in Water (mg/L).	0.008 (Ref. 5, Great Lakes, 1981b)
Log Octanol/Water Partition Coefficient (log P).	5.81 (Ref. 5, Great Lakes, 1981b)

I. Exposure Information

Production/use/disposal/exposure. HBCD is produced in substantial volumes; actual production volumes are CBI. It is used as a flame retardant in textile coatings, adhesives, latex binders, unsaturated polyesters, expanded polystyrene foams, and other styrene resins (Ref. 5, Great Lakes, 1981b). It is also used as a flame retardant in polyvinyl chloride wire, cable, polystyrene, and polypropylene (Ref. 3, Ethyl, 1988). Environmental release and occupational exposure data are scarce but some releases and exposures may occur based on processing or use.

II. Chemical Fate Information

A. *Transport.* Water solubility and K_{ow} data suggest that HBCD may partition to sediments and biota.

B. *Persistence.* An HBCD aerobic biodegradation study suggested that HBCD was susceptible to degradation (Ref. 5, Great Lakes, 1981b).

C. *Rationale for chemical fate recommendations.* The Committee recommends sediment and soil adsorption, vapor pressure, and direct and indirect aqueous photolysis testing because there were no data. The Committee recommends anaerobic biodegradation testing because there were no data and because HBCD should be susceptible to reductive debromination. Chemical fate testing is recommended because there is potential for environmental release of HBCD from use and processing and there are insufficient data to reasonably determine or predict environmental persistence.

III. Health Effects Information

A. *Metabolism and pharmacokinetics.* No information was found.

B. *Acute and subchronic (short-term) effects.* The acute toxicity of HBCD when administered to rats by inhalation or oral route was low (Ref. 3, Ethyl Corp., 1988; Ref. 5, Great Lakes, 1981b). When applied to rabbit eyes, HBCD was a mild irritant (Ref. 3, Ethyl Corp., 1988, Ref. 5, Great Lakes, 1981b). HBCD was minimally irritating to rabbit skin (Ref. 5, Great Lakes, 1981b). No subchronic toxicity studies were found in the literature.

C. *Genotoxicity.* HBCD was not mutagenic in the Ames/*Salmonella* assay with and without metabolic activation (Ref. 5, Great Lakes, 1981b).

D. *Oncogenicity.* No information was found.

E. *Reproductive and developmental effects.* No information on reproductive effects was found. HBCD did not induce developmental toxic effects in offspring of rats fed diets containing HBCD at levels of 0.01, 0.1, or 1 percent during days 0 to 20 of gestation (Ref. 10, Murai et al., 1985).

F. *Chronic (long-term) effects.* No information was found.

G. *Observations in humans.* No information was found.

H. *Rationale for health effects recommendations.* The Committee recommends pharmacokinetics, metabolism and subchronic toxicity studies because there were no data. Health effects testing is recommended because there is a potential for exposure to HBCD from use and processing and there are insufficient data to reasonably determine or predict its health effects.

IV. Ecological Effects Information

A. *Acute and subchronic (short-term) effects.* HBCD algal EC_{50} values ranged from 0.01–0.14 mg/L (Ref. 16, Walsh et al., 1987). These data indicate that HBCD is highly toxic to algae, even though these EC_{50} values exceeded HBCD's water solubility.

B. *Chronic (long-term) effects.* No information was found.

C. *Other ecological effects (biological, behavioral, or ecosystem process).* No information was found.

D. *Bioconcentration and food-chain transport.* Veith, et al., Ref. 15, 1979, estimated HBCD's BCF would be 18,100.

E. *Rationale for ecological effects testing recommendation.* Based on the algal toxicity data the Committee recommends acute aquatic invertebrate and extended acute fish toxicity testing for HBCD. The Committee recommends that HBCD chronic toxicity testing and benthic organism toxicity testing be triggered based on results of its acute toxicity testing. Ecological effects testing is recommended because HBCD is highly toxic to algae and there are insufficient data to reasonably determine or predict its ecological effects.

References

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(5) Great Lakes Chemical Corporation. Product information, toxicity data summary and *Material Safety Data Sheet* on HBCD. (1981b).

(6) Great Lakes Chemical Corporation. Product information, toxicity Data summary and *Material Safety Data Sheet* on DBDPE, OBDPE and PBDPE 1982).

(7) Great Lakes Chemical Corporation. TSCA sec. 8(d) submission 890000045. Thirty-one 1,2-bis(tribromophenoxy)ethane studies, seven pentabromodiphenyl oxide studies and nine octabromodiphenyl oxide studies with cover letter dated 11/28/88. Washington, DC: Office of Toxic Substances, U.S. Environmental Protection Agency. (1988).

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2.3 *Chemicals recommended with intent-to-designate* 2.3.a 4-*Vinylcyclohexene—Summary of recommended studies.* It is recommended that 4-vinylcyclohexene (VCH) be tested for the following:

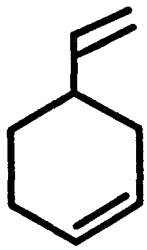
1. *Chemical Fate.* Aqueous volatilization rate.

2. *Health Effects.* Pharmacokinetics and oncogenicity by inhalation route of exposure.

3. *Ecological Effects.* None.

PHYSICAL AND CHEMICAL INFORMATION

CAS Number: 100-40-3

Synonyms:	Cyclohexene, 4-ethenyl- (9 CI) Cyclohexene, 4-vinyl- (8CI) Butadiene dimer 4-Ethenyl-1-cyclohexene 1,2,3,4 tetrahydrostyrene 1-vinyl-3-cyclohexene 1-vinylcyclohex-3-ene 1-vinylcyclohexene-3 4-vinyl-1-cyclohexene 4-vinylcyclohexene-1
Acronym:	VCH
Structural Formula:	
Empirical Formula:	C_8H_{12}
Molecular Weight:	108.2
Physical State at 25 °C:	Liquid (Ref. 21, Sax and Lewis, 1987)
Description of Chemical:	Colorless liquid (Ref. 21, Sax and Lewis, 1987)
Melting Point:	-108.9 °C (Ref. 21, Sax and Lewis, 1987)
Boiling Point:	128 °C (Ref. 21, Sax and Lewis, 1987)
Vapor Pressure:	25.8 mmHg @ 38 °C (Ref. 20, Sandmeyer, 1981) 10.2 mmHg @ 25 °C (Estimated; CHEMBASE)
Specific Gravity:	0.8303 @ 20/4oC (Ref. 21, Sax and Lewis, 1987)
Log Octanol/Water Partition Coefficient:	3.38 (Ref. 10, ISHOW, 1988) 3.314 (estimated; CLOGP3)
Water Solubility at 20 °C:	50 ppm (Ref. 25, USEPA, 1985)
Log K_{oc}:	2.70 (calculated; Ref. 12, Lyman, 1982)
Henry's Constant:	0.218 atm m3/mole (estimated from structure; Ref. 7, Hine and Mookerjee, 1975) 0.0285 atm m3/mole (estimated from water solubility and vapor pressure)

Rationale for Recommendations

I. Exposure Information

A. *Production/use/disposal/exposure/release.* VCH is produced in substantial volumes; actual production volumes are CBI.

VCH is used as an intermediate in the manufacture of 4-vinylcyclohexene mono- and diepoxides, which are used to make epoxy resins, polyesters, coatings, and plastics. VCH also is used in the manufacture of flame retardants, insecticides, plasticizers, and antioxidants (Refs. 8 and 9, IARC, 1976, 1986). Additionally, VCH may have the following uses: as a general chemical intermediate and in the manufacture of flame retardants, flavors and fragrances, and copolymers (Ref. 3, Chemcyclopedia, 1989). VCH may be inadvertently produced by the spontaneous dimerization of butadiene as well as during the manufacture of polymers made from butadiene (e.g., styrene-butadiene rubbers (SBR) and latexes, acrylonitrile-butadiene-styrene (ABS) polymers, and polybutadienes) (Ref. 9, IARC, 1986). The Committee has reviewed the CBI production and exposure information for VCH that was submitted in response to the March 31, 1988 Preliminary Assessment Information Rule (53 FR 10387).

B. *Evidence for exposure—Human Exposure.* Inhalation is the most probable route of worker exposure due to the high vapor pressure of VCH. At locations where VCH is drummed, the air levels typically may be 11 ppm (Ref. 13, Matthiessen, 1986). Dermal exposures may be as high as 4,000 mg/day if protective clothing is not worn (Ref. 26, USEPA, 1985). About 20–25 percent of the chemical produced is isolated, stored in tanks and used at the site of manufacture (Ref. 26, USEPA, 1985).

The air levels of VCH in three manufacturing plants in Italy were: 30–210 $\mu g/m^3$ in a shoe factory (highest levels in the vulcanization area), up to 3 $\mu g/^3$ in a tire retreading factory (highest levels in the extrusion areas), and up to 10 $\mu g/^3$ in an electrical cable insulation plant (Ref. 4, Cocheo, et al., 1983). All three plants used a styrene-butadiene copolymer as the starting material, although natural rubber and cis-polybutadiene polymers also may have emitted some VCH during processing. VCH concentrations of 240–430 $\mu g/^3$ were reported in a room where tires were cured (Ref. 19, Rappaport and Fraser, 1977). The probable source was a cis-polybutadiene elastomer. VCH was found in measurable quantities in the air of two SBR processing plants in Cincinnati, OH (Ref. 15, NIOSH, 1983).

No information was available on consumer exposure to VCH; however, VCH was found at concentrations ranging from 14–210 ppm in ABS plastics used in products such as ladles and food trays. No migration of VCH from these plastics into food simulants (including water, 4 percent acetic acid, 20 percent ethanol) was observed, while some migration into *n*-heptane (a fat simulant) was reported (Ref. 25, Tan and Okada, 1981). The Food and Drug Administration (FDA) refers to VCH as an unregulated additive; a search of FDA information did not reveal any toxicity information that the Committee had not previously retrieved from other sources.

Environmental exposure. In a comprehensive survey sponsored by the Effluent Guidelines Division of the U.S. EPA, VCH was detected at waste water facilities of the following categories (occurrence frequency; median, and maximum concentration in $\mu g/L$): organics and plastics (2; 227, 446.7), rubber processing (6; 78.8, 681.7), publicly owned treatment works (7; 4.9, 8.5).

II. Chemical Fate Information

A. *Transport.* No data were found. The estimated Henry's Law constant suggest that VCH will volatilize from water.

B. *Persistence.* No data were found. In the atmosphere, VCH is likely to react with photochemically-produced hydroxyl radicals and ozone. The estimated half-lives were 4 hr and 1.3 hr, respectively, assuming a hydroxyl radical concentration of 5×10^{-5} per cm^3 and an ozone concentration of 7×10^{11} molecules/cm^3 (Ref. 1, Atkinson, 1987).

C. *Rationale for chemical fate recommendations.* The Committee recommends aqueous volatilization rate testing, because there were no data. Chemical fate testing is recommended because VCH has been detected in the environment and there are insufficient data to reasonably determine or predict its environmental persistence.

III. Health Effects Information

A. *Metabolism and pharmacokinetics.* Metabolism of VCH studied *in vitro* indicated that it was oxidized at either of its two double bonds to produce the corresponding diol compounds via intermediate epoxides (Ref. 6, Gervasi et al., 1981; Ref. 29, Watabe et al., 1981).

Under NTP sponsorship, VCH has been tested for chemical disposition in rats (Ref. 22, Sipes et al., 1989).

No inhalation pharmacokinetics data were found.

B. *Acute and subchronic effects.* Acute effects have been reported by Striegel and Carpenter (Ref. 24, 1961), Bykov (Ref. 2,1968) and Smyth et al. (Ref. 23, 1969). Prechronic (14-day) and subchronic (13-week) studies on VCH were conducted in rats and mice by NTP (Ref. 5, Collins and Manus, 1987). In the 14-day study, NTP reported that:

*** all the mice that received 2,500 or 5,000 mg/kg and 3/5 males that received 1,250 mg/kg 4-vinylcyclohexene died before the end of the studies. Tremors and inactivity were observed in the animals that died. Both vehicle control groups and all dosed groups, except the 300 mg/kg group of females, lost weight (4.0 percent-11.5 percent) during the studies. No compound-related gross changes were noted at necropsy. Histologic examination was limited to the stomach, as it was previously identified as the target organ; no microscopic lesions were detected in this organ.

In the 13-week study, NTP reported that:

*** 9 of 10 male and 5/10 female mice that received 1,200 mg/kg and 2/10 female mice that received 300 mg/kg 4-vinylcyclohexene died before the end of the studies. All other deaths and one of the deaths in the female 1,200 mg/ kg group were considered to be due to gavage error based on tissue injury in the trachea and/or suppurative inflammation in the mediastinum. The sole surviving male receiving 1,200 mg/kg weighed 6 percent less than the vehicle controls, and females receiving 600 mg/kg weighed 5 percent less than the vehicle controls. The final body weights of the other dosed groups were not markedly different from those of the vehicle controls.

Mild, acute inflammation of the stomach was seen in the 1,200 mg/kg groups in three males that died before the end of the study and in one female that lived to the end of the study. In addition, histologic reexamination of the ovaries of the high dose female mice revealed that in all 10 animals, whether they died before or at the end of the study, there was a reduction in the number of primary follicles and mature graafian follicles (the ovaries of female mice receiving lower doses were not similarly examined). No other compound-related clinical signs or histopathologic effects were observed in mice that died or were killed (moribund) during the studies or in mice killed at the end of the studies.

Administration of VCH by inhalation (1 g/m^3 for 6 hours/day, over a period of 4 months), inhibited body weight increase and caused leucocytosis, leucopenia and impairment of hemodynamics in rats and mice (Ref. 2, Bykov, 1968).

C. *Genotoxicity.* VCH was non-mutagenic in *Salmonella typhimurium* strains TA98, TA100, TA1535, and TA1537 with or without metabolic activation (Ref. 30, Zeiger et al., 1987). VCH gave a negative response in the cytogenetic (chromosomal aberration/ sister chromatid exchange) assays and a positive response in the mouse lymphoma assay (Ref. 17, NTP, 1988).

D. *Oncogenicity.* NTP studied the carcinogenic effect of VCH in rats and mice and found clear evidence of carcinogenicity in female mice, based on a significant increase in the incidence of uncommon ovarian neoplasms. The results were inconclusive in male mice and both sexes of rats because of extensive early mortality (Ref. 17, NTP, 1986). Van Duuren et al. (Ref. 27, 1963) observed carcinogenic effects of VCH in a skin painting study in mice using a commercial grade sample of VCH that was purified by removal of auto-oxidation products with ferrous sulfate, followed by distillation in a nitrogen atmosphere. The carcinogenic effect of VCH in a repeat study could not be confirmed (Ref. 27, Van Duuren, 1965).

E. *Reproductive and developmental effects.* As mentioned in the subchronic section above, VCH caused reduction in the number of primary follicles and mature graafian follicles in the ovary. VCH has been selected for a continuous breeding study by the NTP (Ref. 17, NTP, 1989).

F. *Chronic (long-term) effects.* No information was found.

G. *Observations in humans.* Workers exposed to VCH (unspecified levels) at a manufacturing site reportedly suffered from keratitis, rhinitis, headache, hypotonia, leucopenia, neutrophilia, lymphocytosis, and unspecified impairment of carbohydrate metabolism (Ref. 2, Bykov, 1968).

A clinical and immunological evaluation was conducted for 31 workers who complained of eye, chest, skin, or nose/throat symptoms at a chemical plant (Ref. 18, Patterson et al., 1988). The presence of symptoms correlated with the degree of exposure to VCH, but the presence or absence of antibodies did not correlate with the presence or absence of the symptoms.

H. *Rationale for health effects recommendation.* The Committee recommends inhalation pharmacokinetic and oncogenicity testing because inhalation is likely to be the major route of human exposure. Health effects testing is recommended because VCH has been detected in the environment and there are insufficient data to reasonably determine or predict its health effects.

IV. Ecological Effects Information

A. *Acute and subchronic (short-term) effects.* VCH's 48-hour EC_{50} for *Daphnia magna* was greater than 100 mg/L (EPA document #FYI-OTS-0785-0397). This EC_{50} was based on a nominal VCH concentration. The 48-hour VCH concentration (and the 48-hour EC_{50} value) is likely to be substantially less than 100 mg/L, because of VCH's propensity to volatilize.

B. *Chronic (long-term) effects.* No information was found.

C. *Other ecological effects (biological, behavioral, or ecosystem process).* When sewage microorganisms were incubated in the presence of VCH for 16 hours at 23°C, an EC_{50} >200 mg/L was estimated based on turbidity (FYI-OTS-0785-0397). VCH had an LC_{50} of 34.4×10^{-5} M (about 37 mg/L) to the bean plant, *Phaseolus multiflorus* (Ref. 11, Ivens, 1952).

D. *Bioconcentration and food-chain transport.* Based on an estimated log K_{ow} of 3.3, an estimated BCF would be about 260.

E. *Rationale for ecological effects testing recommendation.* Based on results of the disposition study of VCH in mice, the Committee is concerned that fish (if exposed to VCH) might also metabolize VCH to the diepoxide and subsequently develop cancer. The Committee recognizes that while there are no readily-available test guidelines to conduct pharmacokinetic fish studies, that the EPA's Duluth, MN Environmental Research Laboratory has an excellent pharmacokinetics research program. The Committee is not recommending ecological effects testing at this time, but does recommend that if volatilization rate and readily-available monitoring data substantiate the presence of VCH in surface waters, that some fish pharmacokinetic testing be considered.

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2.4 *Chemicals recommended without being designated for response within 12 months*—2.4.a *Brominated flame retardants* (BFRs continued)—*Summary of recommended studies.* Seven BFRs that are produced in substantial quantities, but for which there are few exposure, persistence and effects data, are recommended for testing. With the exceptions noted below, it is recommended that 2,4,6-tribromophenol (TBrP) (CAS No. 118–79–6), 3,4,5,6-tetrabromophthalic anhydride(TBPA) (CAS No. 632–79–1), dibromoneopentyl glycol (DBNG) (CAS No. 3296–90–0), ethylene bis(tetrabromophthalimide) (EBTBPA) (CAS No. 32588–76–4), ethylene bis(5,6-dibromonorbornane 2,3-dicarboximide)(EDBNDC) (CAS No. 41291–34–3), tribrominated polystyrene (TBPS) (CAS No. 57137–10–7) and ethylene bis(pentabromophenoxide) (EBPBP) (CAS No. 61262–53–1) be tested for:

1. *Chemical fate.* Chemical properties and persistence data.

2. *Health effects.* Chronic toxicity.

3. *Ecological effects.* Chronic toxicity.

At this time, based on available TSCA 8(d) submissions, the Committee is not recommending water solubility testing for TBrP and TBPA and octanol-water partition coefficient testing for TBrP, TBPA and DBNG (TSCA 8(d) documents #86–870001215, 870002279, 878216116, 878216117). At this time, the Committee is also not recommending chronic toxicity studies for DBNG, because NTP is conducting carcinogenesis studies.

Physical and Chemical Information

Except for information on water solubility (mg/L) of TBrP (969), TBPA (241) and DBNG (21000) at 25 °C and octanol-water partition coefficients of TBrP (2,198), TBPA (96) and DBNG (12.8), the Committee has no information on physical and chemical properties of the other BFRs at ambient temperatures.

Rationale for Recommendation

I. Exposure Information

A. *Production/use/disposal/exposure/release.* The seven BFRs listed above are all produced in substantial volumes; actual production volumes are CBI.

Three of the BFRs (TBrP, TBPA and DBNG) are reactive flame retardants. In principle, reactive flame retardants should combine with the basic polymer or become part of the basic polymer (as in flame resistant copolymers). However, polymerization processes and other chemical reactions are often not complete and residues of fire-resistant monomers or reactive flame retardants may be entrained in the polymer. Since reactive flame retardants are designed to be retained in the polymer by chemical bonds rather than slow diffusion and slow vaporization, the unreacted residues may be rather mobile. While the Committee is concerned about potential exposures to unreacted residues, it does recognize that there are data for DBNG that suggest that after 2 days of aqueous extraction, a roofing/siding panel resin

released only 0.003 percent of DBNG (#86–870001215). The remaining four BFRs are used to impart flame retardant qualities to polymers, i.e., they are additive flame retardants. The Committee is concerned about potential exposures during manufacturing, processing, use or disposal.

B. *Evidence for exposure—Human exposure.* For TBPA and EBTBPA, the EPA received a FYI submission regarding complaints from employees concerning respiratory problems possibly related to processing (FYI–OTS–0787–0559).

Environmental exposure. TBrP has been detected in the environment. However, the Committee is uncertain of the source of TBrP that is environmentally detected, e.g., from chlorinating waste water, release from polymers, etc.

II. Chemical Fate Information

Few data were found, except those discussed above and the data that suggest DBNG is chemically not microbiologically degraded (#86–870001215). The Committee recommends testing to generate chemical properties and persistence data at ambient temperatures, because there were no data. Chemical fate testing is recommended for the seven BFRs because there is potential for environmental release from manufacturing, processing, use or disposal and there are insufficient data to reasonably determine or predict environmental persistence.

III. Health Effects Information

A number of short-term health effects tests have been conducted for TBrP and DBNG. The NTP is conducting a carcinogenesis study of DBNG (Ref. 1, NTP, 1989); long-term toxicity tests are recommended for the remaining six BFRs, because there were no data. Health effects testing is recommended for six BFRs because there is potential for exposure during manufacturing, processing, use or disposal and because there are insufficient data to reasonably determine or predict health effects.

IV. Ecological Effects Information

Minimal information was available. A TSCA 8(d) submission suggested a DBNG LC_{50} of 97 mg/L for fathead minnows (#86–870002279). Indexing information for another TSCA 8(d) submission indicated that it contained acute toxicity data for a mixture containing TBrP. Closer inspection of this submission revealed that these data were developed using a mother liquor containing only 2 percent tribromophenol (#88–7800184). Long-term ecological effects testing is recommended because there were no data. Ecological effects testing is recommended for the seven BFRs because there is potential for environmental release from manufacturing, processing, use or disposal and there are insufficient data to reasonably determine or predict ecological effects.

Reference

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BILLING CODE: 6560–50–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 712 and 716

[OPTS-82034; FRL-3666-9]

Preliminary Assessment Information and Health and Safety

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Interagency Testing Committee (ITC) in its Twenty-fifth Report to EPA recommended that EPA give priority consideration to thirteen chemical substances in proposing chemical test rules. To assist EPA in its determination of which, if any, tests are needed for these chemical substances, EPA is adding twelve of the chemical substances to two model information-gathering rules: the Toxic Substances Control Act (TSCA) section 8(a) Preliminary Assessment Information Rule (PAIR) and the TSCA section 8(d) Health and Safety Data Reporting Rule. These model rules will require manufacturers, importers, and processors of these chemical substances to report production, use, exposure-related, and unpublished health and safety data to EPA. One chemical substance, (CAS. No. 3296-90-0), was added to the 8(d) Health and Safety Data Reporting Rule on May 1, 1987 (52 FR 16022), and manufacturers, importers, and processors are required to submit lists and copies of studies under that rule. Another substance (CAS No. 100-40-3), was added to the PAIR on March 31, 1988 (53 FR 10387). It is being revised because updated reporting is needed.

DATE: This rule shall become effective on January 11, 1990.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, TSCA Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St. SW., Rm. E-543, Washington, DC 20460, Telephone: (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION: This rule adds thirteen chemical substances to the PAIR and twelve to the section 8(d) Health and Safety Data Reporting Rule. Manufacturers, processors, and importers of these chemicals will be required to report unpublished health and safety data and/or end use, exposure, and volume data to the Agency.

I. Background

Section 4(e) of TSCA established the ITC and authorized it to recommend to EPA chemical substances and mixtures to be given priority consideration in proposing chemical test rules. For some of these chemical substances, the ITC may designate that EPA must respond to its recommendations within 12 months. In this time, EPA must either initiate a rulemaking to test the chemical substance or publish in the **Federal Register** its reasons for not doing so.

Elsewhere in today's issue of the **Federal Register**, EPA is announcing the receipt of the Twenty-fifth Report of the ITC, which was transmitted to EPA on November 1, 1989. The Twenty-fifth Report revises and updates the Committee's priority list of chemicals and adds thirteen chemical substances to the section 4(e) priority list. This rule adds thirteen chemical substances to the PAIR and twelve to the section 8(d) Health and Safety Data Reporting Rule which will require manufacturers, importers, and processors to report unpublished health and safety data and/or volume, end use, and exposure data to EPA.

To assist EPA in responding to the ITC recommendations, EPA has developed two model information-gathering rules (PAIR and the section 8(d) Health and Safety Data Reporting Rule) which provide for the automatic addition of ITC priority list chemical substances. Whenever EPA announces the receipt of an ITC report, EPA may, at the same time without further notice and comment, amend the two model information-gathering rules by adding the recommended chemical substances. The amendment adding these substances to the PAIR and the Health and Safety Data Reporting Rule becomes effective 30 days after publication.

EPA issued PAIR under section 8(a) of TSCA (15 U.S.C. 2607(a)), and it is codified at 40 CFR part 712. This model section 8(a) rule established standard reporting requirements for manufacturers and importers of the chemical substances listed in the rule. These manufacturers and importers are required to submit a one-time report on general volume, end use, and exposure-related information using the Preliminary Assessment Information Manufacturer's Report (EPA Form 7710-35). EPA uses this model section 8(a) rule to gather current information on chemical substances of concern quickly.

EPA issued the model Health and Safety Data Reporting Rule under section 8(d) of TSCA (15 U.S.C. 2607(d)), and it is codified at 40 CFR part 716. The section 8(d) model rule requires past, current, and prospective manufacturers, importers, and processors of listed chemical substances and mixtures to submit, to EPA, copies and lists of unpublished health and safety studies on the listed chemical substances that they manufacture, import, or process. These studies provide EPA with useful information and have provided significant support for EPA's decisionmaking under TSCA sections 4, 5, 6, 8, and 9.

II. Chemicals to be Added

The ITC priority list chemical substances for which reporting is required under 40 CFR parts 712 and 716 are listed by ITC designation in ascending Chemical Abstract Service (CAS) Registry Number order as follows:

A. Designated for Response within 12 Months

CAS No.	Name
1163-19-5	Decabromodiphenyl ether
3194-55-6	Hexabromocyclododecane
32534-81-9	Pentabromodiphenyl ether
32536-52-0	Octabromodiphenyl ether
37853-59-1	1,2-bis(2,4,6-Tribromophenoxy)ethane

B. Recommended with Intent-to-Designate

CAS No.	Name
100-40-3	4-Vinylcyclohexene

C. Recommended without Being Designated for Response within 12 Months

CAS No.	Name
118-79-6	2,4,6-Tribromophenol
632-79-1	Tetrabromophthalic anhydride
32588-76-4	Ethylene bis-(tetrabromophthalimide)
41291-34-3	Ethylene (5,6-dibromonorbornane-2,3-dicarboximide)
57137-10-7	Tribrominated polystyrene
61262-53-1	Ethylene bis(pentabromophenoxide)

III. Reporting Requirements

A. Preliminary Assessment Information Rule

All persons who manufactured or imported the chemical substances named in this rule during their latest complete corporate fiscal year must submit a Preliminary Assessment Information Manufacturer's Report (EPA Form No. 7710-35) for each manufacturing or importing site at which they manufactured or imported a named chemical substance. A separate form must be completed for each chemical

substance and submitted to the Agency no later than March 12, 1990. Persons who have previously and voluntarily submitted a Manufacturer's Report to the ITC or EPA should read § 712.30(a)(3). This section allows these persons to submit a copy of the original Report to EPA or to notify EPA by letter of their desire to have this submission accepted in lieu of a current data submission.

Complete details of the reporting requirements, including exemptions and a facsimile of the reporting form, are fully described in 40 CFR part 712. Copies of the form are available from the TSCA Environmental Assistance Division at the address listed under **FOR FURTHER INFORMATION CONTACT.**

B. Health and Safety Data Reporting Rule

Listed below are the general reporting requirements of the section 8(d) model rule.

1. Persons who, in the 10 years preceding the date a chemical substance is listed, either have proposed to manufacture, import, or process, or have manufactured, imported, or processed, the listed chemical substance must submit to EPA: A copy of each health and safety study which is in their possession at the time the chemical substance is listed.

2. Persons who, at the time the chemical substance is listed, propose to manufacture, import, or process; or are manufacturing, importing, or processing the listed chemical substance must submit to EPA:

a. A copy of each health and safety study which is in their possession at the time the chemical substance is listed.

b. A list of health and safety studies known to them but not in their possession at the time the chemical substance is listed.

c. A list of health and safety studies that are ongoing at the time the chemical substance is listed and are being conducted by or for them.

d. A list of each health and safety study that is initiated after the date the chemical substance is listed and is conducted by or for them.

e. A copy of each health and safety study that was previously listed as ongoing or subsequently initiated and is now complete--regardless of completion date.

3. Persons who, after the time the chemical substance is listed, propose to manufacture, import, or process the listed chemical substance must submit to EPA:

a. A copy of each health and safety study which is in their possession at the time they propose to manufacture, import, or process the listed chemical substance.

b. A list of health and safety studies known to them but not in their possession at the time they propose to manufacture, import, or process the listed chemical substance.

c. A list of health and safety studies that are ongoing at the time they propose to manufacture, import, or process the listed chemical substance, and are being conducted by or for them.

d. A list of each health and safety study that is initiated after the time they propose to manufacture, import, or process the listed chemical substance, and is conducted by or for them.

e. A copy of each health and safety study that was previously listed as ongoing or subsequently initiated and is now complete--regardless of the completion date.

Detailed guidance for reporting unpublished health and safety data is provided in the **Federal Register** of September 15, 1986 (51 FR 32720). Also found there are the reporting exemptions.

C. Submission of Pair Reports and 8(d) Studies

PAIR reports and section 8(d) health and safety studies must be sent to:

TSCA Document Processing Center (TS-790),
Office of Toxic Substances,
Environmental Protection Agency,
401 M St., SW.,
Washington, DC 20460,
ATTN: (insert either PAIR or 8(d) Reporting).

D. Removal of Chemicals from the Rules

Any person who believes that section 8(a) or (d) reporting required by this rule is unwarranted, should promptly submit to the Agency in detail the reasons for that belief. EPA may then remove the chemical substance from this rule. When withdrawing a chemical substance from the rule, EPA will issue a rule amendment for publication in the **Federal Register.**

IV. Release of Aggregate Data

The Agency will follow procedures for the release of aggregate statistics as prescribed in a rule related notice published in the **Federal Register** of June 13, 1983 (48 FR 27041). Included in the notice are procedures for requesting exemptions from the release of aggregate data. Exemption requests concerning the release of aggregate data on any chemical substance must be received by EPA no later than March 12, 1990.

V. Economic Analysis

A. Preliminary Assessment Information Rule

EPA estimates the PAIR reporting cost of this rule is $21,781. To calculate this figure EPA used the TSCA Inventory to generate a list of manufacturers and importers of these chemical substances. Since none of these companies qualify as a small business as defined in 40 CFR 712.25(c), EPA expects 5 firms to report a total of 13 reports.

Reporting Cost (dollars):	
(a) 20 reports expected at $843/report	$16,680
(b) 7 familiarization cases at $703/case	4,921
Total	21,781
Average cost per site	3,112
Average cost per firm	3,112
Reporting burden (hours):	
(a) familiarization: 18 hours per site × 7 sites	126
(b) reporting: 16 hours per report × 20 reports	320
Total (hours)	446
EPA cost (dollars):	
Processing cost=20 reports × $95/reports	1,900

B. Health and Safety Data Reporting Rule

EPA estimates the total reporting costs for establishing section 8(d) reporting requirements for these chemical substances are $37,846. This cost estimate is relatively high, because the Agency is uncertain about the likely number of respondents to the rule. Although EPA has used the best available data to make its economic projections, much of the data are not current. Therefore, EPA intends to overestimate rather than underestimate the reporting burden.

Nevertheless, the cost of this final rule is low in comparison with its potential benefits. Health and safety studies concerning these chemical substances would improve EPA's ability to identify potential public health and environmental problems with regard to these chemicals. Therefore, the Agency would be better able to determine whether further regulatory action would be necessary. The estimated reporting costs are broken down as follows:

Initial corporate review	$2,016
Site identification	5,616
File searches at site	11,583
Title listing	585
Photocopying	1,942
Managerial review	11,232
Reporting on newly-initiated studies	256
Submissions after initial reporting period	4,616
Total	37,846

Reporting Burden (Hours)

(a) initial review 2 hours per firm × 21 firms	42 hours
(b) reporting 25.4 hours per firm × 39 firms	989 hours
Total Reporting Burden Hours	27.4 hours
Subtotal (section 8(d) portion)	$1,015
Total (PAIR and section 8(d) reporting costs)	$22,796

VI. Rulemaking Record

1. This final rule.
2. The economic analysis for this rule.
3. The Twenty-fifth Report of the ITC.

VII. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and, therefore, subject to the requirement of a Regulatory Impact Analysis. This rule is not major because it will not result in an effect on the economy of $100 million or more, an increase in costs or prices, or any of the adverse effects described in the Executive Order.

This amendment was not submitted to the Office of Management and Budget (OMB) for review, because the automatic listing of designated substances is provided for in 40 CFR 712.30(c) and 716.18(b)—final rules which have been previously reviewed by OMB under the terms of the Executive Order.

B. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by OMB under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* and have been assigned OMB control numbers 2070–0054 for PAIR reporting and 2070–0004 for TSCA section 8(d) reporting.

Public reporting burden for this collection of information is estimated to average 27.4 hours for 8(d) and 22 hours for PAIR per response; including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM–223, U.S. Environmental Protection Agency, 401 M St. SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

List of Subjects in 40 CFR Parts 712 and 716

Chemicals, Environmental protection, Hazardous substances, Health and safety data, Recordkeeping and reporting requirements.

Dated: December 1, 1989.

Charles M. Auer,

Acting Director, Existing Chemical Assessment Division, Office of Toxic Substances.

Therefore, 40 CFR chapter I is amended as follows:

PART 712—[AMENDED]

1. In part 712—

a. The authority citation for part 712 continues to read as follows:

Authority: 15 U.S.C. 2607(a).

b. Section 712.30(w) is amended by adding in numerical sequence by CAS number the following chemicals to read as follows:

§ 712.30 Chemical lists and reporting periods.

* * * * *

(w) * * *

CAS Number	Substance	Effective date	Reporting date
100–40–3	4-Vinylcyclohexene	1/11/90	3/12/90
118–79–6	2,4,6-tribromophenol	1/11/90	3/12/90
632–79–1	Tetrabromophthalic anhydride	1/11/90	3/12/90
1163–19–5	Decabromodiphenyl ether	1/11/90	3/12/90
3194–55–6	Hexabromocyclododecane	1/11/90	3/12/90
3296–90–0	Dibromoneopentyl glycol	1/11/90	3/12/90
32534–81–9	Pentabromodiphenyl ether	1/11/90	3/12/90
32536–52–0	Octabromodiphenyl ether	1/11/90	3/12/90
32588–76–4	Ethylene Bis-(tetrabromophthalimide)	1/11/90	3/12/90
37853–59–1	1,2-Bis(tribromophenoxy) ethane	1/11/90	3/12/90
41291–34–3	Ethylene(5,6-dibromonorbornane-2,3-dicarboximide)	1/11/90	3/12/90
57137–10–7	Tribrominated polystyrene	1/11/90	3/12/90
61262–53–1	Ethylene bis(pentabromophenoxide)	1/11/90	3/12/90

PART 716—[AMENDED]

2. In part 716—

a. The authority citation for part 716 continues to read as follows:

Authority: 15 U.S.C. 2607(d).

b. Part 716 is amended in § 716.120(a) by revising the entire entry for CAS No. 100–40–3, and adding 11 new chemical substances in numerical sequence by CAS Number to read as follows:

§ 716.120 Substances and listed mixtures to which this subpart applies.

* * * * *

(a) * * *

CAS Number	Substance	Special Exemptions	Effective Date	Sunset Date
*	*	*		
100–40–3	4-Vinylcyclohexene		1/11/90	1/11/00
*	*	*		
118–79–6	2,4,6-Tribromophenol		1/11/90	1/11/00
*	*	*		
632–79–1	Tetrabromophthalic anhydride		1/11/90	1/11/00
*	*	*		
1163–19–5	Decabromodiphenyl ether		1/11/90	1/11/00
*	*	*		
3194–55–6	Hexabromocyclododecane		1/11/90	1/11/00
*	*	*		
32534–81–9	Pentabromodiphenyl ether		1/11/90	1/11/00
32536–52–0	Octabromodiphenyl ether		1/11/90	1/11/00
32588–76–4	Ethylene Bis-(tetrabromophthalimide)		1/11/90	1/11/00
*	*	*		
37853–59–1	1,2-Bis(tribromophenoxy) ethane		1/11/90	1/11/00
*	*	*		
41291–34–3	Ethylene(5,6-dibromonorbornane-2,3-dicarboximide)		1/11/90	1/11/00
57137–10–7	Tribrominated polystyrene		1/11/90	1/11/00
61262–53–1	Ethylene bis(pentabromophenoxide)		1/11/90	1/11/00
*	*	*		

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federal register

Tuesday
December 12, 1989

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 310 and 333
Topical Antifungal Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; Notice of Proposed Rulemaking

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310 and 333

[Docket No. 80N-0476]

RIN 0905-AA06

Topical Antifungal Drug Products for Over-the-Counter Human Use; Tentative Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of a tentative final monograph that would establish conditions under which over-the-counter (OTC) topical antifungal drug products are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Antimicrobial II Drug Products and public comments on an advance notice of proposed rulemaking that was based on those recommendations. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by March 12, 1990. Because of the length and complexity of this proposed regulation, the agency is allowing a period of 120 days for comments and objections instead of the normal 60 days. New data by December 12, 1990. Comments on the new data by February 12, 1991. Written comments on the agency's economic impact determination by March 12, 1990.

ADDRESSES: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 23, 1982 (47 FR 12480), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC topical antifungal drug products, together with the recommendations of the Advisory Review Panel on OTC Antimicrobial II Drug Products, which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by June 21, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by July 21, 1982.

In a notice published in the **Federal Register** of September 7,1982 (47 FR 39464), the agency advised that it had reopened the administrative record for OTC topical antifungal drug products as it pertains to products used for the treatment of diaper rash to allow consideration of the statement of the Advisory Review Panel on OTC Miscellaneous External Drug Products on these products. Interested persons were invited to submit comments until December 6, 1982. Reply comments in response to comments filed in the initial comment period could be submitted until January 5, 1983. In response to numerous requests, the agency issued a notice in the **Federal Register** of December 28, 1982 (47 FR 57738) granting an extension of the deadline for comments until February 4, 1983, and for reply comments until March 7, 1983.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (address above), after deletion of a small amount of trade secret information. Data and information received after the administrative record was reopened have also been put on display in the Dockets Management Branch.

In response to the advance notice of proposed rulemaking, nine drug manufacturers, one drug manufacturers' association, two medical facilities, and three consumers submitted comments. In response to the reopening of the administrative record to include OTC diaper rash drug products, four drug manufacturers, one manufacturer of fiber products, and one drug manufacturers' association submitted comments. Copies of the comments received are on public display in the Dockets Management Branch.

The advance notice of proposed rulemaking, which was published in the **Federal Register** of March 23, 1982 (47 FR 12480), was designated as a "proposed monograph" in order to conform to terminology used in the OTC drug review regulations (21 CFR 330.10). Similarly, the present document is designated in the OTC drug review regulations as a "tentative final monograph." Its legal status, however, is that of a proposed rule. In this tentative final monograph (proposed rule) to add new subpart C to part 333 (proposed in the **Federal Register** of July 9, 1982; 47 FR 29986), FDA states for the first time its position on the establishment of a monograph for OTC topical antifungal drug products. In this tentative final monograph the agency is also proposing to amend part 310. Final agency action on this matter will occur with the publication at a future date of a final monograph, which will be a final rule establishing a monograph for OTC topical antifungal drug products.

This proposal constitutes FDA's tentative adoption of the Panel's conclusions and recommendations on OTC topical antifungal drug products as modified on the basis of the comments received and the agency's independent evaluation of the Panel's report. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications are reflected in the following summary of the comments and FDA's responses to them.

The OTC drug procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the **Federal Register**. On or after that date, no OTC drug product that is subject to the monograph and that contains a

nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In the advance notice of proposed rulemaking for OTC topical antifungal drug products (47 FR 12480), the agency suggested that the conditions included in the monograph (Category I) be effective 6 months after the date of publication of the final monograph in the **Federal Register**. Experience has shown that relabeling of products covered by the monograph is necessary in order for manufacturers to comply with the monograph. New labels containing the monograph labeling have to be written, ordered, received, and incorporated into the manufacturing process. The agency has determined that it is impractical to expect new labeling to be in effect 6 months after the date of publication of the final monograph. Experience has shown also that if the deadline for relabeling is too short, the agency is burdened with extension requests and related paperwork.

In addition, some products may have to be reformulated to comply with the monograph. Reformulation often involves the need to do stability testing on the new product. An accelerated aging process may be used to test a new formulation; however, if the stability testing is not successful, and if further reformulation is required, there could be a further delay in having a new product available for manufacture.

The agency wishes to establish a reasonable period of time for relabeling and reformulation in order to avoid an unnecessary disruption of the marketplace that could not only result in economic loss, but also interfere with consumers' access to safe and effective drug products. Therefore, the agency is proposing that the final monograph be effective 12 months after the date of its publication in the **Federal Register**. The agency believes that within 12 months after the date of publication most manufacturers can order new labeling and reformulate their products and have them in compliance in the marketplace.

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for data notice published in the **Federal Register** of December 16, 1972 (37 FR 26842) or to additional information that has come to the agency's attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Tentative Conclusions on the Comments and Reply Comments

A. General Comments

1. Two comments contended that OTC drug monographs are interpretive, as opposed to substantive, regulations. The comments referred to statements on this issue submitted earlier to other OTC drug rulemaking proceedings.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the **Federal Register** of May 11, 1972 (37 FR 9464) and in paragraph 3 of the preamble to the tentative final monograph for antacid drug products, published in the **Federal Register** of November 12, 1973 (38 FR 31260). FDA reaffirms the conclusions stated there. Court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. (See, e.g., *National Nutritional Foods Association* v. *Weinberger*, 512 F.2d 688, 696–98 (2d Cir. 1975) and *National Association of Pharmaceutical Manufacturers* v. *FDA*, 487 F. Supp. 412 (S.D.N.Y. 1980), *aff'd*, 637 F.2d 887 (2d Cir. 1981).)

2. One comment requested that a currently marketed OTC spray-on antifungal foot powder be removed from the market immediately because, despite the warning on the container label not to breathe the spray, use of this product results in unavoidable inhalation. The comment maintained that the dispenser is defective in design because the spray cannot be localized to the toe area but envelops the head as well.

The OTC drug review program establishes monograph conditions under which OTC drug products are generally recognized as safe and effective and are appropriately labeled. These conditions principally consist of acceptable ingredients and approved labeling such as indications for use, warnings, and directions. Other agency regulations require warnings for certain drugs in dispensers pressurized by gaseous propellants. (See 21 CFR 369.21.) These warnings are intended to alert consumers to minimize contact of the aerosolized product with the eye and to minimize inhalation of the aerosol.

The agency continually monitors adverse reaction reports. When safety problems arise from the use of a particular ingredient or dosage form, such as an aerosol, the agency takes appropriate action. For example, in the **Federal Register** of August 16, 1977 (42 FR 41374), the agency issued a final regulation declaring that any aerosol drug or cosmetic product containing zirconium is a new drug or an adulterated cosmetic. This action was prompted by the agency's concern about the inhalation of zirconium aerosol by consumers. FDA was aware of reports that zirconium compounds caused skin granulomas and toxic effects in the lungs and other organs of laboratory animals. The regulation was intended to keep zirconium-containing aerosols off the market until adequate safety testing had been completed.

The agency has reviewed the submissions made to the Panel and other data to determine whether there have been adverse reaction reports or potential safety problems reported from inhalation of the product mentioned by the comment. None have been found. Accordingly, the agency considers the label warnings for this product to be adequate, and finds that there is no basis for removing it from the market. The agency also notes that antifungal drug products are available in dosage forms other than aerosols, such as creams, lotions, and powders. Consumers who find aerosols objectionable may select a different dosage form.

3. One comment suggested revisions of several discussions in the Panel's report. These suggestions included expansion or clarification of narrative statements related to sites of infection, fungal cultures, effectiveness criteria, sample size, and indications for a specific ingredient.

The Panel's report represents the Panel's opinion and recommendations based on clinical experience, a review of the scientific literature, and an evaluation of the data presented to it. As stated above, the present tentative

final monograph represents FDA's adoption of the Panel report together with necessary modifications. This document is not, however, a restatement of the Panel report. And, because the revisions suggested by the comment would not alter the tentative final monograph, it is not necessary to address specifically the suggested revisions to the Panel's report as they relate to the form of the report.

4. One comment objected to a television advertisement which claimed that, according to an expert medical panel report to the FDA, a tolnaftate product contains the only medication proven to prevent reinfection from athlete's foot fungus and also "conveyed the message * * * that tolnaftate prevents jock itch." The comment stated that tolnaftate has not been approved for the prevention of jock itch and that "these advertising claims show dramatically the adverse consequences that would ensue if special prophylactic studies were to be required for agents that have already been proven effective in the treatment of fungal infections and if at the same time these requirements were not applied consistently to all drugs." The comment requested that FDA recognize that effective antifungals such as the undecylenates prevent reinfection and that separate prophylaxis studies are not necessary; that studies by Sulzberger et al. demonstrate the prophylactic effect of the undecylenates; and that if prophylaxis studies are to be required, they should be uniformly required of all drugs.

A reply comment responded that the primary regulatory jurisdiction for OTC drug advertising rests with the Federal Trade Commission (FTC), not FDA. The reply comment went on to state that the comment made several misstatements of facts and pointed out that the athlete's foot commercial did not make any claim for use of tolnaftate to prevent jock itch but contained the truthful claim in a tagline that the tolnaftate product for jock itch "cures jock itch fast" and that such a claim is clearly a treatment rather than a prevention claim. The reply comment further asserted that the Panel clearly listed tolnaftate as the only antifungal agent that has been demonstrated to be effective in preventing athlete's foot infection. The comment added that advertising that properly references the OTC drug review process has been commonplace in OTC drug advertising for many years and concluded that it could not understand how the truthful advertising statements could possibly "show dramatically the adverse consequences * * *."

The agency agrees with the reply comment that FTC has the primary responsibility for regulating OTC drug advertising and recommends that concerns about the truthfulness of advertising claims or implications be referred to the FTC. Resolution of the truthfulness of the advertisement in question is outside the scope of the OTC drug review. For a discussion of the Sulzberger study and the effectiveness of undecylenates in preventing reinfection and the need for separate prophylaxis studies, see comment 20 below.

5. In response to the reopening of the administrative record for OTC topical antifungal drug products to include the statement on diaper rash by the Advisory Review Panel on OTC Miscellaneous External Drug Products (47 FR 39464), two comments requested that a separate rulemaking be established for OTC drug products that prevent and treat diaper rash. One of the comments suggested that if a separate monograph is not established, a clearly identifiable subsection of the monograph for OTC skin protectants would be appropriate for diaper rash drug products. The comment argued that in cases where the ingredients in OTC diaper rash drug products are not skin protectants, these ingredients could be handled under appropriate combination policies. Another comment mentioned that several of the ingredients listed by the agency as diaper rash ingredients had not been referred to any rulemaking and suggested that these ingredients, especially those which are barrier-like skin protectants (e.g., cod liver oil, talc), should be referred to the rulemaking on OTC skin protectant drug products.

One comment concerned the use of zinc oxide for treatment of diaper rash. Another comment requested that its earlier submissions on sodium bicarbonate be included in the administrative record for a proposed monograph on OTC drug products for the treatment of diaper rash. The comments included articles on various uses of sodium bicarbonate and excerpts of a marketing study on this ingredient (Ref. 1). One comment stated that a review of ingredients in diaper rash product submissions revealed the use of borax in one product and boric acid in four products in concentrations ranging from 0.5 to 7.14 percent. The comment noted that according to the definition of "active ingredient" in § 210.3(b)(7) (21 CFR 210.3(b)(7)), boric acid and borax are not present as active ingredients but as buffering agents (i.e., pharmaceutical necessities).

One comment suggested two tests for the agency to consider as standards by which the effectiveness of a diaper rash product may be determined for a claimed therapeutic benefit. One comment expressed its opposition "to the inclusion in the OTC monographs of any anecdotal or superfluous comments about disposable diapers that are not confirmed by scientific data."

The agency has determined that it would be more appropriate to address the entire issue of diaper rash prevention and treatment at one time, either in a separate rulemaking or concurrently in each respective rulemaking. Accordingly, the comments on diaper rash drug products submitted to the rulemaking on antifungal drug products will be considered at a later time. An antifungal ingredient that is determined to be appropriate for the relief of diaper rash will be included in the appropriate tentative final monograph applicable to OTC diaper rash drug products. The same antifungal ingredient also may be determined to be appropriate for use in athlete's foot, ringworm, and jock itch and, therefore, can remain in this rulemaking for OTC antifungal drug products.

B. Comment on Definitions

6. Referring to the definition of dermatophyte in § 333.203(d) of the Panel's recommended monograph (47 FR 12480 at 12564), one comment pointed out that the definition should be revised to state that "filamentous fungi are *saprophytic* on human skin, hair or nails, (dead tissue only) and are *not* parasitic."

In its report the Panel discussed dermatophytes as follows:

> Dermatophytes. A group of taxonomically related fungi which normally live in soil, where they metabolically decompose organic keratinous debris through the enzymatic digestion of keratin (a fibrous protein also found in cornified epidermis). Many of these fungi cause superficial skin infections including athlete's foot, jock itch, and ringworm in humans and in animals by invading and living in the cornified epidermis or in the hair or nails. These fungi are subdivided and classified according to their usual source of isolation from soil, from animals, or from man.
>
> The dermatophytic fungi most commonly mentioned in this document include *Trichophyton rubrum (T. rubrum), Trichophyton mentagrophytes (T. mentagrophytes),* and *Epidermophyton floccosum (E. floccosum).* These organisms are the most frequent causes of human infections in the United States, but other strains may be involved. (See 47 FR 12480 at 12485.)

The Panel's definition of dermatophyte in § 333.203(d) i.e., "a fungus that is parasitic upon the skin, hair, or nails of humans or animals," was based on the above discussion. Words such as "parasitic" and "saprophytic," both of which may be applicable to fungi, have scientific definitions that are not generally understood by laymen and thus require further definition in order to be understood. Therefore, to make the term dermatophyte more understandable to laymen, the agency has deleted the word "parasitic" from its definition and is proposing the following definition in this tentative final monograph: *"Dermatophyte.* A fungus that invades and lives upon the skin or in the hair or nails." This definition is abstracted from the Panel's discussion, does not include any words that need further definition, and is sufficiently clear for use in this tentative final monograph. The Panel's reference to "animal" has been deleted from the definition because this rulemaking concerns only drugs intended for OTC human use.

C. Comment on Chloroxylenol

7. In response to the Panel's recommendation that one double-blind, placebo-controlled clinical trial be conducted to establish the effectiveness of chloroxylenol, one comment submitted such a study (Ref. 1) and stated its belief that the results will enable chloroxylenol to be moved from Category III to Category I. The comment also submitted three additional studies (Refs. 2, 3, and 4) containing safety data in response to the agency's concern (Ref. 5) about the irritation/sensitization potential of 2 percent chloroxylenol. The comment concluded that all of these studies demonstrate that a product containing 2 percent chloroxylenol is safe for human use against fungal infections.

The Panel concluded that chloroxylenol for OTC topical antifungal use is safe for application to small areas of the skin over short periods of time, at least over a 13-week period, but that there were insufficient efficacy data available to permit final classification (47 FR 12480 at 12533). The study submitted by the comment was a double-blind controlled trial (Ref. 1) in which 2 percent chloroxylenol (vehicle not specified) was compared with its aqueous emollient base vehicle in the treatment of postassium hydroxide (KOH) positive, culture positive tinea pedis. The patients were treated twice a day for 28 days and evaluated at time 0 (entry into the study) and at 14, 28, and 42 days (no therapy for 2 weeks before the last evaluation). In order for a patient to be considered cured, the patient must have had neither signs nor symptoms of active fungal infection in addition to a negative KOH and a negative culture at both the 28-day and 42-day evaluations. Of the 53 subjects who completed the study, 9 were changed to the active drug after initially being on the placebo. Four of the nine were changed to the active products after 3 to 14 days of placebo therapy. Five of the nine were changed to the active drug after 28 days of placebo therapy. The latter five cases were counted as placebo failures in the statistical analysis. When changed to the active drug, they were treated as new cases. Thus, 39 patients were treated with 2 percent chloroxylenol, and 33 were considered cured (92.3 percent). Nineteen patients were treated with placebo, and only three were considered cured (15.8 percent).

The agency has some concerns about this study. Of the 53 patients cultured, 46 yielded *Trichophyton tonsurans (T. tonsurans).* Although *T. tonsurans* is becoming a more common pathogen on the body and produces almost all of the scalp ringworm seen in the United States, it remains uncommon to find this pathogen on the feet. A published study indicates that only 5 to 15 percent of pedal lesions yield. *T. tonsurans* (Ref. 6). Consequently, it was most unusual for the submitted study to find 46 of 53 (86.8 percent) of the fungal isolates yielding this organism from the feet. It is not known whether chloroxylenol or other antifungals are as active against *T. tonsurans* as they are against the most common organisms cultured in athlete's foot. Only a very few patients in this study had the fungi *Trichophyton rubrum (T. rubrum), Trichophyton mentagrophytes (T. mentagrophytes),* or *Epidermophyton floccosum (E. floccosum),* and none were reported to have *Mricrosporum canis (M. canis)* or *Candida albicans (C. albicans).* The Panel stated that when establishing antifungal activity the antifungal action of the specific ingredient must be tested using all these fungi (47 FR 12480 at 12561).

This study is also flawed by inadequate documentation of the randomization procedure, a low proportion of evaluable patients, and a mistaken classification of patient outcomes. Also, patients were allowed to switch therapy during the trial. This shifting of patients between treatment groups not only interfered with the randomization process, but also jeopardized the double-blind nature of the study. In view of these problems, the comment's analysis and claim of drug efficacy based on data from 53 patients (5 entered twice) has questionable validity.

After the patient outcome data were corrected and reclassified, there were nine patients with unknown outcomes due to incomplete followup data (less than 4 weeks) on placebo. Consequently, out of 85 patients who entered the study, there were only 44 patients with evaluable data. There is no assurance that the treatment groups are still comparable after nearly half of the patients were excluded from the analysis. Thus, even if the randomization procedure had been adequate and data following drug reassignment are disregarded, this study does not provide sound statistical evidence that 2 percent chloroxylenol is effective for the treatment of athlete's foot. Consequently, the agency concludes at this time that chloroxylenol should not be reclassified as Category I for the treatment of athlete's foot because the data submitted are inadequate to show effectiveness.

Although noting that some cases of minor irritation had been reported, the Panel concluded that chloroxylenol in concentrations of 3.75 percent or less is safe for OTC antifungal use in the treatment of athlete's foot, jock itch, or ringworm. Nevertheless, the agency expressed concern that if chloroxylenol is irritating it could cause severe dermatitis on areas other than the feet, such as the groin, and recommended standard irritation and sensitization tests on the formulations being marketed to determine whether a warning against use on areas other than the feet would be needed (Ref. 5). In response to the agency's concern, the comment submitted primary skin irritation and primary eye irritation studies on rabbits (Refs. 2 and 3). In the skin irritation study, the test material was applied to 18 intact and 18 abraded sites on rabbits' backs, covered for 24 hours, and evaluated. The highest Draize score on any site was a 2, and all redness was gone by 48 hours. Thus, the product was classified as nonirritating. The standard Draize primary eye irritation study also indicated that the product was nonirritating. The agency has reviewed these studies and concurs with the comment that 2 percent chloroxylenol was shown to be nonirritating.

The comment also submitted two human studies. One study used a repeated insult patch test with a formulation containing 2 percent chloroxylenol (Ref. 4). Ten subjects were treated in the groin area using a modified Draize-Schelanski test. The

area was covered for 24 hours following each application, rested for 24 hours, and then applications were repeated for a total of 10 times. Following a 14-day rest period, a challenge application was made to the same area. There were no adverse reactions, indicating a lack of irritation or sensitization. In the second human study, the efficacy study discussed above (Ref. 1), in which 39 subjects with athlete's foot were treated with the 2-percent chloroxylenol product, there were no adverse reactions, the regenerated tissue was good, and subject acceptance of the product was very good.

The agency concludes that these data indicate that 2 percent chloroxylenol does not appear to have a potential for irritation or sensitization and, therefore, can be considered safe for topical use on all areas of the body. In addition, the agency agrees with the Panel that 3.75 percent or less chloroxylenol is safe for use in the treatment of athlete's foot, jock itch, or ringworm over short periods of time, at least over a 13-week period.

In conclusion, safety appears to have been adequately demonstrated, but there is insufficient evidence of effectiveness to reclassify 2 percent chloroxylenol to Category I as an OTC antifungal agent for use in the treatment of athlete's foot, jock itch, and ringworm. The agency's detailed comments and evaluations are on file in the Docket's Management Branch (Ref. 7).

References

(1) Tilton, R.C., and R.E. Pinkerton, "A Controlled Clinical Study to Evaluate the Effectiveness of Chloroxylenol for the Treatment of Tinea Pedis," unpublished study in Comment No. LET011, Docket No. 80N–0476, Dockets Management Branch.

(2) Fanaras, J.C., and M. Schmidt, "Primary Skin Irritation Evaluation of Absorbine Athlete's Foot Product (L) 2119A," unpublished study in Comment No. LET010, Docket No. 80N–0476, Dockets Management Branch.

(3) Fanaras, J. C., and M. Schmidt, "Primary Eye Irritation Evaluation of Absorbine Athlete's Foot Product (L) 2119A," unpublished study in Comment No. LET010, Docket No. 80N–0476, Dockets Management Branch.

(4) Pinkerton, R. E., "Chloroxylenol Repeated Insult Patch Test in Human Subjects," unpublished study in Comment No. LET010, Docket No. 80N–0476, Dockets Management Branch.

(5) Letter from W. E. Gilbertson, FDA, to D. R. Smith, W. F. Young, Inc., coded LET007, Docket No. 80N–0476, Dockets Management Branch.

(6) Bronson, D. M., et al., "An Epidemic of Infection with *Trichophyton Tonsurans* Revealed in a 20-year Survey of Fungal Infections in Chicago," *Journal of the American Academy of Dermatology*, 8:322–330, 1983.

(7) Letter from W. E. Gilbertson, FDA, to D. R. Smith, W. F. Young, Inc., Coded LET014, Docket No. 80N–0476, Dockets Management Branch.

D. Comments on Clioquinol

8. One comment requested that clioquinol (iodochlorhydroxyquin) (alone or in combination with hydrocortisone) be added to the Panel's list of drugs effective in the treatment of candidal infections (cutaneous candidiasis). The comment cited four studies in support of clioquinol's effectiveness for this use (Refs. 1 through 4).

The combination of clioquinol and hydrocortisone is discussed in comment 23 below. In this comment the agency is presenting its review of the four studies submitted by the comment and its determination that the data are inadequate to establish the effectiveness of clioquinol when used alone in the treatment of cutaneous candidiasis.

In a study by Brecker et al. (Ref. 1), a patient group (unidentified with respect to sex) was diagnosed as having moniliasis. The treatment sites were the following: axilla, buttocks, groin, genitalia, perianal area, and perineal area. Only 32 patients out of the 354 culture-verified patients were shown to have infections caused by *Candida albicans*, and only 7 of these patients were treated with the single ingredient clioquinol. Other patients were treated with a combination of clioquinol and hydrocortisone, hydrocortisone alone, and the vehicle alone. Therefore, as stated by the authors themselves, the number of patients in the clioquinol treatment group was too small to make the results statistically significant.

Carpenter et al. (Ref. 2) tested the same four components in 112 female patients diagnosed as having secondary bacterial or fungal infections. The study analyzed data from only those patients having organisms of accepted pathogenicity: Coagulase positive *Staphylococcus aureus, Candida albicans, Candida tropicalis, Microsporum gypseum, Microsporum canis, Trichophyton rubrum, Trichophyton mentagrophytes*, and mixed *Staphylococcus aureus* and fungal infections. However, the distribution of the infections caused by these organisms in the treatment populations was not specified. Therefore, this study provides no specific data on the activity of clioquinol as a single ingredient in infections caused by *Candida*.

The study by Abdel-Aal et al. (Ref. 3) was not designed to demonstrate the effectiveness of clioquinol as a single ingredient and therefore does not provide any useful information relative to the activity of clioquinol in the treatment of cutaneous candidiasis.

The study of Barba-Rubio (Ref. 4), designed in the same manner as the Abdel-Aal study, also did not provide any useful data on the activity of clioquinol used alone in the treatment of cutaneous candidiasis.

In summary, the four studies cited by the comment did not demonstrate the effectiveness of clioquinol as a single ingredient in the treatment of cutaneous candidiasis. Further, in the preamble of the advance notice of proposed rulemaking, the agency dissented from the Panel's recommendation that OTC antifungal drug products be labeled for the "treatment of superficial skin infections caused by yeast (*Candida*)" (47 FR 12480). The agency solicited comments on the Panel's recommendations that haloprogin, miconazole nitrate, and nystatin be available OTC for the treatment of candidal infections. Except for the comments received on the use of those drugs for external feminine itching associated with vaginal yeast (*Candida*) infection, no comments were received. Therefore, the agency reaffirms its position that no antifungal ingredient can be labeled for OTC use for the treatment of cutaneous candidiasis. However, based on the Panel's Category I recommendations, the agency finds this claim to be a valid professional labeling claim and, therefore, is moving the Panel's recommended labeling in § 333.250(b)(4) to the professional labeling section of this tentative final monograph. This professional labeling approach is appropriate for haloprogin and miconazole nitrate because these ingredients have other appropriate OTC antifungal claims, but is not appropriate for nystatin, which currently does not have any OTC labeling claims and remains a prescription drug. As discussed in comment 35 below, the agency is deferring consideration of the use of antifungal ingredients for external vaginal itching associated with vaginal yeast (*Candida*) infection to the rulemaking for OTC vaginal drug products.

References

(1) Brecker, L. J., et al., "Protocol #02," draft of unpublished paper in OTC Volume 070193.

(2) Carpenter, C. L., et al., "Combined Steroid Antiinfective Topical Therapy in Common Dermatoses: A Double-Blind, Multi-Center Study of Iodochlorhydroxyquin-Hydrocortisone in 277 Patients," *Current Therapeutic Research*, 15:650–659, 1973.

(3) Abdel-Aal, H., et al., "A Double-Blind Comparison of a New Combination (Halcinonide-Neomycin-Amphotericin) and Active Controls in Cutaneous Candidiasis and Steroid-Responsive Dermatoses," *The Journal of International Medical Research*, 4:232–236, 1976.

(4) Barba-Rubio, J., "Clinical Evaluation of a New Halcinonide-Antifungal Combination," *Current Therapeutic Research*, 20:655–660, 1976.

9. One comment stated that the Panel made several errors in its review of antibacterial data submitted for clioquinol (Refs. 1 and 2) and that these errors resulted in the Panel's conclusion that clioquinol has little or no antibacterial activity (47 FR 12480 at 12497). The comment submitted an analysis that addressed each of the errors it claimed the Panel made in reviewing the submitted data.

One point noted by the comment in its analysis was that in discussing the submitted in vitro data the Panel stated that "soybean-casein digest agar was used, although Mueller-Hinton is the standard medium" (47 FR 12496). The comment pointed out that trypticase soy agar (BBL) is a general purpose nutrient medium that is also used for sensitivity testing, such as minimal inhibitory concentration (MIC) determination. The comment added that Mueller-Hinton agar is the accepted standard medium for the Standardized Disc Agar Diffusion Assay; but that because the studies reported were not being correlated with disc zone sizes, any suitable growth medium was acceptable for the MIC determination.

The comment also stated that the Panel's assessment of the MIC for the tested organisms (47 FR 12496 to 12497) is incorrect because the Panel misread the table that summarized the results of the MIC determination; that the values recorded in the table are the cumulative percentage of organisms inhibited at the clioquinol concentrations indicated in the heading as micrograms per milliliter (μg/mL); and that all strains, without exception, were inhibited at concentrations below 100 μg/mL.

The comment further stated that the Panel incorrectly identified the growth medium used in the agar dilution MIC determination as Dermatophyte Sporulation Test agar (47 FR 12480 at 12497), when in fact the medium used was Diagnostic Sensitivity Test Agar (DST) (oxoid), the medium recommended by the World Health Organization for conducting sensitivity tests. The comment also disagreed with the Panel's determination that the MIC for *Pseudomonas aeruginosa* (*P. aeruginosa*) was greater than 128 μg/mL, when actually only 24 percent of the 165 strains of *P. aeruginosa* tested had an MIC greater than 128 μg/mL.

The agency has reviewed the analysis submitted by the comment and concurs with the comment's assessment as described above. Although the comment did not specifically request that an antibacterial claim be allowed, the agency considers it appropriate to note here that such a claim as it relates to antifungal activity remains in Category III as the Panel recommended (47 FR 12553).

References

(1) Ciba-Geigy Laboratories (U.S.A. and Switzerland), "Inhibitory Activity of Vioform," unpublished study in OTC Volume 070233.

(2) Scherrer, M., et al., "The Antimicrobial Activity of Broad-Spectrum Antimicrobials with Special Regard to Salicylic Acid," *Mykosen*, 14:323-334, 1971.

E. Comment on Coal Tar

10. One comment noted the Panel's Category II recommendation for coal tar as a topical antifungal ingredient and, while not taking issue with the recommendation, expressed concern that the decision may have been based on relative safety and effectiveness grounds. The comment stated that the Panel considered animal studies and anecdotal human studies, but did not include recent retrospective human studies. Therefore, the Panel did not provide a balanced review of the available information. The comment provided information on the chemistry and toxicity of medicinal coal tar and referred to the symposium on coal tar held by the Antimicrobial II and Miscellaneous External Panels on June 25, 1977 (Ref. 1). The comment pointed out that the composition of medicinal coal tar is more consistent than indicated in the Panel's report and that data presented at the symposium (but not cited in the Panel's report) and other data (Refs. 2, 3, and 4) indicate there is not a significant carcinogenic burden from the proper use of medicinal coal tar.

The Panel's review of coal tar as an antifungal was based on data available to it at the time that it met. The Panel noted that there were abundant data on the carcinogenic potential of coal tar and that there were no double-blind controlled clinical studies supporting the effectiveness of this ingredient as an antifungal (47 FR 12480 at 12516). In the tentative final monograph for OTC dandruff, seborrheic dermatitis, and psoriasis drug products, the agency discussed the results of more recent studies that evaluated the carcinogenic risks from using medicinal coal tar and proposed that coal tar be classified as Category I for use in control of all three conditions because the agency believes that, for these uses, the benefits to be derived from coal tar outweigh the potential risks. (See 51 FR 27346; July 30, 1986.)

Although the comment submitted additional information, it did not dispute the Category II classification of coal tar as an antifungal. Coal tar remains in Category II in this tentative final monograph because no new data have been submitted to show that it is effective for antifungal use.

References

(1) Summary Minutes of the 27th Meeting of the Advisory Review Panel on Antimicrobial (II) Drug Products, June 24–26, 1977.

(2) Pittelkow, M.R., et al., "Coal Tar, Ultraviolet Light and Cancer," *Journal of the American Academy of Dermatology*, 4:234–235, 1981.

(3) Maughan, W.Z., et al., "Incidence of Skin Cancers in Patients with Atopic Dermatitis Treated with Coal Tar," *Journal of the American Academy of Dermatology*, 3:612-615, 1980.

(4) Stern, R.S., et al., "Skin Carcinoma in Patients with Psoriasis Treated with Topical Tar and Artificial Ultraviolet Radiation," *Lancet*, 1:732–735, 1980.

F. Comment on Menthol

11. One comment requested that menthol be reclassified from Category II to Category III for effectiveness and from Category III to Category I for safety. The comment noted that the Panel had placed menthol in Category III in the information copy of its report (dated November 1979), stating that menthol was a "potentially viable antifungal ingredient" and that an in vitro study and one clinical study were required to establish proof of its effectiveness. However, in the advance notice of proposed rulemaking (47 FR 12480), the Panel placed menthol in Category II for effectiveness. The comment maintained that the Panel's original findings were consistent with a Category III classification for menthol and that the change to Category II was unwarranted.

The comment also disagreed with the Panel's conclusion that there are insufficient safety data for menthol in concentrations greater then 0.2 percent. The comment cited the conclusions of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (Topical Analgesic Panel) that menthol is safe for topical analgesic, anesthetic, and antipruritic use in concentrations of 0.1 to 1 percent and as a counterirritant at 1.25 to 16 percent (44 FR 69768 at 69827; December 4, 1979).

The information copy of the Panel report was a preliminary report; the final decisions of the Panel were presented in its report published in the **Federal Register** on March 23, 1982 (47 FR 12480). In its final report, the Panel concluded that, although menthol may be useful in providing symptomatic relief of fungal infections through its antipruritic action, it is not an effective antifungal ingredient. Thus, the Panel classified menthol in Category II. The agency has reviewed the data evaluated by the Panel (47 FR 12517) and agrees with the Panel's conclusion that the limited in vitro data available show menthol to be a poor fungicide.

The agency agrees with the comment that menthol has been shown to be safe at concentrations greater than 0.2 percent. In the tentative final monograph for OTC topical analgesic drug products (48 FR 5852 at 5867; February 8, 1983), menthol was included as an analgesic, anesthetic, or antipruritic at concentrations of 0.1 to 1 percent and as a counterirritant at concentrations of 1.25 to 16 percent. However, counterirritants carry a warning against use on wounds or damaged skin; therefore, the concentrations approved for counterirritant use would not be appropriate for athlete's foot, jock itch, or ringworm. The agency considers menthol concentrations of 0.1 to 1 percent safe (Category I) for topical applications of athlete's foot, jock itch, or ringworm. Concentrations greater than 1 percent will remain as Category III for safety.

Because no new data have been submitted on the effectiveness of menthol as an antifungal agent, the agency is classifying this ingredient in Category II for efficacy in this proposed rule.

G. Comments on Phenol

12. Two comments disagreed with the Antimicrobial II Panel's Category II classification of phenol/phenolate sodium at less than or equal to 1.5 percent concentration for antifungal use (47 FR 12480 at 12519). Both comments pointed out that four other OTC advisory review panels placed phenol in Category I for safety: Dentifrice and Dental Care and Antimicrobial I Panels at concentrations up to 1.5 percent (47 FR 22712 at 22734 (May 25, 1982) and 39 FR 33102 at 33133 (September 13, 1974)), Oral Cavity Panel at concentrations of 0.5 to 1.5 percent (47 FR 22760 at 22814 (May 25, 1982)), and Topical Analgesic Panel at concentrations of 0.5 to 2 percent (44 FR 69768 at 69832).

One of the comments (Ref. 1) submitted copies of some of the studies (Refs. 2 through 12) submitted to the Antimicrobial II Panel and one new study (Ref. 13) on a phenol-based mouthwash. The comment also submitted animal safety data already reviewed by the Panel and requested Category I status for safety. The comment also contended that "the uncontrolled in vivo studies submitted to the Antimicrobial II Panel indicate that phenol/phenate [phenolate] sodium has been demonstrated to be more effective than other Category III ingredients."

The other comment (Ref. 14) asserted that the data are not consistent with Category II classification and requested that phenol/phenate [phenolate] sodium be placed in Category I for safety and Category III for effectiveness. The comment discussed several studies (Refs. 2 through 5) that were submitted to the Panel and claimed that these studies demonstrated no adverse effects of phenol/phenolate when applied to both broken and intact skin. The comment also discussed studies by a number of clinical investigators (Refs. 6 through 12) on the use of phenol/phenolate sodium on oral and vaginal mucosal membranes and stated that no irritant, toxic, or sensitizing effects were observed in any of the studies. The comment contended that these studies demonstrate the safety of phenol/phenolate sodium when used to treat athlete's foot and similar dermatologic disorders exhibiting broken and denuded epithelialized areas. Both comments stated that the Panel's conclusion "that the symptomatic and pruritic relief which would be offered by the inclusion of phenol/phenate [phenolate] sodium does not justify the potential risk of skin irritation or systemic toxicity that may result from the topical application of the formulation" was not consistent with in vivo and in vitro studies conducted, nor with the fact that millions of consumers have used the ingredients for more than 30 years with no reportable adverse effects.

The agency acknowledges that four other panels described by the comments have placed phenol/phenolate sodium in Category I for safety. Two of these panels, the Oral Cavity Panel and the Dentifrice and Dental Care Panel, evaluated the use of phenol on oral mucosa. The studies submitted by the comments on the safety of phenol on oral mucosa (Refs. 6 through 11 and 13) involved the short-term use of a combination product on the throat. The agency believes that, because the throat is constantly moist, use of the ingredient in this area is not considered analogous to the use of the ingredient on broken or intact skin infected with fungus. The comment also submitted an uncontrolled study (Ref. 12) which reported the safe use of a combination product containing sodium phenolate and phenol (less than 2 percent) on the vaginal mucous membranes of 529 gynecological patients with cervicitis or for prehysterectomy surgery or vaginitis. Three of the four studies (Refs. 3, 4, and 5) submitted by the comments in support of the safety of phenol on skin were uncontrolled clinical studies using a preparation containing sodium phenolate, phenol (less than 2 percent), menthol, thymol, sodium tetraborate, glycerin and either methyl salicylate or chlorophyll. The fourth skin study (Ref. 2) was a repeated insult patch test using an unspecified combination product. All of the studies lack details of material, methods, and evaluation procedures. Thus, the reported results (no toxic or sensitizing effects) in some of these studies are considered supportive information but are not adequate to demonstrate the safety of phenol at concentrations of 1.5 percent or less when applied to broken or intact skin infected with fungus.

The agency is concerned about the safe use of phenol/phenolate sodium in the treatment of athlete's foot, jock itch, and ringworm. In the tentative final monograph for OTC external analgesic drug products, the agency proposed that phenol/phenolate sodium carry the label warning "Do not apply over large areas of the body or bandage" and that use be limited to 7 days if symptoms persist (48 FR 5852 at 5868 to 5869). In considering phenol/phenolate sodium as an antifungal agent, the Antimicrobial II Panel was concerned that using phenol in athlete's foot, jock itch, and ringworm would be similar to using it under a bandage because the affected areas would be covered by clothing (47 FR 12480 at 12518). The Panel noted that "in most reports of toxicity from dilute solutions of phenol, bandaging the application was necessary to produce severe local changes." The Topical Analgesic Panel also recommended that preparations containing 1 to 2 percent phenol should be applied only to the smallest area needing treatment and should not be bandaged to prevent severe skin irritation (44 FR 69768 at 69833). Because it may be necessary to use an antifungal drug for 4 weeks to clear the infection, this prolonged exposure period and the occlusion of the affected area increase the potential risk of skin irritation and systemic toxicity from phenol. Data are needed to establish that phenol/phenolate sodium is safe for use under these conditions.

For these reasons, the agency agrees with the Panel that more data are needed to demonstrate that phenol/phenolate sodium in concentrations less than or equal to 1.5 percent is safe for use in the treatment of athlete's foot, jock itch, and ringworm. Therefore, phenol/phenolate at less than or equal to 1.5 percent is classified in this tentative final monograph as Category III for safety for use as an antifungal.

With regard to effectiveness, the Panel found that the in vitro concentrations required for effective antifungal action often exceed 1.5 percent concentration of phenol (47 FR 12480 at 12517). The studies (Refs. 3, 4, and 5) referred to by the comment to support the statement that phenol is more effective than other Category III ingredients were uncontrolled studies with a product containing less than 2 percent phenol and a number of other ingredients, as mentioned above. None of the studies met the Panel's guidelines for effectiveness testing of an active ingredient for fungicidal or fungistatic activity. The agency finds the results of the studies inadequate to demonstrate the efficacy of phenol as an antifungal drug and, therefore, is classifying phenol/phenolate in Category III for effectiveness.

References

(1) Comment No. C00011, Docket No. 80N-0476, Dockets Management Branch.

(2) Leach, E. D., An Unpublished Controlled Skin Sensitivity Study, Milligan College, TN, June 1970, in OTC Volume 070101.

(3) Freeman, C. W., " Evaluation of Chloraderm in the Topical Therapy of 'Athlete's Foot,' " *Medical Annals of the District of Columbia*, 32:98–99, 1963.

(4) Freeman, C. W., J. G. Gathings, and T. Gopinathan, "Evaluation of Chloraderm as a Dermatologic Agent," *Medical Annals of the District of Columbia*, 30:213–215, 1961.

(5) Streiker, F. B., "Chloraderm in Tinea Pedis," *Journal of the American Podiatry Association*, 54:29–30, 1961.

(6) Pinson, T. J., and J. Stanback, "Evaluation of Choloraseptic Solution as an Anesthetic Mouthwash," *The Quarterly of the National Dental Association*, 22:49–52, 1964.

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(14) Comment No. C00015, Docket No. 80N-0476, Dockets Management Branch.

H. Comments on Povidone-iodine

13. One comment submitted data (Ref. 1) addressing two of the Panel's concerns on povidone-iodine: The availability of elemental iodine from the complex and the stability of povidone-iodine (47 FR 12480 at 12546). The comment stated that substantial data were submitted to the OTC Antimicrobial (I) Panel and other panels showing that iodine is freely released from the complex, and the rate of iodine release is controlled by tissue demand. The comment contended that at equilibrium any iodine that is removed from the complex is replaced within less than 25 milliseconds (ms) (Refs. 2 and 3). The comment pointed out that chemical titration studies were submitted to the antimicrobial rulemaking, and these studies show that povidone-iodine provides the same amount of available iodine as tincture of iodine (Ref. 4). Regarding the stability of the complex, the comment contended that even if a stability issue existed it would be outside the scope of the review because stability is covered by the Current Good Manufacturing Practice regulations (CGMP) (21 CFR parts 210 and 211). The comment stated that, under the CGMP regulations, minimum standards have been set to ensure product stability for finished drug products (21 CFR 211.166), and the manufacturer of the finished dosage form is responsible for complying with these stability standards. The comment added that expiration dating as well as appropriate storage conditions are determined through required written testing programs.

The Panel considered povidone-iodine to be safe, but recommended that further studies were needed on the stability of povidone-iodine and on the availability of elemental iodine from the complex. The agency has reviewed the data submitted regarding availability (Refs. 2 and 3) and agrees with the comment that iodine is rapidly released from the povidone-iodine complex. According to Schenck et al. (Ref. 2), a povidone-iodine solution at a concentration of 1 to 10 percent contains over 99 percent complexed iodine. The concentration of free iodine in the solution reaches a maximum of 8×10^{-5} moles/liter. At equilibrium, the povidone-iodine complex is self-monitoring. The rate of iodine release from the complex is controlled by tissue demand, and any iodine that is removed from the complex would be replaced within less than 25 ms (Ref. 3).

The agency also agrees with the comment that issues regarding stability would be governed by the CGMP regulations (21 CFR parts 210 and 211). These regulations require a written testing program to assess the stability of finished products and to determine appropriate storage conditions and an expiration date. Section 211.137(a) requires that drug products bear an expiration date supported by appropriate stability testing. However, § 211.137(g) provides that expiration dating requirements are not enforced for human OTC drug products if their labeling does not bear dosage limitations and they have been shown to be stable for at least 3 years by appropriate stability data. Therefore, FDA concludes that further submissions of data on the stability of povidone-iodine are not needed for purposes of this rulemaking proceeding. For additional information, see the agency's comments on the stability and availability of povidone-iodine in connection with the rulemaking for OTC topical acne drug products (Ref. 5). (See also the **Federal Register** of January 15, 1985; 50 FR 2172 at 2173.)

References

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(4) Comment No. C00108, Docket No. 75N-0183, Dockets Management Branch.

(5) Letter from W. E. Gilbertson, FDA, to L. Blecher, GAF Corp., coded LET004, Docket No. 81N-0114, Dockets Management Branch.

14. One comment submitted the results of a clinical study (Ref. 1) in response to the Panel's statement (47 FR 12480 at 12546) that a double-blind, placebo-controlled clinical trial was needed to determine the effectiveness of povidone-iodine for the treatment of athlete's foot, jock itch, and ringworm.

The comment also included a statistical analysis of the study (Ref. 2) and the results of an in vitro assay of two povidone-iodine solutions for antifungal activity (Ref. 3). The comment stated that these data should be sufficient to meet the Panel's requirement for reclassifying povidone-iodine into Category I for effectiveness.

In the clinical study (Ref. 1), 40 patients with clinically and laboratory diagnosed athlete's foot were divided into two groups, one group using a 10-percent povidone-iodine solution and the other using the same solution without the povidone-iodine. Patients applied the medication to all involved areas of the feet every morning and night for 4 weeks. Cultures and potassium hydroxide (KOH) preparations were done before the study and repeated at the end of the treatment period and at a followup visit 4 weeks later. Signs and symptoms were scored weekly during treatment and at the followup visit. When the patients were evaluated at the end of the treatment period and signs and symptoms, KOH preparations, and cultures were considered simultaneously, the patients using povidone-iodine solution had a 68.4-percent therapeutic cure rate whereas the patients using placebo had a 30-percent therapeutic cure rate (Ref. 2). These cure rates were sustained to 4 weeks after therapy, and the difference is statistically significant ($p < 0.05$). No side effects were reported in the study.

An in vitro study (Ref. 3) was performed to show that there was no difference in the fungicidal activity of the povidone-iodine solution used in this study, which also contained 0.05 percent methyl salicylate, and an identical solution of 10 percent povidone-iodine without the methyl salicylate.

The agency concludes that this study, along with the information previously reviewed by the Panel, provides adequate evidence of the safety and effectiveness of 10 percent povidone-iodine in the treatment of fungal infections such as athlete's foot, jock itch, and ringworm. Therefore, the agency is proposing that 10 percent povidone-iodine be classified Category I for this indication.

The agency's detailed comments and evaluations are on file in the Dockets Management Branch (Ref. 4).

References

(1) Jolly, H. W., "Final Clinical Summary: Double-Blind Comparison Study of Isodine Athlete's Foot Solution Versus Placebo in the Treatment of Patients with *Tinea Pedis*," unpublished study submitted with Comment No. C00005, Docket No. 80N-0476, Dockets Management Branch.

(2) Jolly, H. W., and R. G. Mora, "Final Statistical Report: Double-Blind Comparison Study of Isodine Athlete's Foot Solution Versus Placebo in the Treatment of patients with *Tinea Pedis*," unpublished study in Comment No. C00005, Docket No. 80N-0476, Dockets Management Branch.

(3) Axler, D., "Final Clinical Summary: *In vitro* Assay of Two Povidone-Iodine Solutions for Antifungal Activity," unpublished study in Comment No. C00005, Docket No. 80N-0476, Dockets Management Branch.

(4) Letter from W. E. Gilbertson, FDA, to E. A. Conrad, The Perdue Frederick Co., Coded LET012, Docket No. 80N-0476, Dockets Management Branch.

I. Comment on Rubbing Alcohol

15. One comment noted that rubbing alcohol applied between the toes morning and night is one of the most economical methods of controlling and eliminating athlete's foot as well as maintaining cleanliness of the feet. The comment suggested that the public be made aware of this economical alternative to more expensive OTC drugs that may not be as effective a remedy.

A number of alcohols were included in the products submitted to the Panel for review. The Panel considered these ingredients as possible antifungal agents based on the available literature and in some cases based on concentrations reported in a submission. The Panel concluded that these alcohols are inactive ingredients when used in products labeled for fungal infections of the foot, body, or groin (47 FR 12480 at 12485). Because the comment did not submit any data to support its contention that rubbing alcohol is an effective athlete's foot treatment and because the agency is not aware of any rubbing alcohol product labeled for antifungal use, the agency is unable to evaluate the basis for the comment's conclusion. Therefore, rubbing alcohol is not being classified in this rulemaking.

J. Comment on Tannic Acid

16. One comment requested that tannic acid be reclassified from Category II to Category III. The comment noted that the Panel had placed tannic acid in Category III in the information copy of its report (dated November 1979), stating that tannic acid was a "potentially viable antifungal ingredient" and that an in vitro study and one clinical study were required to establish proof of its effectiveness. No safety issues were raised. However, in the advance notice of proposed rulemaking (47 FR 12480), the Panel placed tannic acid in Category II. The comment maintained that the Panel's original placement of tannic acid in Category III was consistent with the criteria for other ingredients classified in Category III in the published report and that the change to Category II was unwarranted.

The information copy of the Panel report was a preliminary report; the final decisions of the Panel were presented in its report published in the **Federal Register** of March 23, 1982 (47 FR 12480). In its final report, the Panel reassessed the available data and concluded that the inclusion of tannic acid in antifungal medications is largely of historical interest. Having found no in vitro or clinical data on the effectiveness of tannic acid, the Panel concluded that this ingredient is not effective in the treatment of athlete's foot, jock itch, or ringworm and placed it in Category II (47 FR 12521). The agency has reviewed and agrees with the Panel's conclusions on tannic acid. Because no new data have been submitted, the agency is classifying tannic acid in Category II in this proposed rule.

K. Comment on Thymol

17. One comment requested that thymol be reclassified from Category II to Category III for effectiveness and from Category III to Category I for safety. The comment noted that the Panel had placed thymol in Category III in the information copy of its report (dated November 1979), stating that thymol was a "potentially viable antifungal ingredient" and that an in vitro study and one clinical study were required to establish proof of its effectiveness. However, in the advance notice of proposed rulemaking (47 FR 12480), the Panel placed thymol in Category II for effectiveness. The comment maintained that the Panel's original findings were consistent with a Category III classification for thymol and that the change to Category II was unwarranted.

The comment also disagreed with the Panel's conclusion that there are insufficient safety data for thymol in concentrations greater than 0.2 percent. The comment cited the conclusions of the Topical Analgesic Panel that "clinical use has confirmed that thymol is safe in the dosage range used as an OTC external analgesic" and that "thymol has little effect when applied topically to the skin and is virtually unabsorbed" (44 FR 69768 at 69855).

The information copy of the Panel report was a preliminary report; the final decisions of the Panel were presented in its report published in the **Federal Register** of March 23, 1982 (47 FR 12480). In its final report, the Panel

placed thymol at concentrations greater than 0.2 percent in Category II because the only clinical trial in which thymol was evaluated showed it to be ineffective in clearing athlete's foot and often irritating (47 FR 12523).

The agency has reviewed and agrees with the Panel's conclusions on thymol. The agency concludes that there are insufficient data to determine the safety of thymol at concentrations greater than 0.2 percent. The Panel determined and the agency concurs that additional data are needed to ensure the safety of thymol at concentrations greater than 0.2 percent. Based on the information it reviewed, the Panel concluded that more data are necessary on the absorption of thymol from small areas of application to broken and intact skin, on the local effects of thymol on wound healing, and on the irritation potential of thymol (47 FR 12522). However at concentrations less than or equal to 0.2 percent, thymol is safe and may be used as an inactive ingredient in formulations for product identification. The agency concurs with this recommendation.

The agency also notes that the Topical Analgesic Panel only reviewed thymol for use as an OTC external analgesic. That Panel referred thymol "to another Panel for the determination of its safety and efficacy as an antimicrobial and antifungal agent" (44 FR 69768 at 69855). Because of the different nature of the skin conditions being treated, the agency does not believe that the Topical Analgesic Panel's conclusions are applicable to the antifungal use of thymol.

Because no new data have been submitted on the effectiveness of thymol, the agency is classifying this ingredient in Category III (safety) and Category II (effectiveness) in this proposed rule.

L. Comments on Tolnaftate

18. Two comments stated that tolnaftate should be permitted to be labeled for the prevention of jock itch in addition to the prevention of athlete's foot. The comments noted that the Panel's reservation about long-term use of any antifungal agent in the groin (47 FR 12480 at 12490) was applied generally to all ingredients without regard to the safety margin of any ingredients. One comment added that the wide margin of safety of tolnaftate, including a very low potential for irritation, has been well established both through laboratory and clinical studies and through extensive use experience. The comment stated that results of this experience were presented to the Panel in oral and written submissions and by cross-reference to data contained in the new drug application for tolnaftate. The other comment asserted that after 19 years of extensive controlled and uncontrolled human studies, as well as lifetime studies in animals, tolnaftate is completely nontoxic to man and animal, and the potential for systemic absorption of tolnaftate through sensitive genital tissues and the groin with resultant toxicity is a nonexistent risk.

Although the safety of tolnaftate in the treatment of athlete's foot, jock itch, and ringworm is well established, the agency agrees with the Panel's recommendation that claims of prevention for this ingredient be limited to athlete's foot. The Panel concluded that tolnaftate may be used in the prevention of athlete's foot, but not in the prevention of jock itch or ringworm (47 FR 12480 at 12508). The Panel recognized that use of this ingredient for prevention of these fungal conditions would likely result in long-term use, whereas OTC treatment of a particular condition is limited to a specific time period. Because there is generally no limitation to the period of use when a product is used to prevent a condition, and because the groin is a more sensitive area than the feet, the Panel concluded that antifungal drugs, including tolnaftate, should not be used indefinitely in the groin (47 FR 12508). The comments did not submit any new data, but referred to studies that had been reviewed by the Panel. Those studies focused on the prevention of athlete's foot and not on jock itch. Therefore, the agency concludes that clinical studies on the prevention of jock itch are needed to establish the long-term safety of using tolnaftate or any other antifungal drug in the groin area. At this time, the agency finds insufficient data to support labeling tolnaftate for the prevention of jock itch. Although the comments did not discuss the prevention of ringworm, the agency considers it appropriate to express agreement with the Panel's statement that it would be impractical to use an antifungal agent prophylactically over large areas of the body to prevent ringworm (47 FR 12490 and 12508).

19. One comment contended that the Panel's Category I recommendation for a prophylaxis claim for tolnaftate was inconsistent with the Panel's own specific requirement of a study lasting a minimum of 12 weeks (47 FR 12480 at 12563). The comment argued that in one of the studies reviewed by the Panel three of the four centers participating in the study treated their patients for only 8 weeks (Ref. 1). The fourth center, which did test for 12 weeks, failed to show any difference between vehicle and tolnaftate therapy. The comment argued that two other studies reviewed by the Panel were also only conducted for 8 weeks (Refs. 2 and 3). The comment requested that the agency abandon the distinction between treatment and prophylaxis for antifungals because if an agent is effective in the treatment of a fungal infection it will also be effective in the prevention of the disease. As an alternate suggestion, the comment requested that the prophylaxis indication for tolnaftate be dropped. The comment also contended that the wording of § 333.250(b)(2) unfairly singles out tolnaftate. The comment requested that the heading for § 333.250(b)(2) should be in the same general format as § 333.250(b)(1), i.e., the word "tolnaftate" should not be in the heading for § 333.250(b)(2).

A reply comment stated that the referenced studies do, in fact, meet the criteria established by the Panel for prophylaxis and that the Panel properly applied these criteria in evaluating the clinical data on tolnaftate. The reply comment submitted a copy of an oral presentation made to the Panel which explains the results of the studies (Ref. 4).

The agency has reevaluated the data reviewed by the Panel to support its Category I recommendation for a prophylaxis claim for tolnaftate. The study by Charney et al. (Ref. 1) was conducted at four centers (California, Mississippi, Puerto Rico, and Texas), with a total of 168 subjects who entered the study with no evidence of fungal infection. At three of the four centers (California, Mississippi, and Puerto Rico), therapy was continued for 12 weeks with evaluations either taking place at 4, 8, and 12 weeks (Mississippi) or during the last 4 weeks of the 12-week period (California and Puerto Rico). At the other center (Texas), therapy was given for about 8 weeks. Thus, at three of the four centers the study met the Panel's 12-week criteria for length of the trial because therapy continued during the evaluation period.

The study showed that subjects treated with tolnaftate were significantly more likely to be free of athlete's foot at the end of the treatment period than were the control subjects. When the subjects at the center that continued therapy for only 8 weeks are excluded from the analysis, the following results are obtained: 38 of 41 subjects treated with tolnaftate were negative (93 percent) while 48 of 63 subjects treated with placebo were negative (76 percent). Regarding the comment's concern about the

significance of the results from one of the centers, the agency concludes that results with a p-value of less than 0.05 were obtained by pooling data from the three centers with 12-week trials.

In the study by Burrill and Nemlick (Ref. 2), therapy also continued for 12 weeks. The therapy consisted of an 8-week treatment period for each subject and a 4-week evaluation period, during which therapy continued. The study concluded that tolnaftate powder was superior to placebo in preventing the occurrence of athlete's foot in subjects free of tinea pedis at the start of the study. The study by Smith, Dickson, and Knox (Ref. 3) was similar in design to the Burrill and Nemlick study and arrived at a similar conclusion; however, the report of the Smith study did not make clear whether therapy continued during the evaluation period or only during the 8-week treatment period.

Although one part of the Charney study does not meet the Panel's 12-week criteria, the remainder of the Charney study and the Burrill and Nemlick study do meet the Panel's criteria, and the agency finds these studies adequate to support a prophylaxis claim for tolnaftate. Although the study by Smith, Dickson, and Knox does not meet the Panel's 12-week criteria, the results of the study can be considered supportive of the other two studies discussed above.

The agency disagrees with the comment's request to abandon a distinction between treatment and prophylaxis for antifungals. Treatment of an existing fungal condition and prevention of a condition are clearly different clinical entities. The intended use of the antifungal drug is different in each instance. Likewise, there is no reason to drop the prophylaxis indication for tolnaftate. This use has been satisfactorily established by the clinical data cited above.

However, the agency is revising the heading for § 333.250(b)(2), as suggested by the comment, so that it is consistent with the style and format of the other headings in the tentative final monograph.

References

(1) Charney, P., V. M. Torres, A. W. Mayo, and E. B. Smith, "Tolnaftate as a Prophylactic Agent for Tinea Pedis," *International Journal of Dermatology*, 12:179–185, 1973.

(2) Burrill, B. B., and A. S. Nemlick, "Prophylaxis of Tinea Pedis," *Journal of the Medical Society of New Jersey*, 67:629–631, 1970.

(3) Smith, E. B., J. E. Dickson, and J. M. Knox, "Tolnaftate Powder in Prophylaxis of Tinea Pedis," *Southern Medical Journal*, 67:776–778, 1974.

(4) Comment No. RC0002, Docket No. 80N–0476, Dockets Management Branch.

M. Comments on Undecylenates

20. One comment contended that under proper application of the governing scientific and legal standards FDA must conclude that the undecylenates are safe and effective for both treatment and prevention of athlete's foot, jock itch, and ringworm. The comment maintained that by definition an effective antifungal drug kills fungi and, with daily use, prevents the onset of infection. According to the comment, there is no evidence that fungi, unlike bacteria, develop resistance to topical agents, and separate prophylaxis studies are unnecessary to sustain prophylaxis claims. However, if separate evidence of prophylactic effect is to be required, the comment stated that such evidence has already been submitted to the agency for undecylenates (Ref. 1). In this study by Sulzberger and Kanof, 1,384 patients who received no treatment were compared with 1,213 patients treated with undecylenates. The researchers found that 28 percent of the untreated patients developed signs and symptoms of athlete's foot, but that only 4 percent of those on undecylenates developed the disease (Ref. 1). A reply comment reiterated the points made in the initial comment.

Another reply comment stated that the study of undecylenates by Sulzberger and Kanof (Ref. 1) falls quite short of the Panel's criteria to establish a prophylactic claim and gave the following reasons:

(1) No accurate record was made of actual treatment periods.

(2) No mycology was performed on any of the subjects. The only criterion was presence or absence of clinical symptoms.

(3) The control group received "no prophylactic agent" rather than a placebo vehicle control. This factor is especially important in a prophylactic study because the vehicle and proper hygiene make a significant contribution in the prevention of athlete's foot infections.

Another comment submitted new data consisting of the results of a study conducted with an undecylenate powder to prevent athlete's foot (Ref. 2). According to the comment, this study was designed in accordance with the Panel's recommendations, and the results of the study demonstrate the prophylactic effectiveness of undecylenates.

The Panel recognized that many Category I drugs effective in the treatment of athlete's foot might also be effective in its prevention. However, the Panel believed that data from human studies were necessary to support a prophylactic indication. The long-term effects of prophylactic drugs on the feet and on the fungi that cause athlete's foot are also not known. Accordingly, the agency concurs with the Panel that separate prophylaxis studies are necessary to support prophylactic claims.

With regard to the undecylenates, the agency concurs with the Panel and the reply comment that the study by Sulzberger and Kanof (Ref. 1), submitted to support a prevention claim for undecylenates, has the following serious deficiencies: The length of treatment was unclear; no potassium hydroxide (KOH) preparations or cultures were done; and the control group was "no treatment" controlled rather than "placebo vehicle" controlled.

The study submitted by the comment enrolled 87 subjects, some with and some without a history of athlete's foot; all had no lesions, negative cultures, and negative KOH preparations. Active drug (20 percent zinc undecylenate and 2 percent undecylenic acid) and vehicle were used in a double-blind manner. After 6 weeks of twice daily therapy, visual examination was performed on all patients and KOH preparations and cultures were done on those with lesions. Eight patients with positive mycological findings at week 6 were counted as prophylaxis failures and placed on therapy. All eight patients had been receiving the vehicle. Four other patients were dropped from the study for failing to appear at week 6. The remaining patients were kept on therapy until week 12, when cultures and KOH preparations were performed on all patients. No drug-related adverse effects were reported. The study, which included both 6-week and 12-week prophylaxis failures, concluded that infection occurred in 28 percent of the untreated groups, while infection occurred in only 7 percent of the treated group.

The agency has reviewed the study and finds that it does not provide sufficient evidence to support a claim for the effectiveness of undecylenates in the prevention of athlete's foot. A major flaw in this trial was the decision to perform mycological evaluations at week 6 only on those patients with visible foot lesions and to drop from the study those patients with positive mycology. Had mycological evaluations been done on all patients at week 6, additional failures (positive mycology but no clinical symptoms) might have been detected and the difference

between vehicle and treatment groups may not have been as large. This point takes on added significance when one considers that, at the end of the 12-week study, 3 of 31 patients in the vehicle control group had positive mycology while 3 of 38 patients in the treatment group were positive. In addition, double blinding may have been compromised by the elimination of eight patients from the placebo group. It is the agency's view that either all patients or no patients should have been cultured at week 6. Because the study included both patients with and without a previous history of athlete's foot, there would be an expected difference at 12 weeks between those 2 groups without treatment. There is no evidence that the groups were evenly balanced to rule out this factor. Further, the results of the study were incompletely reported with regard to the grading system for clinical signs and symptoms, and specific organisms cultured from each group. The apparently superior performance of the group treated with the undecylenates cannot be accepted as evidence for the prophylactic properties of the drug because of the deficiencies in the study design. A new properly-controlled study would be necessary to prove the prophylactic effect of the undecylenates.

The agency's detailed comments and evaluations are on file in the Dockets Management Branch (Ref. 3).

References

(1) Sulzberger, M. B., and A. Kanof, "Undecylenic and Propionic Acids in the Prevention and Treatment of Dermatophytosis," *Archives of Dermatology and Syphilology*, 55:391–395, 1947, included in OTC Volume 070306.

(2) Gundersen, K., "Use of Undecylenates in the Prophylaxis in Tinea Pedis," unpublished study in Comment No. LET008, Docket No. 80N–0476, Dockets Management Branch.

(3) Letter from W. E. Gilbertson, FDA, to R. E. Dann, Pennwalt Corp., Coded LET–13, Docket No. 80N–0476, Dockets Management Branch.

N. Comments on Drug Combinations

21. One comment disagreed with the Panel's 2.2-percent concentration limit for cresol in topical antifungal drug products. Citing the long marketing history of a particular product containing as its active ingredient a camphor metacresol complex (66-percent camphor and 22-percent metacresol), the comment stated that no adverse drug reactions have been reported and that the absence of complaints is especially significant considering that the product is primarily marketed to doctors, nurses, and paramedics. The comment cited a study submitted to the Panel to support the claim that there is strong evidence that a complex of camphor and metacresol exists and that only 1.5 percent of the metacresol in the product is "free" cresol (Ref. 1). The comment presented calculations showing that the daily exposure to metacresol from 80 milliliters (mL) of the product would be no more than 17 mL, released very gradually. According to the comment, this amount is many times lower than the lower toxic limit of cresol. The comment also referred to a National Institutes of Health (NIH) study on cresol that reportedly showed no toxic effect when the ingredient was injected subcutaneously in rabbits every second day for 2 weeks. The total amount injected was equivalent to 450 mL in a human adult (Ref. 2).

The comment indicated a willingness to limit the size of the container for its product to 1 fluid ounce and the recommended dose rate to 1 ounce applied in a 48-hour period in order to reduce further the amount of metacresol available for human exposure. The comment requested that, with these limitations on size and dose rate, the 66-percent camphor/22-percent metacresol combination be placed in Category I for safety and effectiveness.

The Antimicrobial II Panel proposed a concentration limit for cresol in topical antifungal drug products of 2.2 percent when combined with camphor in a 1-to-3 ratio. The Panel concluded that "evidence that a complex forms between metacresol and camphor [limiting the amount of the cresol to 1.5 percent] is lacking" and that "in the combination of 66 percent camphor and 22 percent metacresol all of the cresol would be available for absorption" (47 FR 12480 at 12536). To support its contention that only 1.5 percent of the metacresol in the product is free cresol, the comment cited only the study previously reviewed by the Panel (Ref. 1). The agency agrees with the Panel that this study does not provide adequate evidence of the amount of free cresol present. Without this evidence, the data on the toxicity of cresol in the NIH study (Ref. 2) are not directly applicable to the camphor/metacresol product.

Subsequently, in the rulemaking for OTC external analgesic drug products, the agency classified camphorated matacresol in a 3-to-1 ratio with a limit of 10.8-percent camphor and 3.6-percent metacresol as Category I for short-term use (i.e., 7 days) as an external analgesic (48 FR 5852 at 5858). The agency stated that there were insufficient data to establish general recognition of the safety of a concentration of metacresol greater than 3.6 percent when this ingredient is combined with camphor. The studies reviewed by the Topical Analgesic Panel and submitted to the agency in comments were very limited in scope. Most of the animal toxicity studies tested only one animal, observed the animal only for a short period of time, and did not include a detailed examination of the animal following drug application. Therefore, concentrations above 3.6-percent metacresol and 10.8-percent camphor were classifed in Category III. The use of camphorated metacresol as a first aid antiseptic will be addressed in the tentative final monograph for OTC first aid antiseptic drug products, to be published in a future issue of the **Federal Register**.

In regard to the comment's claim of "long history of safe use," marketing history alone cannot be regarded as adequate proof of safety. Moreover, there are no data showing that a limitation on the size of the container to 1 fluid ounce applied over a 48-hour time period would ensure safety. However, the agency believes, based on its previous determination in the external analgesic tentative final monograph and its pending determination in the first aid antiseptic tentative final monograph, that camphorated metacresol (a complex consisting of camphor and metacresol combined in a ratio of 3 parts camphor to 1 part metacresol) can be recognized as safe in OTC topical antifungal drug products. Concentrations above 3.6-percent cresol and 10.8-percent camphor remain in Category III for safety.

The effectiveness of metacresol as an antifungal agent has not been established. The Panel recommended one double-blinded clinical trial to determine the effectiveness of cresols in the treatment of athlete's foot, jock itch, and ringworm. The agency agrees with this recommendation. Until such a study is performed and evaluated and effectiveness is shown, camphorated metacresol at all concentrations remains in Category III for efficacy for antifungal use.

References

(1) Francis, A.W., "Physical Evidence of Association of Camphor with Phenol and the Cresols," *Journal of the American Pharmaceutical Association* (Scientific Ed.), 30:229–240, 1941, included on OTC Volume 070302.

(2) von Oettingen, W.F., "Phenol and Its Derivatives: The Relation Between Their Chemical Constitution and Their Effect on the Organism," *National Institutes of Health Bulletin*, No. 190, pp. 59–71 (1949), Public Health Service, The National Institutes of Health.

22. Two comments supported the Panel's recommendation to allow OTC combinations containing an antiperspirant and an antifungal ingredient. Referring to the agency's dissent in the preamble to the Panel's report in which FDA stated that it would not allow reformulation of these types of combination products to include Category I antifungal ingredients that are prescription to OTC "switches" (47 FR 12480 at 12481), the comments stated that whether or not the antifungals are "switch" ingredients has no relevance to whether or not the addition of an antiperspirant would enhance effectiveness or treat additional symptoms. The comments added that because there is no reason to believe that an antiperspirant could decrease the effectiveness of the antifungal and because the agency did not state any reservation about the safety of antiperspirants in antifungal combinations, combinations of antiperspirants and antifungals, including "switch" ingredients, should be placed in Category I. The comments contended that the rationale for such combinations, particularly for the treatment of athlete's foot, is threefold: (1) Moist conditions favor the growth of fungi; helping to keep the affected area dry should aid the antifungal drug in eliminating the fungi; (2) wetness, particularly in the toeweb area, is a common symptom of athlete's foot, and treating this symptom with an antiperspirant is consistent with the FDA combination policy; and (3) because bacterial growth is more likely to accompany fungal infection when the environment is moist, the addition of an antiperspirant should help keep the environment dry and thus minimize bacterial infection that may accompany athlete's foot.

A third comment noted the Panel's statement that moisture contributes to the development and continuation of athlete's foot and jock itch (47 FR 12480 at 12488) and requested that combinations containing an antifungal and an antiperspirant be classified in Category I both for the treatment of athlete's foot, jock itch, and ringworm and for the prevention of athlete's foot.

The Advisory Review Panel on OTC Antiperspirant Drug Products (Antiperspirant Panel) placed in Category I several active ingredients that had been shown through numerous clinical tests to be safe and effective antiperspirants when used in the axillae. (See the **Federal Register** of October 10, 1978; 43 FR 46694 at 46718 to 46719.) Although the Panel concluded that these ingredients would very likely reduce perspiration from other body surfaces, the Panel stated that to establish a standard for antiperspirant activity for the foot or hand, it is necessary to have information from the test subjects regarding their perception of effectiveness. The Panel did receive and evaluate two controlled studies (Ref. 1) that tested an aluminum chlorhydrate formulation as a foot antiperspirant. However, the Panel concluded that the data were not sufficient to support a claim of antiperspirant activity on body parts other than the axillae. Although the two controlled studies demonstrated a reduction of perspiration for the treated foot, the level of effectiveness was not correlated with user-perception of effectiveness. Therefore, in the absence of adequate user-perception effectiveness data, the Panel recommended that the claim of antiperspirancy on body surfaces other than the axillae be considered a Category III claim. In the tentative final monograph for OTC antiperspirant drug products, the agency concurred in the Panel's recommendation and placed claims for the use of antiperspirant drug products on the hands and feet in Category III (47 FR 36492 at 36497; August 20, 1982).

Although the agency did not directly state reservations about the safety of antiperspirants in antifungal combinations, it should be noted that the agency proposed that products covered by the tentative final monograph for OTC antiperspirant drug products contain the warning "Do not apply to broken skin" (47 FR 36504). Broken skin is common in fungal infections such as athlete's foot, jock itch, and ringworm. Data submitted to the Antiperspirant Panel suggested that the direct application of antiperspirant drug products to intact skin has not been associated with systemic toxic effects because of the relatively impermeable properties of the skin to metallic salts and complexes contained in antiperspirant drug products. In addition, results of percutaneous dermal toxicity tests performed on animals indicated no ill effects on the animals. However, some users of antiperspirant drug products have experienced local cutaneous irritation. Thus, although the Panel acknowledged that these adverse reactions are ordinarily not serious and are reversible, it recommended that antiperspirant drug products not be applied to open, broken, or abraded skin where the skin's barrier is breached (43 FR 46694 at 46707 to 46708).

The agency believes there is merit on one comment's argument that, because moisture contributes to the development and continuation of athlete's foot and jock itch, the combination of an antiperspirant to reduce moisture with an antifungal constitutes rational therapy. However, because broken skin is common in these infections and because sufficient data have not been submitted to demonstrate the safety of antiperspirants used on broken skin or to demonstrate effectiveness of antiperspirants used on the feet, groin, or other body parts except the axillae, the combination of an antifungal and an antiperspirant for the treatment of athlete's foot, jock itch, and ringworm and for the prevention of athlete's foot remains in Category III in this tentative final monograph.

There is a related issue concerning antifungal ingredients in combination with deodorant (cosmetic) ingredients. In the tentative final monograph for OTC antiperspirant drug products, the agency stated that deodorancy is a cosmetic claim and that the deodorant effectiveness of antiperspirant ingredients would not be further considered in that rulemaking (47 FR 36492 at 36494). Final OTC drug monographs do not address drug-cosmetic combination products, but cover only the drug aspects of products. If a product containing a monograph ingredient(s) is intended for both drug and cosmetic use, it must conform to the requirements of the final OTC drug monograph. In addition to the monograph labeling for OTC antifungal drug products, an antifungal-deodorant product must also bear appropriate labeling for cosmetic deodorant uses, in conformity with section 602 of the act (21 U.S.C. 362) and the provisions of 21 CFR part 701.

In accordance with the revised labeling requirements for OTC drug products, it is the agency's view that cosmetic claims may not appear within the boxed area designated "APPROVED USES." As discussed in the **Federal Register** of May 1, 1986 (51 FR 16258 at 16264 (paragraph 14)), cosmetic terminology is not reviewed and approved by FDA in the OTC drug monographs and therefore could not be placed in the box. Cosmetic claims may appear elsewhere in the labeling but not in the box, should manufacturers choose the labeling alternative provided in § 330.1(c)(2) (i) or (iii) for labeling cosmetic/drug products. Although the agency does not prohibit commingled drug and cosmetic labeling separate from the indications section, the agency requests that such claims be appropriately described so that consumers will more readily be able to differentiate the drug aspects from the

cosmetic aspects of such labeling. If commingled drug and cosmetic labeling claims are confusing or misleading, the agency may determine that the product's labeling is misleading within the meaning of the act and declare the product misbranded under sections 502(a) and 602(a) of the act (21 U.S.C. 352(a) and 362(a)).

The use of prescription to OTC "switch" antifungal ingredients in reformulated products is addressed in comment 24 below.

Reference

(1) OTC Volume 140017.

23. Three comments supported the Panel's recommendation that combinations of up to three Category I antifungal ingredients with hydrocortisone or hydrocortisone acetate (0.5 to 1 percent) should be available for OTC use in the treatment of athlete's foot, jock itch, and ringworm (47 FR 12480 at 12554). The comments listed the following reasons why such combinations are rational: (1) They are consistent with FDA's September 1978 combination policy guidelines, which provide that Category I active ingredients from different therapeutic categories may be combined to treat different symptoms concurrently (Ref. 1); (2) the less-than-effective classification by FDA of two prescription products (discussed in the preamble to the Panel's report at 47 FR 12481) appears to have been based solely on the lack of demonstrated contribution of hydrocortisone to the antifungal effectiveness of the products, rather than on a judgment concerning the ability of hydrocortisone to relieve the concurrent symptoms of burning and itching, which is the only reason that it is included in the combination product; (3) although the Topical Analgesic Panel recommended that hydrocortisone and hydrocortisone acetate be approved for OTC use only as single ingredients, it gave no reason for that position. If the Panel had simply wanted to exercise caution until widespread experience had been gained with OTC hydrocortisone products, such experience has now been accumulated with no safety problems apparent; and (4) consumers should have available a product that treats the fungal infection as well as relieves the burning and itching caused by the fungal infection.

Another comment agreed with and supported the Panel's conclusion that the specific combination of clioquinol and hydrocortisone is safe and effective for OTC use in the treatment of athlete's foot, jock itch, and ringworm. The comment recognized that FDA had previously declared this combination product as lacking substantial evidence of effectiveness within the meaning of the agency's combination drug product policy. (See the **Federal Register** of September 25, 1981; 46 FR 47408.) The comment stated its belief that the agency's position on the effectiveness of this combination product was erroneous and contradicted by the adequate and well-controlled clinical studies reviewed by the Antimicrobial (II) Panel and previously reviewed by the agency itself during its Drug Efficacy Study Implementation (DESI) deliberations. The comment included a copy of its November 24, 1981, submission to the DESI proceeding to support the Panel's conclusion that the combination of clioquinol and hydrocortisone is effective.

The comment added that the Panel's proposed labeling for the combination should be modified to distinguish it from the indications for use of clioquinol alone. The comment recommended that the following language be adopted for the indications for use of clioquinol/hydrocortisone products: "Iodochlorhydroxyquin [Clioquinol]/hydrocortisone is effective in the treatment (or cure) of athlete's foot, jock itch, and ringworm and is recommended when additional relief from associated redness, scaling, and itching is desired." The comment cited four studies (Refs. 2 through 5) to support its position that the combination provided significant improvement over clioquinol alone for scaling and itching and for healing of lesions.

As an initial matter, the agency acknowledges that the Panel mentioned that several combinations of an antifungal agent with hydrocortisone or hydrocortisone acetate 0.5 to 1 percent were submitted for evaluation, and that antifungal agents included in the various submitted combinations include clioquinol, miconazole nitrate, and calcium undecylenate. (See 47 FR 12480 at 12554.) As the Panel pointed out, double-blind controlled studies were not performed on combinations containing calcium undecylenate. The Panel also discussed some studies done with a 2-percent miconazole nitrate/1-percent hydrocortisone combination in Belgium and Colombia, South America. However, such a product has never been marketed in the United States, and, although supportive, these studies alone cannot be used to establish the general recognition of the safety and effectiveness of antifungal/hydrocortisone combinations for OTC use.

The agency has been evaluating the effectiveness of the clioquinol/hydrocortisone combination product under the DESI program. The agency's position is that there is a lack of substantial evidence that the combination product is effective for its labeled indications, and that the available data do not demonstrate that each component of the combination makes a significant contribution to the claimed effects of the drug. In the **Federal Register** of August 21, 1984 (49 FR 33173), the agency announced a formal evidentiary hearing on its proposal to withdraw approval of the prescription combination product composed of clioquinol/hydrocortisone because there are no adequate and well-controlled investigations (including clinical investigations) by experts qualified by scientific training and experience to evaluate the effectiveness of the drug to demonstrate that clioquinol/hydrocortisone is an effective combination and will have the effects claimed or suggested in its labeling. The hearing concluded in March 1986. On February 5, 1988, the FDA Administrative Law Judge issued an Initial Decision, concluding that there is a lack of substantial evidence of the effectiveness of the combination product, and ordering the new drug application (NDA) for the product withdrawn (Ref. 6). Exceptions to the Initial Decision and replies to the exceptions (Ref. 7) have been filed with the Dockets Management Branch and are currently under review by the Commissioner.

Because the agency believes that resolution of the status of the clioquinol/hydrocortisone combination in the DESI proceeding will be pivotal to the final classification of antifungal/hydrocortisone combinations in this rulemaking, the agency is deferring classification of such combinations in this rulemaking until all administrative remedies have been exhausted and the matter is fully resolved in the DESI proceeding.

The agency also notes that the data upon which the Panel based its recommendation were for combinations of single antifungal ingredients and hydrocortisone or hydrocortisone acetate. No data have been submitted to demonstrate the safety and effectiveness of a combination of up to three antifungal ingredients and hydrocortisone or hydrocortisone acetate. The agency has evaluated the Panel's recommendation that up to three antifungal ingredients may be combined and has found no evidence to establish that such a combination offers any

advantage over the antifungal ingredients when used alone and has placed this combination in Category III. (See comment 24 below.) The agency further notes that the Topical Analgesic Panel recommended that hydrocortisone and hydrocortisone acetate 0.25 to 0.5 percent be allowed OTC as single ingredients, but not in any combination. In the tentative final monograph for OTC external analgesic drug products, the agency concurred with the Panel's recommendation (48 FR 5852 at 5854). Also, as noted above, the studies on the miconazole nitrate/hydrocortisone combination product involved the use of hydrocortisone at a 1-percent concentration, a strength currently not approved for OTC marketing.

In conclusion, the combination of up to three Category I antifungal ingredients and hydrocortisone or hydrocortisone acetate is not being included in the tentative final monograph for OTC antifungal drug products at this time. The degree to which this combination complies with FDA's September 1978 combination policy guidelines is discussed further in comment 27 below, in which the combination of an antifungal with any Category I analgesic/anesthetic/antipruritic is addressed.

References

(1) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products," September 1978, Docket No. 78D–0322, Dockets Management Branch.

(2) Brecker, L. J., et al., "Protocol #02," unpublished study in OTC Volume 070103.

(3) Abdel-Aal, H., et al., "A Double-Blind Comparison of a New Combination (Halcinonide-Neomycin-Amphotericin) and Active Controls in Cutaneous Candidiasis and Steroid-Responsive Dermatoses," *The Journal of International Medical Research*, 4:232–236, 1976.

(4) Barba-Rubio, J., "Clinical Evaluation of a New Halcinonide-Antifungal Combination," *Current Therapeutic Research*, 20:655–660, 1976.

(5) Carpenter, C. L., et el., "Combined Steroid-Antinfective Topical Therapy in Common Dermatoses: A Double-Blind, Multi-Center Study of Iodochlorhydroxyquin-Hydrocortisone in 277 Patients," *Current Therapeutic Research*, 15:650–659, 1973.

(6) Food and Drug Administration Initial Decision: "Proposal to withdraw Approval of the New Drug Application for Vioform-Hydrocortisone Cream, Ointment and Lotion Containing Iodochlorhydroxquin and Hydrocortisone Under the Drug Efficacy Study Implementation Program, February 5, 1988, Coded IDF, Docket No. 80N–0012, Dockets Management Branch.

(7) Comments No. EXC00001, EXC00002, EXC00003, EXC00004, REX00001, and REX00002, Docket No. 80N–0012, Dockets Management Branch.

24. Two comments disagreed with the agency's decision not to allow the reformulation of combination products to include Category I ingredients where prescription to OTC switches are involved. The comments asserted that nowhere in the **Federal Register** of May 11, 1972 (37 FR 9464), which established the OTC drug review procedures, nor in the September 1978 guidelines for OTC drug combination products (Ref. 1), did the agency state that general recognition of the safety and effectiveness of ingredients for OTC use would be limited to those ingredients already marketed on an OTC basis. One comment also disagreed with the agency's decision to refuse to permit combinations of Category I antifungal ingredients and stated that the Panel's recommendation that a Category I combination may contain up to three antifungal ingredients "provided that each ingredient broadens the antifungal spectrum" (47 FR 12480) fully meets the FDA's combination policy (21 CFR 330.10(a)(iv)). The other comment pointed out that there is no precedent set by other panels for limiting switch ingredients to single-ingredient products except in the case of hydrocortisone, where the Topical Analgesic Panel recommended "a specific ingredient for a specific use." The comment added that the Antimicrobial II Panel intended its combination policy to encompass ingredients recommended for prescription to OTC switch. The comment urged that the Panel's recommendations be followed because the agency gave no rationale or justification for its restriction. The comment concluded that, in the absence of any stated rationale, the agency's decision is both arbitary and contrary to the purpose of the OTC drug review.

In the preamble to the Panel's report, the agency noted that the Panel had recommended that up to three Category I antifungal ingredients may be combined, provided that each ingredient broadens the antifungal spectrum, for the treatment of athlete's foot, jock itch, and ringworm. Under § 330.13 (12 CFR 330.13), combination products containing prescription-to-OTC switch antifungal drugs recommended as Category I by the Panel could have been marketed immediately following publication of the Panel's report and proposed monograph unless the agency disagreed with the Panel's recommendations at that time. FDA stated that it was not aware of any such Category I antifungal combinations on the OTC market at that time (47 FR 12480). The agency also stated that the Panel's report had been prepared independently of FDA, and that the agency had not yet fully evaluated the report. Therefore, the agency did not want new combination antifungal products containing switch drugs entering the OTC marketplace until it had fully evaluated the data relating to these products. The agency was willing, however, to permit reformulation of combinations of antifungal ingredients already on the OTC market to include Category I ingredients already in the OTC marketplace.

The agency has evaluated the Panel's recommendations that a combination may contain up to three antifungal ingredients provided each ingredient broadens the antifungal spectrum (47 FR 12480 at 12554). The agency has examined the antifungal spectra of the various Category I ingredients and determined that, with the exception of nystatin, the spectra of the various ingredients are similar. The ingredients clioquinol, tolnaftate, and undecylenic acid and its salts are effective against the dermatophytes cited by the Panel, namely, *T. rubrum*, *T. metagrophytes*, *E. floccosum*, and *M. canis*, in its criteria for evaluating the effectiveness of antifungal ingredients (47 FR 12491). In addition, the switch ingredients haloprogin and miconazole nitrate and effective against these four dermatophytes and *Candida*. Furthermore, the spectra of the switch ingredients are sufficiently broad as to make it unnecessary to combine these ingredients with any other Category I antifungal ingredient. Because of the similarity of spectra of the Category I antidermatophytic antifungal ingredients, combinations of up to three of these ingredients that are effective against the same dermatophytic fungi that cause athlete's foot, jock itch, and ringworm would not broaden the antifungal spectra. Clinical data are needed to show that a combination of any two of these ingredients would increase the spectrum of the product, or offer some other advantage over the single ingredients in terms of enhanced effectiveness, safety, patient acceptance, or quality of formulation, as provided in the OTC combination guidelines (Ref. 1). Also, the agency is not aware of any such combinations currently available on the market. Therefore, in the absence of data to support such combinations, the agency is not including combinations of antifungal ingredients effective against dermatophytic fungi in this tentatives final monograph.

Regarding the comment's reference to the guidelines for OTC drug combination products (Ref. 1), paragraph 3 of those guidelines states that Category I active ingredients from the same therapeutic

category that have the same mechanism of action may be combined in selected instances. However, the guidelines also state that such combinations must meet the OTC combination policy in all respects, offer some advantage over the active ingredients used alone, and, on a benefit-risk basis, be equal to or better than each of the active ingredients used alone at its therapeutic dose. The advantage of combinations of antifungals as defined by the Panel is the broadening of the antifungal spectrum. However, the spectrum was defined by the Panel as being those organisms that are the most common causes of jock itch, ringworm, and athlete's foot in the United States. Given this specific spectrum, combinations of Category I antifungal ingredients would not result in a broadening of the antifungal spectrum. No advantage over the active ingredients used alone has been shown to justify such combinations.

The Panel also stated that some fungal diseases are caused both by dermatophytes and by *Candida* and that, because most consumers cannot distinguish between these diseases, a combination containing an antidermatophytic ingredient, as discussed above, and an anticandidal ingredient, e.g., nystatin, would offer broader therapy (47 FR 12480 at 12554). However, the Panel did not cite any data to support this theory. In the absence of information showing that infection by *Candida* is a significant cause of athlete's foot or jock itch (see the Panel's discussion at 47 FR 12487), or that secondary infections of *Candida* are common, the combination of an antidermatophytic ingredient with an anticandidal ingredient is classified in Category III at this time. If information is submitted to the agency demonstrating that *Candida* is a significant problem in dermatophytic infections, the agency will consider data in support of the appropriations of these combinations. Specifically, these data would have to show increased effectiveness of the product resulting from the inclusion of nystatin in the combination product. As stated in the proposed rule for OTC antimicrobial drug products (43 FR 1210 at 1239; January 6 ,1978), "The Commissioner believes that antimicrobial agents are somewhat different from combinations of other OTC ingredients in that they act upon a foreign entity, the microorganism, rather than the host. In combinations of nonantimicrobial ingredients, the advantage of the combination may be that therapeutic activity is obtained at lower dosages for each component ingredient, whereas there can be no contribution of effectiveness of an antimicrobial ingredient by combining it with antimicrobial ingredients having identical bactericidal, virocidal, and fungicidal properties. Consequently, the Commissioner concludes that a rational combination of antimicrobials should have one of the following purposes: expansion of the microbial spectrum relevant to the product class for which the combination is intended, reduction of the toxicity of one or both of the ingredients, or a synergistic effect." This conclusion is equally applicable to antifungal drugs.

In conclusion, the agency is proposing in this tentative final monograph that all combinations of antifungal active ingredients, as permitted by the Panel in § 333.220(a), be placed in Category III. Because nystatin was included in the Panel's recommended monograph only for use in combination antifungal products, the agency is also placing nystatin in Category III because no combinations are currently included in the tentative final monograph.

Reference

(1) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products," September 1978, Docket No. 78D–0322, Dockets Management Branch.

25. Two comments supported the Panel's recommendation at 47 FR 12480 at 12557 that an antifungal ingredient may be combined with a broad-spectrum antibacterial ingredient that is active against gram-positive and gram-negative bacteria for the treatment of athlete's foot. Although the Panel recognized the combination as rational, one of the comments questioned why the Panel required a double-blind, controlled clinical study to demonstrate the effectiveness of the combination. The comment stated that such a study was submitted to the Panel and was, in fact, the basis for the Panel's recognition of the need for an antifungal/antibacterial combination (Ref. 1). This comment asserted that the study was carefully conducted and that it adequately demonstrated the effectiveness of such therapy. Therefore, according to the comment, the only requirement for marketing such a combination should be the identification of appropriate Category I antibacterial agents and adding the combination of an antifungal and an antibacterial ingredient to the list of combinations in § 333.220 of the tentative final monograph.

The agency agrees with the Panel that a broad-spectrum antibacterial ingredient that is active against gram-positive and gram-negative bacteria is rational for use in combination with an antifungal for the treatment of athlete's foot. However, recognition of medical rationale by itself does not determine that this combination is generally recognized as safe and effective for the intended use. In fact, based on the data, including the study referred to by the comment, the Panel classified the combination in Category III (47 FR 12480 at 12557).

The study (Ref. 1), according to the authors, demonstrated that topical antibacterials produced definite clinical benefit in the treatment of athlete's foot, although the disease was "not cured, merely curbed," and that a combination of neomycin 1 percent and tolnaftate 1 percent was thought to be more effective than either treatment alone (47 FR 12557). After reviewing the study, the agency concurs in the Panel's conclusion that the combination of an antifungal with a broad-spectrum antibacterial is sometimes desirable for the treatment of athlete's foot characterized by soggy toewebs, but that a double-blind clinically controlled study is needed to show effectiveness (47 FR 12558). In addition, it should be noted that the Panel was concerned that chronic use of certain antibacterial ingredients could result in potential toxicity, including contact sensitization (47 FR 12558). Accordingly, the agency also concurs with the Panel that any antibacterial ingredient considered for inclusion in a combination antifungal product should be both safe and effective.

Because no new data on specific antibacterial/antifungal combinations have been submitted, such combinations remain in Category III in this tentative final monograph.

Reference

(1) Leyden, J. J., and A. M. Kligman, "Interdigital Athlete's Foot. The Interaction of Dermatophytes and Resident Bacteria," *Archives of Dermatology*, 114:1466–1472, 1978, in OTC Volume 070304.

26. One comment supported the Panel's recommended Category I combination of a keratolytic agent, e.g., salicylic acid, with up to three antifungal ingredients based on the action of an effective keratolytic that removes the outer layers of the stratum corneum, thus better exposing the infecting fungus to the action of the antifungal ingredients (47 FR 12480 at 12554). The comment disagreed with the agency's concerns about the lack of data to support such combinations and the concerns expressed by the Miscellaneous External Panel about the

safety of salicylic acid used on skin areas other than those being treated (47 FR 12481). The comment argued that antifungals are for use on areas directly affected and thus the antifungal/keratolytic combination should be allowed as Category I.

The agency notes that the Antimicrobial II Panel stated that, theoretically, an effective keratolytic agent such as salicylic acid could remove the outer layers of the stratum corneum, thus better exposing the infecting fungus to the action of the antifungal ingredient (47 FR 12554). In the preamble to the Panel's report, the agency noted that the Panel provided no data to support its recommendation and that there was no evidence submitted to the Panel to show that a keratolytic agent would be useful or safe in treating fungus conditions. The comment did not submit any safety and effectiveness data to support the use of keratolytics in general, or the use of salicylic acid in particular, in combination with antifungal ingredients. Although the combination may theoretically be useful, this alone is not an adequate basis to include such a combination in the tentative final monograph.

The Miscellaneous External Panel recommended that salicylic acid be classified as Category I as a corn and callus remover at concentrations from 12 to 40 percent in pads, plasters, and disks and at concentrations from 12 to 17.6 percent in collodion. (See the **Federal Register** of January 5, 1982; 47 FR 522 at 527.) The agency concurred with this recommendation in the tentative final monograph for OTC corn and callus remover drug products. (See the **Federal Register** of February 20, 1987; 52 FR 5412.)

The Miscellaneous External Panel also recommended that salicylic acid be classified as Category I as a wart remover at concentrations of 5 to 17 percent in a collodion vehicle. (See the **Federal Register** of October 3, 1980; 45 FR 65609 at 65613.) The agency concurred with this recommendation in the tentative final monograph for OTC wart remover drug products. (See the **Federal Register** of September 3, 1982; 47 FR 39102.) The agency further expanded the proposed monograph to include 12 to 40 percent salicylic acid in a plaster vehicle and redesignated "a collodion vehicle" as a "collodion-like" vehicle for the dosage form containing 5 to 17 percent salicylic acid. (See the **Federal Register** of March 27, 1987; 52 FR 9992.)

In discussing the safety of salicylic acid as an antifungal agent, the Antimicrobial II Panel stated that this drug was safe when used in a concentration less than or equal to 3 percent and if the use of the drug is restricted to relatively small body areas (47 FR 12480 at 12549). The Panel also pointed out that the systemic toxicity of topical salicylic acid, like its keratolytic effects, appears to result from a combination of factors. Some of these factors are (1) a high concentration of salicylic acid in a vehicle that allows rapid absorption, (2) the frequency of application, (3) whether the surface area is occluded, and (4) the condition and area of skin to which the preparation is applied (47 FR 12549).

Subsequent to these reports, the agency classified salicylic acid as Category I for use in acne drug products, but proposed to limit the concentration to a range of 0.5 to 2 percent because there may be an increased potential for irritation from concentrations greater than 2 percent. (See the **Federal Register** of January 15, 1985; 50 FR 2172). Broken, denuded, diseased, or infected skin areas occur in fungal infections. In the case of athlete's foot and jock itch (and often ringworm), the affected area is occluded after the drug product is applied. The agency is concerned that a keratolytic agent such as salicylic acid combined with antifungal ingredients may further irritate the skin, especially in areas likely to be occluded, particularly sensitive areas like the groin. The agency is also concerned about a possible occurrence of some systemic toxicity. Further safety data are needed to ensure that these problems will not occur with such a combination product.

With regard to efficacy, the effective keratolytic concentrations recommended by the Miscellaneous External Panel discussed above are higher than the "safe" 3 percent concentration recommended by the Antimicrobial II Panel and the "safe" 0.5 to 2 percent range proposed by the agency for topical acne drug products. If a lower concentration of the keratolytic agent must be used, it must also be shown that that concentration is effective. Also, as a combination drug product, evidence is needed to show that the keratolytic component contributes to the effect of the product. There is a lack of data showing that the antifungal-keratolytic combination is more effective than the antifungal agent used alone. Therefore, the agency classifies the combination of an antifungal(s) and a keratolytic agent for the treatment of athlete's foot, jock itch, and ringworm and for the prevention of athlete's foot as Category III for both safety and effectiveness.

27. Two comments disagreed with the Panel's Category II classification of an antifungal ingredient with a local anesthetic (47 FR 12480 at 12555). The comments contended that it is rational therapy and beneficial to the consumer to combine a Category I antifungal with any Category I analgesic/anesthetic/antipruritic ingredient identified in § 348.10(b) of the OTC Topical Analgesic Panel's recommended monograph for OTC external analgesic drug products (44 FR 69768 at 69865). One comment stated that curing the disease (i.e., athlete's foot, jock itch, and ringworm) ultimately results in relief of the symptoms of burning and itching, but that it often requires several weeks of treatment to accomplish with an antifungal drug alone. Therefore, the comments maintained that topical analgesics/anesthetics/antipruritics would provide prompt short-term relief of such common symptoms as itching while the antifungal agent treated the underlying disease.

Both comments mentioned that the Panel concurred with the basic rationale for these combinations (47 FR 12554), but that the Panel had expressed some concern regarding these combinations. According to the comments, the Panel's concern that use of an anesthetic/antifungal combination would result in the anesthetic's masking the symptoms without eradicating the fungus was addressed at 47 FR 12564 where the Panel specified that any product labeled as an antifungal must contain a Category I antifungal ingredient. Masking symptoms would not be a concern because the antifungal ingredient would be eradicating the fungus simultaneously. Another concern was that some individuals would stop treatment once symptomatic relief (of the itching) was obtained but before the infection was cured. The comments believed that this concern could be handled by including on the label the directions recommended by the Panel in § 333.250(d)(1), which state that best results in athlete's foot and ringworm are usually obtained with 4 weeks' use of the product and in jock itch, with 2 weeks' use. The comments asserted that this combination meets the general OTC combination drug requirement that provides that one basis for combining active ingredients is for the concurrent treatment of multiple symptoms. The comments did not submit any data.

The agency agrees with the comments that the combination of an analgesic/anesthetic/antipruritic with a Category I antifungal is rational and is consistent with the agency's OTC combination policy requirement that active ingredients may be combined if they provide concurrent treatment of multiple symptoms (Ref. 1). The agency also

agrees with the comments that the Panel's concerns could be addressed by specific labeling in the monograph. However, the recognition of medical rationale alone cannot establish that this combination is generally recognized as safe and effective for the intended OTC use. The purpose of combining the two individual components in this particular combination is to increase the effectiveness of the product in relieving burning and itching. Because the analgesic/anesthetic/antipruritic drug is being included in the combination to provide relief of burning and/or itching, an action that also results once the antifungal drug begins to cure the underlying disease, the contribution of the analgesic/anesthetic/antipruritic must be shown by demonstrating that the combination is more effective in relieving the burning and itching sooner (or in reducing the severity) than the antifungal drug used individually. The Panel found the data submitted to it to establish general recognition of the safety and effectiveness of such a combination to be inadequate, and the comments did not submit any additional data. However, based on the medical rationale presented by the comments, the agency is classifying these combinations in Category III, pending receipt of data on specific combinations. (See also comment 23 above, which discusses the combination of hydrocortisone with an antifungal.)

Reference

(1) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products," September 1978, Docket No. 78N-0322, Dockets Management Branch.

28. One comment disagreed with § 333.250(b)(2) of the Panel's recommended monograph in which a claim for prevention of athlete's foot is limited to products containing tolnaftate "as a single ingredient." The comment argued that there is no reason to exclude a prophylaxis claim for combination products containing two Category I antifungal ingredients, where one or both are approved for prophylaxis, or for combination products containing an antifungal for prophylaxis and an antiperspirant. The comment requested that the heading for § 333.250(b)(2) be reworded as follows: "For products containing any ingredient identified in § 333.210(e) alone or in a combination identified in § 333.220(b)(1) labeled for the prevention of athlete's foot."

Claims for prevention of athlete's foot for individual active ingredients are discussed in comments 18, 19 and 20 above. The agency has not received any data showing that a combination antifungal drug products is safe and effective in the prevention of athlete's foot. Data would have to be submitted to demonstrate the contribution of each active ingredient in the product in preventing athlete's foot. Such combinations are classified in Category III in this tentative final monograph. Therefore, the heading of § 333.250(b)(2) is not being changed as requested by the comment, but has been changed in response to another comment. (See comment 19 above.)

O. Comments on Testing

29. One comment recommended that the safety testing guidelines in the Panel's report be retained as guidelines for use only when applicable to a specific antifungal ingredient, as noted in the individual evaluation of that ingredient. The comment stated that requiring a standard battery of safety tests as outlined in the safety testing guidelines (47 FR 12480 at 12559) is appropriate for new drugs but is not appropriate for drugs that have been in widespread use for a long period of time, such as Category III antifungal ingredients. The comment suggested that if there is a particular area of concern for the safety of a given ingredient, then testing should be done in that particular area of concern rather than wasting resources by including testing in areas where safety is well known. Also, the comment pointed out that in several instances the Panel recommended specific tests for certain ingredients.

Another comment contended that, as written, the antifungal guidelines for safety and effectiveness testing are incomplete, confusing, and/or lack feasibility. The comment cited a number of examples to support its contention and recommended that two appropriate scientists from FDA and two from the pharmaceutical industry with experience in antifungal product development review, edit, and finalize these guidelines on laboratory testing.

The agency has not addressed specific testing guidelines in this document. In revising the OTC drug review procedures relating to Category III, published in the Federal Register of September 29, 1981 (46 FR 47730), the agency advised that tentative final and final monographs will not include recommended testing guidelines for conditions that industry wishes to upgrade to monograph status. Instead, the agency will meet with industry representatives at their request to discuss testing protocols. The revised procedures also state the time in which test data must be submitted for consideration in developing the final monograph. (See also part II. paragraph A.2. below—*Testing of Category II and Category III Conditions.).*

P. Comments on Labeling

30. Three comments disagreed with the use of the term "antifungal" as the required statement of identity on the product label. The comments maintained that antifungal is a technical term that is meaningful to FDA, industry, and health professionals, but may be meaningless to laypersons. The comments suggested that the statement of identify be made more flexible to allow alternative terminology that is more easily understood by consumers to enable them to identify the type of product appropriate for treating a condition they can recognize and self-treat, e.g., "athlete's foot remedy" or "jock itch remedy." Two comments argued that the word "antifungal" was recommended by the Panel as the statement of identity and as such should not have been classified as a Category II labeling statement. Stating that the term is medically correct and meaningful to many consumers, the comments recommended that it be placed in Category I for use elsewhwere on the label, regardless of whether it is also used as a statement of identity.

The agency agrees that the examples of alternative sttements of identity suggested by the comments are understood by consumers, but finds that the terms are similar to the indications statements recommended by the Panel in § 333.250(b) (47 FR 12480 at 12565). The agency sees no need to include in the statement of identity for antifungal drug products the same information found in the indications section. Wherever possible, the agency prefers to use the general pharmacologic category as the statement of identity because information on the principal intended action of the product is provided in the indications section. The agency believes that the indications section is fully informative and will allow consumers to identify the product as being appropriate for a particular condition they wish to self-treat. Therefore, the comment's suggestion is not being proposed in this tentative final monograph. However, the agency has no objection to terms such as "athlete's foot remedy" or "jock itch remedy" appearing elsewhere in the labeling provided they are not intermixed with labeling established by the monograph and do not detract from the required information.

In regard to the Panel's classification of "antifungal" as a Category II labeling claim, the agency concurs with the Panel that " 'antifungal' (when used alone)" in

labeling would be inadequate (47 FR 12480 at 12524) because the term does not provide sufficient information to inform consumers of the particular condition they wish to self-treat. However, the term "antifungal" may be used elsewhere in the labeling, as with the terms "athlete's foot remedy" and "jock itch remedy," discussed above.

31. Two comments asserted that the Panel erroneously expanded the scope of Category II labeling statements (47 FR 12524) by inappropriately including statements that are not "conditions that would result in the drug not being generally recognized as safe and effective or would result in misbranding," but rather are statements describing the performance of the product.

Both comments cited the following Category II claims: "promotes healing," "helps heal," "helps restore normal skin even in severe or persistent cases," "speeds healing of athlete's foot," "speeds healing of jock itch," "kills all major types of athlete's foot fungi," "kills most athlete's foot fungi," and "kills all major types of jock itch fungi." These terms should logically be in Category I, the comments maintained, because the medicinal agent actually kills the fungus and thus allows the infected area to heal. The comments added that this is not the case with many other types of OTC drug products that primarily ameliorate signs and symptoms rather than treat the underlying causes.

One comment added that the claim "for the treatment of athlete's foot and ringworm of the skin, exclusive of bodyfold areas" is simply an accurate statement of the proper use of such products and is not a Category II condition for which the products are not safe and effective.

Because of the comments' assertions, the agency has reevaluated all of the Category II labeling identified by the Panel at 47 FR 12524 for topical antifungal drug products. The agency notes that the Panel considered and classified each claim (that appeared in the labeling of the products that it reviewed) as an indication for use. It should be noted that the OTC drug review program establishes conditions under which OTC drugs are generally recognized as safe and effective and not misbranded. One aspect of the program is to develop standards for certain parts of the labeling of OTC drug products. FDA has found that it is simply not practical—in terms of time, resources, and other considerations—to set standards for all labeling found in OTC drug products. Accordingly, OTC drug monographs directly address only those labeling items that are related in a significant way to the safe and effective use of covered products by lay persons. Those labeling items are the product statement of identity; names of active ingredients; indications for use; directions for use; warnings against unsafe use, side effects, and adverse reactions; and claims concerning mechanism of drug action.

The agency believes that a number of the claims considered by the Panel are descriptive statements that do not relate in a significant way to the safe and effective use of antifungal drug products that are already labeled with the required information, and, therefore, are outside the scope of the monograph. The following claims are included: "athlete's foot, ringworm, jock itch (when these words are used alone)," "antifungal (when used alone)," "kills most athlete's foot fungi," " 'scientific treatment' for athlete's foot," "proven fungicide for athlete's foot, jock itch, and body ringworm fungi," "fungicidal against athlete's foot, jock itch, and ringworm fungi," "broad spectrum antifungal (for treatment of athlete's foot and jock itch)," "kills all major types of athlete's foot fungi," "kills all major types of jock itch fungi," "fungicidal," and "kills fungus spores." The agency believes that such information may be useful to the consumer in describing a product's action or intended effect. However, these and any other terms that are outside the scope of the monograph, even though they are truthful and not misleading, may not be intermixed with labeling established by the monograph and may not detract from the required information. They may be included elsewhere in the labeling.

In contrast, the agency believes that product performance claims such as "kills athlete's foot fungi on contact," "kills athlete's foot on contact," "kills jock itch fungi on contact," "kills athlete's foot fungi fast," "kills jock itch fungi fast," and "for fast relief of itching and burning of athlete's foot and jock itch" are misleading because such claims create a false impression of instant results, while the directions for use of antifungals state that athlete's foot and ringworm products should be used for 4 weeks and jock itch products for 2 weeks. Therefore, these claims remain in Category II.

Claims related to healing, e.g., may promote healing, and wound healing agents are classified as Category III in the rulemaking for OTC skin protectant drug products (48 FR 6820 at 6831; February 15, 1983) and in the rulemaking for OTC anorectal drug products (53 FR 30756 at 30765; August 15, 1988). However, the agency agrees with the comments that antifungal drugs are different from most OTC drug products in that they actually treat the underlying disease rather than only ameliorate signs and symptoms. "Treats," "cures," and "clears up" are included as part of the allowed indications for use in the proposed monograph. The agency believes that labeling that represents or suggests healing, e.g., "promotes healing," "helps heal," "helps restore normal skin even in severe or persistent cases," may be meaningful to the lay person who may consider "heals" and "cures" or "clears up" to be synonymous. Therefore, the agency would allow "helps heal" or "promotes healing" claims to appear elsewhere on the label provided they are not intermixed with labeling established by the monograph. However, data are inadequate to support any product performance claims, e.g., "speeds healing of athlete's foot" and "speeds healing of jock itch." The agency is unaware of any clinical studies for any antifungal ingredient that demonstrates such an effect. Such claims are classified as Category III.

The agency is proposing in this tentative final monograph to classify as Category III claims related to the antibacterial activity of antifungal drug products such as "inhibits growth of fungi and bacteria," "helps prevent germ and fungus infections," "controls bacteria and fungi," "bactericide," "germicide," "antiseptic," and "inhibitory antiseptic," the Panel acknowledged that some Category I antifungal ingredients, i.e., miconazole nitrate and iodochlorhydroxyquin, have in vitro antibacterial activity but concluded that the term "antibacterial" should not be used in labeling of OTC antifungal drug products without supportive clinical studies demonstrating an in vivo antibacterial activity of these ingredients (47 FR 12480 at 12553). The agency agrees with the Panel's recommendation.

The agency is also reclassifying the claims "penetrating action goes under crust and skin surface to kill athlete's foot fungi," "protects broken skin from infection," and "kills all known athlete's foot and jock itch fungi" to Category III because of the lack of data which demonstrate effectiveness for such claims and the lack of data that any Category I ingredient is known to "kill all known" athlete's foot and jock itch fungi.

The agency concludes that the other claims should remain in Category II for various reasons. "Adjunctive treatment," "for treatment of athlete's foot and ringworm of the skin, exclusive

of body fold areas," and "invisible shield" are unclear and confusing. "Temporary relief of ringworm" and "temporary relief of itching and discomfort due to athlete's foot" are inaccurate because Category I antifungal ingredients, when used as directed, provide effective treatment of these conditions, not temporary relief. "The broadest proven dermatophyte spectrum" is not true because Category I antifungals are all effective and are not ranked as good, better, best in the monograph. "Fungistatic" is not true because Category I antifungal ingredients must be fungicidal not just fungistatic.

The agency believes that the term "first aid" is inappropriate in the labeling of a product promoted for the treatment of athlete's foot, jock itch, or ringworm. The term "first aid" is generally perceived as an emergency treatment, and in the context of OTC drug products, for the prevention of infection in minor cuts, scrapes, and burns. (See, e.g., the definition of "first aid antibiotic" in § 333.103(b) of the final monograph for OTC first aid antibiotic drug products (52 FR 47312 at 47323; December 11, 1987).)

Antifungal containing products for "athlete's foot, jock itch, or ringworm" should be used daily for up to 4 weeks and, therefore, are not considered a first aid treatment. The agency agrees with the Panel that the term is misleading and proposes that any claim which represents or suggests an antifungal product is a first aid remedy is Category II labeling.

The Panel recommended that a number of claims be Category II because they are to broad and unspecific to be meaningful. These include: "minor fungus skin infections," "prevention and control of minor skin infections including athlete's foot," "minor skin irritations associated with fungus," "combats and controls infection-causing fungi," "for irritations caused by fungus infections," "for fungus of hands, groin or body," "for superficial fungal infections of the skin," "helps prevent fungal infections," and "guards against fungus growth." The agency believes that these statements standing alone could broaden the intended OTC uses of these products and, therefore, should remain in Category II. However, these descriptive statements, if combined with the conditions for which the product is intended to be used, would be acceptable information for consumers. For example, the following statements would be acceptable: "for irritations caused by athletes foot infections," "for ringworm of hands, groin, or body," and "combats and controls athlete's foot infection-causing fungi." However, any statements that broaden the intended OTC uses of the product would not be acceptable.

A number of claims reviewed by the Panel remain in Category II. The claims "other skin fungus infections," "for the treatment of inflamed conditions of the skin, such as eczema and other fungal infections," and "aids in drying up excessive secretions," remain in Category II because they are too broad and unspecific. These claims imply effectiveness for conditions that are not supported by available data (e.g., eczema or excessive secretions). In addition, when used with the approved monograph indications, those claims that refer to other skin fungus infections may promote self-treatment of fungal infections other than athlete's foot, jock itch, and ringworm.

The claims "clinical improvement was obtained in 88 percent of athlete's foot cases" and "clinical studies show that it cured 78 percent of athlete's foot cases" are also classified as Category II. Specific percentages of successful and unsuccessful treatment will vary according to the test, i.e., an identical product in a different clinical study will result in different findings. All monograph drugs show clinical improvement in a certain percentage of patients. The agency believes that such labeling would not be very meaningful to consumers and could be confusing in selecting which product to use. Therefore, the agency concludes that such labeling should remain in Category II.

32. One comment requested that the statement "this product is not effective on the scalp or nails," which appears in the Panel's recommended directions in § 333.250(d)(1) for products labeled to treat athlete's foot, jock itch, and ringworm, be changed to read "this product is not effective in the treatment of fungal infections of the hair and nails." According to the comment, fungal infections of the skin of the scalp respond just as well to topical agents as does infected skin on other parts of the body.

The Panel provided the following reasons to support its position that topical antifungals are not effective for the treatment of ringworm of the scalp or nails: "Fungal infections of the scalp and nails tend to be chronic. They respond poorly to topical therapy, partly because of the thickness of the nails and the depth of the hair roots. Both sites of infection provide inaccessible locations for fungi, thus drastically decreasing the penetration of topical antifungals." (See 47 FR 12480 at 12487.)

Because the comment did not submit any data to support this suggested change, the agency is retaining the Panel's statement in the directions in this tentative final monograph.

33. Noting its continuing opposition to the exclusivity policy, one comment stated that FDA should not prohibit the use of alternative OTC labeling terminology to describe indications if that terminology is truthful, not misleading, and intelligible to the consumer. The comment stated that the existing statutory provisions (15 U.S.C. 1453(a), 21 CFR 201.61, and sections 502(e) and 508 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(e) and 358)) do not show a congressional intent to authorize FDA to legislate the exact wording of OTC drug claims to the exclusion of other equally accurate and truthful claims for these products. The comment also stated that if manufacturers use some of the terms recommended by some OTC advisory review panels, their labeling may be in violation of section 502(c) of the act (21 U.S.C. 352(c)), which requires label information to be in such terms as to render it likely to be read and understood by consumers under ordinary conditions of purchase and use. Other comments also stated that it is inappropriate and improper for FDA to prescribe exclusive lists of terms that must be used in labeling.

In the **Federal Register** of May 1, 1986 (51 FR 16258), the agency published a final rule changing its labeling policy for stating the indications of use for OTC drug products. Under 21 CFR 330.1(c)(2), the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED USES"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All other OTC drug labeling required by a monograph or other regulation (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under the OTC drug

monograph or other regulation where exact language has been established and identified by quotation marks, e.g., 21 CFR 201.63 or 330.1(g).

In this tentative final monograph for OTC topical antifungal drug products, supplemental language relating to indications has been proposed and captioned as *Other Allowable Statements.* Under FDA's revised labeling policy (51 FR 16258), such statements are included at the tentative final stage as examples of other truthful and nonmisleading language that would be allowed elsewhere in the labeling. In accordance with the revised labeling policy, such statements would not be included in a final monograph. However, the agency has decided that, because these additional terms have been reviewed by FDA, that should be incorporated, wherever possible, in final OTC drug monographs under the heading "Indications" as part of the indications developed under the monograph.

34. Referring to the Panel's guidelines for effectiveness studies and effectiveness standards for labeling indications of antifungal drug products for the treatment of ringworm of the body (47 FR 12480 at 12562), one comment disagreed with the Panel and stated that the treatment period should be 2 weeks and not 4 weeks with followup studies at 2 weeks and 4 weeks. The comment requested that the Panel's recommended directions in § 33.250(d)(1) be revised to provide for a 2-week treatment period of ringworm of the body rather than the 4-week period recommended by the Panel. The comment also requested that the directions be revised to alert consumers that "if a ringworm infection of the body does not clear within 2 weeks, professional consultation is recommended."

As discussed in comment 29 above, specific testing requirements are not being addressed in this tentative final monograph. With regard to the directions for use of antifungal drug products for the treatment of ringworm of the body, the Panel stated in its report that "The dosing regimen is standardized. Athlete's foot and ringworm are more difficult to treat than jock itch. For this reason the treatment period should be at least 4 weeks for athlete's foot and ringworm and 2 weeks for jock itch" (47 FR 12480 at 12492). The comment gave no reasons for changing the treatment period from 4 weeks to 2 weeks and did not submit any data to support its request. Thus, the agency concurs in the Panel's recommendation. Until data to support the comment's requests are submitted and evaluated, the changes recommended by the comment will not be made.

35. Several comments objected to the agency's dissent from the Panel's recommendation that certain prescription to OTC antifungal drugs be labeled "for the treatment of external itching associated with vaginal yeast (candidal) infections." One of the comments contended that "properly labeled anti-yeast and anti-inflammatory agents can be used safely and with benefits as OTC products." Another comment pointed out that 0.5 percent hydrocortisone for OTC use has an approved indication for the temporary relief of itching around the vagina.

After reconsidering its intention to include OTC antifungal drug products labeled for the treatment of external feminine itching in this rulemaking, the agency believes that it would be more appropriate to defer the consideration of antifungals for this labeling claim to the rulemaking for OTC vaginal drug products. (See the **Federal Register** of October 13, 1983; 48 FR 46694 at 46695 and 46729.) Therefore, comments on this subject that were submitted to the rulemaking for OTC antifungal drug products will be incorporated into the rulemaking for OTC vaginal drug products. If any antifungal ingredient is determined to be appropriate for the relief of external vaginal itching, it will be considered in the rulemaking for OTC vaginal drug products. The same antifungal ingredient may be determined to be appropriate for the prevention and/or treatment of athlete's foot and the treatment of ringworm and jock itch and will remain in the rulemaking or OTC antifungal drug products for this indication.

In the tentative final monograph for OTC external analgesic drug products, the agency proposed that hydrocortisone and hydrocortisone acetate 0.25 to 0.5 percent be available OTC for temporary relief of "genital" or "feminine" itching. (See the **Federal Register** of February 8, 1983; 48 FR 5852.) Thus, some of the concerns that the agency raised in the rulemaking for OTC antifungal drug products in 1982 were subsequently addressed in the external analgesic rulemaking. The agency will present its final conclusions on this use of hydrocortisone in the final monograph for OTC external analgesic drug products in a future issue of the **Federal Register.**

II. The Agency's Tentative Adoption of the Panel's Report

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. *Summary of ingredient categories.* The agency has reviewed all claimed active ingredients submitted to the Panel, as well as other data and information available at this time, and is proposing to reclassify povidone-iodine (10 percent) from Category III to Category I and phenol (less than or equal to 1.5 percent) from Category II to Category III. The agency is also proposing to reclassify nystatin from Category I to Category III. As a convenience to the reader, the following list is included as a summary of the categorization of topical antifungal active ingredients recommended by the Panel and the categorization proposed by the agency.

Topical antifungal active ingredients	Panel	Agency
Aluminum salts	III	III
Alcloxa		
Aluminum sulfate		
Potassium alum		
Basic fuchsin	III	III
Benzethonium chloride	III	III
Benzoic acid	III	III
Borates	III	III
Boric acid		
Sodium borate		
Camphor	II	II
Candicidin	II	II
Caprylates	III	III
Sodium caprylate		
Zinc caprylate		
Chlorothymol	III	III
Chloroxylenol	III	III
Clioquinol (Iodochlorhydroxyquin)	I	I
Coal tar	II	II
Cresols	III	III
Camphorated metacresol		
m-Cresol		
Secondary amyltricresols		
Dichlorophen	III	III
Haloprogin	I	I
Menthol	II	II
Miconazole nitrate	I	I
Nystatin	I	III
Oxyquinolines	III	III
Benzoxiquine		
Oxyquinoline		
Oxyquinoline sulfate		
Parabens	III	III
Methylparaben		
Propylparaben		
Phenolates	II	III
Phenol		
Phenolate sodium		
Phenyl salicylate	III	III
Povidone-iodine	III	I
Propionic acid and its salts	III	III
Sodium propionate		
Zinc propionate		
Resorcinol	II	II
Salicylic acid	III	III
Sulfur	III	III
Tannic acid	II	II
Thymol	II	II
Tolindate	II	II
Tolnaftate	I	I

Topical antifungal active ingredients	Panel	Agency
Triacetin	III	III
Undecylenic acid and its salts	I	I
Calcium undecylenate		
Copper undecylenate		
Zinc undecylenate		

2. *Testing of Category II and Category III conditions.* The Panel recommended testing guidelines for topical antifungal drug products in 47 FR 12480 at 12558. The agency's position regarding the Panel's testing guidelines is discussed in comment 29 above. Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any topical antifungal ingredient or condition included in the review by following the procedures outlined in the agency's policy statement published in the **Federal Register** of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Changes

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the Panel's report and recommended monograph with the changes described in FDA's responses to the comments above and with other changes described in the summary below. A summary of the changes made by the agency follows.

1. The agency has revised the definition of dermatophyte in § 333.203 to read: "A fungus that invades and lives upon the skin or in the hair or nails." (See comment 6 above.) The agency has also revised the definition of jock itch in § 333.203 to read: "A chronic and recurrent dermatophyte infection which affects the upper, inner thighs and sometimes extends to the groin and the pubic area; the condition most frequently occurs in men, but may also occur in women."

2. The agency has reclassified phenol from Category II to Category III. (See comment 12 above.)

3. The agency has reclassified povidone-iodine 10 percent into Category I. (See comment 14 above.)

4. The wording of § 333.250(b)(2) has been revised to be consistent with the style and format of § 333.250(b)(1), thereby including tolnaftate by reference rather than by name. (See comment 19 above.)

5. The Panel recommended that two or three antifungal ingredients identified in § 333.210 be combined provided each ingredient broadens the antifungal spectrum and provided the product is labeled according to § 333.250(b)(1). Because the Category I antidermatophytic antifungal ingredients have very similar spectra and combinations of up to three of these ingredients would result in duplication with respect to target organisms (that cause athlete's foot, jock itch, and ringworm) rather than broaden the antifungal activity, the agency is not proposing these combinations in this tentative final monograph. These combinations are classified in Category III in this document. (See comment 24 above.)

6. The agency is not proposing that any single active ingredient identified in § 333.210 or any combination of antifungal active ingredients be allowed in combination with an antiperspirant active ingredient for the treatment of athlete's foot, jock itch, and ringworm. These combinations are classified in Category III in this document. (See comment 22 above.)

7. The agency is not proposing that combinations of up to three Category I antifungal ingredients and hydrocortisone or hydrocortisone acetate 0.5 to 1 percent be available for OTC use in the treatment of athlete's foot, jock itch, and ringworm. The agency is deferring classification of such combinations in this rulemaking until the DESI proceeding involving one specific combination (clioquinol/hydrocortisone) is completed. (See comment 23 above.)

8. Because of the lack of efficacy data and a concern about safety of such products, the agency is not proposing combinations of Category I antifungal ingredients and any single keratolytic agent that is generally recognized as safe and effective in an OTC drug final monograph. These combinations are classified in Category III in this document. (See comment 26 above.)

9. The agency believes that it is more appropriate to defer the consideration of antifungal ingredients for treatment of external feminine itching to the rulemaking for OTC vaginal drug products. If any antifungal ingredient is determined to be appropriate for the relief of external vaginal itching, it will be considered in the rulemaking for OTC vaginal drug products. (See comment 35 above.)

10. The agency has determined that it is more appropriate to discuss the entire subject of diaper rash at one time. The comments on diaper rash drug products submitted to this rulemaking will be addressed at a later date when OTC diaper rash products are evaluated. (See comment 5 above.)

11. In the absence of information showing that infection by *Candida albicans* is a significant cause of athlete's foot or jock itch or that secondary infections of *Candida* are common in these conditions, the agency is not proposing the combination of an antidermatophytic ingredient with an anticandidal ingredient such as nystatin. Accordingly, the agency is reclassifying nystatin used in combination with other antifungal ingredients from Category I to Category III. (See comments 8 and 24 above.)

12. The agency is not including nystatin as a single Category I antifungal ingredient in this tentative final monograph. The Panel placed nystatin in Category I for the treatment of vaginal and superficial skin infections caused by *Candida albicans.* Because the agency has decided to defer the external feminine itching issue to another rulemaking and has determined that treatment of superficial skin infections caused by yeast (*Candida*) is not an appropriate OTC claim, nystatin as a single ingredient is not included in this tentative final monograph. (See comments 8, 24, and 35 above.)

13. The agency has concluded that no OTC antifungal drug product ingredient may be labeled for the treatment of cutaneous candidiasis, but that such claims may be included in the professional labeling for these products. Therefore, the agency is moving the labeling recommended by the Panel in § 333.250(b)(4) to the professional labeling section of this tentative final monograph. (See comment 8 above.)

14. No combinations are being proposed in this tentative final monograph. Therefore, the Panel's recommended § 333.220 is not being included in this tentative final monograph. (See comments 22 through 28 above.)

15. The agency has reevaluated all of the Category II labeling identified by the Panel and changed the status of certain claims. (See comment 31 above.)

16. The agency is not proposing the labeling for product attributes recommended by the Panel in § 333.250(b)(8). The Panel recommended that terms used to describe certain physical and chemical qualities of a drug product may be used in the labeling as long as these terms do not imply any therapeutic effect and are distinctly separated from the indications statements. These terms, such as "greaseless" or "nonstaining," are intended to provide consumer

information and relate to a product's color, odor, or feel. OTC drug monographs regulate only labeling information related in a significant way to those therapeutic properties of covered products having a direct bearing on their safe and effective use by lay persons. Claims concerning nontherapeutic characteristics of drugs, such as product attributes, are not dealt with in OTC drug monographs. Such terms may not appear in any portion of the labeling that is required by the monograph, but may appear elsewhere in the labeling. Labeling claims of this type are, however, subject to the misbranding provisions of the act.

17. In several places in the warnings and directions sections, the Panel recommended that the consumer consult a doctor or pharmacist if certain conditions occur. These included: (1) If irritation occurs or if there is no improvement within 2 or 4 weeks, (2) if the condition persists or recurs, (3) do not use longer than 30 days, and (4) if satisfactory results have not occurred within these times (2 or 4 weeks' use of the antifungal product). Although the pharmacist is an important member of the health care team, FDA believes that the situations covered by these warnings and directions are more appropriately handled by the physician. In cases where there is no improvement or the condition persists or recurs, diagnosis of the condition by the physician is necessary to determine the actual nature of the condition and the appropriate treatment. It is likely in such cases, where the OTC drug product has not provided satisfactory relief, that the physician will treat the patient with a prescription medication. Therefore, the agency is not including the word pharmacist, as recommended by the Panel, in these warnings and directions as proposed in this tentative final monograph.

18. In the warnings section, the agency is proposing the statement "Avoid contact with the eyes" in addition to the warning "For external use only" recommended by the Panel. Use of both statements is consistent with the warnings included in a number of other OTC drug monographs for topical drug products. (See, for example, the tentative final monograph for OTC external analgesic drug products (48 FR 5852; February 8, 1983); the tentative final monograph for OTC skin protectant drug products (48 FR 6820; February 15, 1983); and the final monograph for OTC topical otic drug products (51 FR 28656; August 8, 1986).)

19. In an effort to simplify OTC drug labeling, the agency proposed in a number of tentative final monographs to substitute the word "doctor" for "physician" in OTC drug monographs on the basis that the word "doctor" is more commonly used and better understood by consumers. Based on comments to these proposals, the agency has determined that final monographs and any applicable OTC drug regulations will give manufacturers the option of using either the word "physician" or the word "doctor." This tentative final monograph proposes that option. (See § 333.250(e) below.)

20. Under agency regulations relating to official names and established names for drugs in § 299.4(b) (21 CFR 299.4(b)), the established name of a drug is defined in section 502(e) of the act (21 U.S.C. 352(e)) as (1) an official name designated pursuant to section 508 of the act (21 U.S.C. 358); (2) if no such official name has been designated for the drug and the drug is an article recognized in an official compendium, then the official title thereof in such compendium; and (3) if neither paragraphs (1) or (2) applies, then the common or usual name for the drug. "Iodochlorhydroxyquin" and 'Clioquinol" are synonyms for the same chemical entity for which an official name has not been designated pursuant to section 508 of the act. However, "Clioquinol" is the official title in an official compendium (Ref. 1) and therefore is the established name; accordingly "Iodochlorhydroxyquin" in § 333.210(b) of the Panel's recommended monograph has been replaced with "Clioquinol" in § 333.210(a) of this tentative final monograph.

Reference

(1) "The United States Pharmacopeia XXI—The National Formulary XVI," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 227, 1985.

21. For products containing clioquinol, the agency is proposing the following warnings: "Do not use on children under 2 years of age" and "Do not use for diaper rash." These statements must appear in bold face type as the first warnings under the "Warnings" heading. (See Citizen Petition below.)

III. Citizen Petition

On July 24, 1985, a Citizen Petition was filed urging FDA to remove from the market as dangerous to infants and adults all prescription and OTC drugs containing clioquinol (formerly named iodochlorhydroxyquin) (Ref. 1). The petition stated that these drugs, when applied directly to the skin, are used in many cases for diaper rash and other skin problems in infants and children. The oral form of clioquinol was previously used to treat travelers' diarrhea and a rare disease known as acrodermatitis enteropathica. This form of the drug was taken off the market in most countries, including the United States, because it was linked to over 10,000 cases of subacute myelo-opticoneuropathy (SMON) in Japan and other countries.

While no cases of SMON related to the dermatologic use of clioquinol have been reported, the petition stated that there is now reason to believe that the topical form of the drug poses a significant threat of toxicity. According to the petition, recent studies have demonstrated that there is substantial percutaneous absorption of clioquinol resulting from topical use in humans and dogs, and that amounts of the drug not excreted from the body are stored in tissue. Further, it contended that animal studies suggest that toxicity may occur at fairly low levels of exposure, levels close to those an infant may receive. The petition expressed the view that clioquinol is dangerous because it concentrates in the organs and can cause SMON and liver toxicity. In support of its views, the petition cited recently published studies by Stohs et al. (Ref. 2) and Ezzedeen et al. (Ref. 3). (Those studies were published after publication of the Panel's report and thus were not evaluated by the Panel.)

In the Stohs study (Ref. 2), 5 gram (g) doses of 3 percent clioquinol cream were applied to the forearms of five healthy male subjects. Each dose was applied over a 200 square centimeter (cm^2) area, and the entire area was occluded with plastic wrap. Blood and urine samples were collected and assayed regularly. Twelve hours after application, the remaining drug was removed from the subjects' forearms. The amount removed was quantitatively analyzed and, based on this analysis, the authors concluded that approximately 40 percent of the topically applied drug had been absorbed.

In the Ezzedeen study (Ref. 3), 5 g doses of 3 percent clioquinol cream were applied twice daily to the backs of five mongrel dogs. The cream was applied over a shaved 200 cm^2 area and occluded with plastic wrap. The applications were continued for 28 days. Blood samples were drawn and assayed for clioquinol on a regular basis. The percentage of drug absorbed was estimated by measuring the amount of drug remaining on the back of each dog. Using this unvalidated method, the authors estimated that approximately 52 percent of the drug was absorbed.

This study was primarily a percutaneous absorption study.

However, the authors also made several observations that they suggest are toxic effects related to topical treatment with clioquinol. One dog died after 15 days of topical treatment, and microscopic examination of the liver revealed necrosis. One dog developed partial hand limb paralysis similar to that reported in a Japanese study of oral administration of clioquinol (Ref. 4). However, histologic and neurologic evaluations of this dog were not performed. All treated dogs lost weight, while no weight loss occurred in control animals.

In the second phase of this study, in addition to the topical application of clioquinol, three dogs were injected with a 100 milligrams (mg) intravenous (IV) bolus dose of clioquinol 2 months after topical treatment. The three dogs were killed 2 weeks after the bolus injections. Liver, kidney, and mesenteric adipose tissues were analyzed for clioquinol, and mean levels of 1.22, 0.83, and 0.88 mg/g, respectively, were found. The authors also microscopically examined the liver tissues of the 3 dogs and found liver lesions similar to those found in the dog that died after 15 days of topical treatment. The control dogs were not sacrificed or examined similarly.

The petition contended that if 1 g of a 3-percent clioquinol preparation was applied to a child's diaper rash three times a day, a total daily dose of 90 mg per day would be applied. If the child weighed 10 kilograms (kg) (22 lbs), the amount of clioquinol would be 9 mg/kg/day, which is close to the 17 mg/kg/day dose in the dog study and over three times higher than the single dose of 2.5 mg/kg in the human study in which blood levels of 0.37–0.56 mg/milliliter (mL) were obtained. The petition also expressed concern about the 9 mg/kg/day an infant might receive because of its proximity to the oral doses received by SMON victims (many between 12.5 and 25 mg/kg/day).

On November 18, 1985, FDA's Dermatologic Drugs Advisory Committee met to consider the petition. Sidney J. Stohs, a principal investigator in both cited studies, appeared before the Committee and discussed the results of his work.

After extensive questioning and discussion, the Committee generally agreed that the two studies upon which the petition is largely based are not adequate to support the removal of all clioquinol products from the market. The Committee expressed concern however that absorption of the drug by infants, even in small amounts, poses a potential risk, and voted to recommend that clioquinol be moved from the OTC market to prescription status to prevent indiscriminate use of the drug, especially in infants (Ref. 5).

The agency has reviewed the data presented in the petition. With regard to the Stohs' study (Ref. 2), the agency is unable to conclude that the extent of percutaneous absorption was reliably established. The method used to determine the extent of absorption is an indirect method of determining the absorption of topically applied drugs and, to the agency's knowledge, has not been validated as an accurate method. The published report on this study does not provide any information regarding the validity of this method. Furthermore, at the November 1985 Dermatologic Drug Advisory Committee meeting (Ref. 5), Dr. Stohs was unable to provide assurance that the method had been validated as accurate. The agency believes that it is highly probable that this method will greatly overestimate the amount of drug absorbed because of the difficulty in removing all of the drug remaining on the skin.

The agency believes that the observations made during the topical application phase of the Ezzedeen study are of concern, but also believes that the evidence linking the effects observed to the drug is weak. The published paper provides no information documenting that the pretreatment status and the handling of the dogs during the study were comparable for the treatment and control groups. Furthermore, at the November 1985 Dermatologic Drugs Advisory Committee meeting (Ref. 5), Dr. Stohs, one of the investigators in the Ezzedeen study, stated that the treatment and control dogs were not handled in a similar fashion.

The agency also finds the toxicity and tissue retention observations concerning the three dogs that received IV injections of clioquinol inadequate to support a conclusion that topical application of the drug would cause similar effects. The relationship between the effects of IV clioquinol administration and the effects of topical clioquinol application is unknown. Moreover, because of the inadequate control procedures used, the liver toxicity observations cannot be confidently attributed to the IV administration of clioquinol.

Overall, the agency believes that the two studies primarily relied upon to support the petition are inadequate to demonstrate that OTC topical clioquinol, prescription topical clioquinol/hydrocortisone, and prescription topical clioquinol/nystatin are dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in their labeling. Based upon the extensive marketing history of this ingredient, the agency concludes that there are insufficient data available to justify removing all clioquinol-containing drug products from the market as misbranded under section 502(j) of the act (21 U.S.C. 352(j)) based upon the information presented in the petition.

Although the agency does not believe that the existing information requires removal of topical clioquinol from the market as suggested by the petition, or restriction to prescription-only status as recommended by the Dermatologic Drugs Advisory Committee, the agency shares the concern expressed by the petition and the Advisory Committee that use of topical clioquinol on infants may potentially place them at increased risk. This risk is not well defined because of the lack of information relating to the use of topical clioquinol on infants.

The Antimicrobial II Panel evaluated possible blood levels and the potential toxicity resulting from several "worst case" situations in which clioquinol would be applied topically to broken skin. The Panel considered application to a jock itch or ringworm condition, both of which represent a larger surface area than an athlete's foot condition, and assumed total and rapid absorption occurs after each application. The Panel reported that the blood levels estimated from such exposure would be well below the reported 15-to-30 μg/mL blood levels obtained during a 2-week oral administration of clioquinol in which no toxic symptoms were observed. (See 47 FR 12480 at 12496.)

In an adult, the surface area of contact is small (probably less than 5 percent) when clioquinol is used for its approved OTC indications. If clioquinol were used for diaper rash in infants, the affected area may be 10 to 15 percent of the body surface. Additionally, inflamed and often open surface areas are more permeable and permit a greater degree of absorption. Clioquinol is detoxified in the adult liver by conjugation with a glucuronide. Infants do not have as fully developed a conjugation pathway as adults; thus, clioquinol may accumulate in infants due to a reduced ability to detoxify the drug. Additionally, a young child has less percent body fat and a developing nervous system. Although clioquinol is not specifically approved for diaper dermatitis and there are no known reports of SMON or major systemic toxicity in children following topical use, children under age 2 are on theoretical grounds the population with the highest potential risk for an adverse outcome. Accordingly, while the agency

believes that clioquinol may remain on the OTC market labeled for its approved OTC uses (i.e., athlete's foot, jock itch, and ringworm), it must be labeled that it is not for use on children under 2 years of age and that it is not for use for diaper rash. Therefore, the agency is proposing that 2 warning statements appear on all OTC drug products containing clioquinol, and that these statements appear in bold face type as the first warnings on the label, as follows: "Do not use on children under 2 years of age." "Do not use for diaper rash."

References

(1) Citizen Petition, Public Citizen Health Research Group, July 24, 1985, Coded CP, Docket No. 85P-0344, Dockets Management Branch.

(2) Stohs, S. J., et al., "Percutaneous Absorption of Iodochlorhydroxyquin in Humans," *The Journal of Investigative Dermatology*, 82:195-198, 1984.

(3) Ezzedeen, F. W., et al., "Percutaneous Absorption and Disposition of Iodochlorhydroxyquin in Dogs," *Journal of Pharmaceutical Sciences*, 73:1369-1372, 1984.

(4) Kono, R. "Introductory Review of Subacute Myelo-optico Neuropathy (SMON) and Its Studies Done by the SMON Research Commission," *Japanese Journal of Medical Science and Biology (Supp.)*, 28:1-21, 1975.

(5) Summary Minutes of the 26th Meeting of the Dermatologic Drugs Advisory Committee, November 18, 1985.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC antifungal drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96-354). That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC antifungal drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invited public comment in the advance notice of proposed rulemaking regarding any impact that this rulemaking would have on OTC antifungal drug products. No comments on economic impacts were received. Any comments on the agency's initial determination of the economic consequences of this proposed rulemaking should be submitted by March 11, 1990. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR part 25).

The agency is proposing to remove § 310.201(a)(29) because the conditions in that section for tolnaftate preparations will be superseded by the requirements of the final monograph on OTC antifungal drug products (subpart C of 21 CFR part 333).

Interested persons may, on or before March 11, 1990, submit to the Dockets Management Branch written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before March 11, 1990. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register**.

Interested persons, on or before December 12, 1990, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before February 2, 1991. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the **Federal Register** of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (address above). Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on February 12, 1991. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the **Federal Register**, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects

21 CFR Part 310

Administrative practice and procedure, Drugs, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 333

Antifungal drug products, Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act, it is proposed that subchapter D of chapter I of title 21 of the Code of Federal Regulations be amended in parts 310 and 333 as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512-516, 520, 601(a), 701, 704, 705, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b-360f, 360j, 361(a), 371, 374, 375, 376); secs. 215, 301, 302(a), 351, 354-360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b-263n).

§ 310.201 [Amended]

2. Section 310.201 *Exemption for certain drugs limited by new-drug*

applications to prescription sale is amended by removing paragraph (a)(29).

PART 333—TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

3. The authority citation for 21 CFR part 333 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

4. Part 333 is amended by adding new subpart C to read as follows:

Subpart C—Topical Antifungal Drug Products

Sec.
333.201 Scope.
333.203 Definitions.
333.210 Antifungal active ingredients.
333.250 Labeling of antifungal drug products.
333.280 Professional labeling.

Subpart C—Topical Antifungal Drug Products

§ 333.201 Scope.

(a) An over-the-counter antifungal drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 333.203 Definitions.

As used in this subpart:

(a) *Antifungal.* A drug which inhibits the growth and reproduction of fungal cells and decreases the number of fungi present.

(b) *Athlete's foot.* An infection of the feet caused by dermatophytic fungi.

(c) *Dermatophyte.* A fungus that invades and lives upon the skin or in the hair or nails.

(d) *Fungus.* Any of a large division of plants, including dermatophytes, yeasts, and molds, characterized by a simple cell structure and the absence of chlorophyll.

(e) *Jock itch.* A chronic and recurrent dermatophyte infection which affects the upper, inner thighs and sometimes extends to the groin and the pubic area; the condition most frequently occurs in men, but may also occur in women.

(f) *Ringworm.* A skin infection caused by dermatophytic fungi.

§ 333.210 Antifungal active ingredients.

The product consists of any of the following active ingredients within the specified concentrations established for each ingredient and the product is labeled according to § 333.250.

(a) Clioquinol 3 percent.

(b) Haloprogin 1 percent.

(c) Miconazole nitrate 2 percent.

(d) Povidone-iodine 10 percent.

(e) Tolnaftate 1 percent.

(f) Undecylenic acid, calcium undecylenate, copper undecylenate, and zinc undecylenate may be used individually or in any ratio which provides a total undecylenate concentration of 10 to 25 percent.

§ 333.250 Labeling of antifungal drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "antifungal."

(b) *Indications.* The labeling of the product states, under the heading "Indications," any of the phrases listed in this paragraph, as appropriate. Other truthful and nonmisleading statements describing only the indications for use that have been established in this paragraph (b), may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For products containing any ingredient idenified in § 333.210 labeled for the treatment of athlete's foot, jock itch, and ringworm.* (Select one of the following: "Treats," "For the treatment of," "For effective treatment of," "Cures," "For the cure of," "Clears up," or "Proven clinically effective in the treatment of") (select one condition from any one or more of the following groups of conditions: (i) "athlete's foot," "athlete's foot (dermatophytosis)," "athlete's foot (tinea pedis)," or "tinea pedis (athlete's foot)"; (ii) "jock itch," "jock itch (tinea cruris)," or "tinea cruris (jock itch)"; or (iii) "ringworm," "ringworm (tinea corporis)," or "tinea corporis (ringworm).")

(2) *For products containing the ingredient identified in § 333.210(e) labeled for the prevention of athlete's foot.* (Select one of the following: "Clinically proven to prevent," "Prevents," "Proven effective in the prevention of," "Helps prevent," "For the prevention of," "For the prophylaxis (prevention) of," "Guards against," or "Prevents the recurrence of") (select one of the following: "athlete's foot," "athlete's foot (dermatophytosis)," "athlete's foot (tinea pedis)," or "tinea pedis (athlete's foot)") "with daily use."

(3) *Other allowable statement for products labeled according to paragraph (b)(1) of this section.* The labeling of the product may contain an additional indication statement as follows: (Select one of the following: "Relieves," "For relief of," "For effective relief of," or "Soothes,") (select one or more of the following: "itching," "scaling," "cracking," "burning," "redness," "soreness," "irritation," "discomfort," "chafing associated with jock itch," "itchy, scaly skin between the toes," or "itching, burning feet").

(4) *Other allowable statement for products labeled according to paragraph (b)(2) of this section.* The labeling of the product may contain an additional indication statement as follows: "Clears up athlete's foot infection and with daily use helps keep it from coming back."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) *For products containing any ingredient identified in § 333.210.* (i) "Do not use on children under 2 years of age except under the advice and supervision of a doctor."

(ii) "For external use only."

(iii) "Avoid contact with the eyes."

(2) *For products labeled according to paragraph (b)(1) of this section for the treatment of athlete's foot and ringworm.* "If irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor."

(3) *For products labeled according to paragraph (b)(1) of this section for the treatment of jock itch.* "If irritation occurs or if there is no improvement within 2 weeks, discontinue use and consult a doctor."

(4) *For products labeled according to paragraph (b)(2) of this section for the prevention of athlete's foot.* "If irritation occurs, discontinue use and consult a doctor."

(5) *For products containing the ingredient identified in § 333.210(a) labeled according to paragraph (b)(1) of this section.* The following statements must appear in bold face type as the first warnings under the "Warnings" heading. (i) "Do not use on children under 2 years of age." (This warning is to be used in place of the warning in paragraph (c)(1)(i) of this section.)

(ii) "Do not use for diaper rash."

(d) *Directions.* The labeling of the product contains the following statements under the heading "Directions:"

(1) *For products labeled according to paragraph (b)(1) of this section for the treatment of athlete's foot, jock itch, and ringworm.* "Cleanse skin with soap and water and dry thoroughly. Apply" (the

word "spray" may be used to replace the word "apply" for aerosol products) "a thin layer over affected area morning and night or as directed by a doctor. For athlete's foot, pay special attention to the spaces between the toes. It is also helpful to wear well-fitting, ventilated shoes and to change shoes and socks at least once daily. Best results in athlete's foot and ringworm are usually obtained with 4 weeks' use of this product, and in jock itch, with 2 weeks' use. If satisfactory results have not occurred within these times, consult a doctor. Children under 12 years of age should be supervised in the use of this product. This product is not effective on the scalp or nails."

(2) *For products labeled according to paragraph (b)(2) of this section for the prevention of athlete's foot.* "To prevent fungal infection of the feet (athlete's foot), cleanse skin with soap and water and dry thoroughly. Apply" (the word "spray" may be used to replace the word "apply" for aerosol products) "a thin layer to feet once or twice daily, paying special attention to the toenails and the spaces between the toes. It is also helpful to wear well-fitting, ventilated shoes and to change shoes and socks at least once daily."

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

§ 333.280 Professional labeling.

The labeling provided to health professionals (but not to the general public) may contain the following additional indication:

(a) *For products containing haloprogin or miconazole nitrate identified in § 333.210 (a) and (c).* "For the treatment of superficial skin infections caused by yeast (*Candida albicans*)."

(b) [Reserved]

Dated: October 28, 1989.

James S. Benson,

Acting Deputy Commissioner of Food and Drugs.

[FR Doc. 89-28816 Filed 12-11-89; 8:45 am]

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Federal Register

Tuesday
December 12, 1989

Part V

Department of Justice

Bureau of Justice Assistance

Drug Control and System Improvement Formula Grants for Fiscal Year 1990; Notice

DEPARTMENT OF JUSTICE

Bureau of Justice Assistance

Drug Control and System Improvement Formula Grants for Fiscal Year 1990

AGENCY: Bureau of Justice Assistance, Justice.
ACTION: Notice.

SUMMARY: The Bureau of Justice Assistance is publishing this notice of Program Guidance and Application Kit for implementation of the Drug Control and System Improvement Grant Program. This notice deals with procedures and requirements for formula grant applications and grant administration for Fiscal Year 1990.

EFFECTIVE DATE: This program guidance is effective November 21, 1989.

FOR FURTHER INFORMATION CONTACT: Curtis H. Straub II, Bureau of Justice Assistance, 633 Indiana Avenue NW., Washington, DC 20531 (202–724–6838). (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The Bureau of Justice Assistance is publishing a program guidance and application kit for Fiscal Year 1990 for implementation of the Drug Control and System Improvement Formula Grant Program. The Anti-Drug Abuse Act of 1988, title VI, subtitle C, of Public Law 100–690 authorizes the Bureau of Justice Assistance to provide funds to eligible States for the purpose of making subgrants to State agencies, units of local government and private, nonprofit organizations.

The purpose of this program is to address the most pressing drug control and criminal justice system improvement problems as determined through the statewide strategic planning process to be implemented by the States. Grant funds are provided to the States to support specific programs which offer a high probability of improving the function of the criminal justice system, with a special emphasis placed on multilevel and multi-jurisdictional drug control efforts. Programs and projects are to be developed to assist State and local drug control efforts and to support national drug control priorities.

The States may award formula grant funds to State agencies and local units of government for the purpose of enforcing State and local laws which establish offenses similar to offenses established in the Controlled Substances Act (21 U.S.C. 801 *et seq.*) and to improve the functioning of the criminal justice system with emphasis on violent and serious offenders. Grants may provide personnel, equipment, training, technical assistance and information systems for the more widespread apprehension, prosecution, adjudication, detention and rehabilitation of persons who violate such laws and to assist the victims of such crime other than compensation. No program may be funded that is not contained in a State strategy that has been approved by the Bureau of Justice Assistance. The program guidance lists 21 purpose areas for which programs can be funded under the Act.

The program guidance and application kit describe a general process the States must follow to develop the required statewide strategy to qualify for funding under this Act and to make application for such funding. They succeed the prior program guidance for Fiscal Year 1989. Specific deadlines for application submission and award of subgrants are identified as required by the Act. In distributing the funds, States shall give priority to those jurisdictions with the greatest documented need. The State strategy should include goals and objectives to address the drug control and system improvement priorities and include identification of programs, needed legislative and administrative changes and establish mechanisms to improve the coordination of efforts at the State and local level.

Charles P. Smith,
Director, Bureau of Justice Assistance.

Introduction

The Bureau of Justice Assistance (BJA) of the Office of Justice Programs (OJP), under the Drug Control and System Improvement Formula Grant Program of the Anti-Drug Abuse Act of 1988, provides Federal financial assistance to state and local units of government for programs which improve the enforcement of state and local laws that establish offenses similar to offenses established in the Controlled Substances Act (21 U.S.C. 801, *et seq.*), and to improve the functioning of the criminal justice system with emphasis on violent crime and serious offenders.

This document provides the guidance, forms, instructions, and information necessary for an eligible grantee to apply to BJA for formula grant funds.

Key Program Elements

The Anti-Drug Abuse Act provides financial and technical resources to state and local units of government, as well as the Federal government, to engage them in the nation's fight against drugs. The National Drug Control Strategy was announced by President Bush on September 5, 1989. It sets priorities and makes recommendations for action by Federal, state and local governments and communities to reduce drug use in this country. Key policy elements from the Act and the National Strategy are outlined below to provide guidance to the states in their drug control efforts.

Drug Testing

Drug testing has been shown to be an effective tool in identifying drug users and discouraging use. Programs should be implemented within the state criminal justice systems to test defendants/offenders for drugs including arrestees, prisoners, parolees and those out on bail and to use the test results to make release decisions and set conditions of release, to monitor drug use while under court supervision and to make referrals to drug treatment. A description of the state's drug testing program should be included as part of the state strategy.

Street-level Enforcement

The National Drug Control Strategy identifies street-level drug enforcement as a "crucial component" of an effective drug strategy. It states that "street-level enforcement remains the best tool we have for restoring a sense of order and civility to neighborhoods where drugs—with all their attendant crime, violence and decay—have wrought havoc. The first priority of local drug enforcement, then, is to employ effective police methods capable of fighting drugs at the neighborhood level." States are encouraged to make street-level enforcement an important component of their strategy.

User Accountability

The criminal justice system has an important role to play in reducing the demand for drugs by holding drug users as well as dealers accountable for their actions. User accountability programs should be developed and implemented, including vigorous prosecution and use of fines for misdemeanor drug offenses and the increased use of civil penalties (e.g., the loss of professional and drivers licenses, fines and community service).

Alternative Sentencing Programs for Non-violent Drug Offenders

Many drug offenders receive inadequate, if any, supervision. Alternative sentencing programs, including house arrest and boot camp programs, should be developed to hold non-violent drug offenders accountable for their actions.

Planning and Designing Judicial and Correctional Facilities

New judicial and correctional facilities are needed in many states to expedite drug cases and to punish drug traffickers and violent and repeat drug offenders. Formula Funds may be used for actual construction of penal or correctional institutions. Priority also should be given to planning and designing new judicial and correctional institutions.

Marijuana Eradication

The National Drug Control Strategy recommends expansion of programs to eradicate the domestic marijuana crop. Marijuana producing states are encouraged to increase their eradication efforts.

Evaluation of the Strategy

To be effective in the fight against drugs, we must know what works and what does not. An evaluation capability should be established within the state to evaluate the impact of the statewide drug strategy and programs and projects instituted to implement the strategy.

Key Implementation Elements

Coordination

Success in the fight against drugs requires coordination and cooperation at all levels, including intergovernmental, interdisciplinary and public/private sector.

Coordination of State and Local Drug Control Efforts with Federal Efforts—States should incorporate the recommendations from the National Drug Control Strategy into their state strategy with an emphasis on street-level enforcement, planning and designing court and correctional facilities, alternative sentencing, user accountability and drug testing.

States are encouraged to contact and work with the Law Enforcement Coordinating Committee (LECC) of the United States Attorney(s) within the state. The LECC, which brings together Federal, state and local law enforcement and prosecutors, can serve as an important resource in the strategy development process. The LECC's role in the development of the strategy should be described in the application.

Coordination of Drug Control Efforts within the State—It is essential that State and local law enforcement, prosecutors, and other criminal justice personnel participate closely in developing the statewide drug strategy. State planning agencies should not draft the strategy and then submit the document for review, thereby depriving operational agencies from making substantive contributions at the beginning of the strategy development process. States are also encouraged to increase coordination among criminal justice, treatment and education systems within the state to achieve a comprehensive and effective approach to drug control. States are also encouraged to promote multi-jurisdictional and inter-agency activities which result in increased coordination and cooperation among criminal justice agencies.

Local Participation in Strategy Development—Taking our neighborhoods back from drug dealers and getting the community involved in drug prevention efforts is primarily a local responsibility. Thus, local units of government, including police, prosecutors and other justice officials, especially in jurisdictions with major drug problems, should be actively involved in the planning and strategy development process including the initial stages.

Matching Requirement

The fight against drug use must involve the active participation of all levels of government and the community. The matching requirement encourages state and local units of government to expand the resources committed to drug control efforts.

Distribution of Formula Funds within the State

As part of the requirements for the Anti-Drug Abuse Act, the states develop a statewide drug control strategy which defines the drug problem in the state, analyzes current efforts and resource needs and establishes priorities for the implementation of the strategy. The distribution of the formula funds within the state should be based on the strategy and should give priority to those jurisdictions with the greatest need.

Drug-Free Workplace

Clearly defined policies against drug use in the workplace and employee assistance programs for workers with drug problems provide an effective means of reducing drug use in the American workforce. All grantees of Federal funds, other than an individual, must provide a drug-free workplace in accordance with title V, sec. 5153 of the Anti-Drug Abuse Act of 1988 as defined by 28 CFR part 67, subpart F.

Purpose of Formula Grant Funds

The purpose of the Drug Control and System Improvement Grant Program is to assist states and units of local government in carrying out specific programs which offer a high probability of improving the functioning of the criminal justice system. Special emphasis is placed on a nationwide and multi-level drug control strategy. Programs and projects are to be developed to assist multi-jurisdictional and multi-state organizations in the drug control problem and to support national drug control priorities. Sec. 501(a) of the Act.

In accordance with Sec. 501(b) of the Act, the states may award formula grant funds to state agencies and units of local government for the purpose of enforcing state and local laws which establish offenses similar to offenses established in the Controlled Substances Act (21 U.S.C. 801 *et seq.*) and to improve the functioning of the criminal justice system, with emphasis on violent crime and serious offenders. Grants may provide personnel, equipment, training, technical assistance and information systems for the more widespread apprehension, prosecution, adjudication and detention and rehabilitation of persons who violate such laws, and to assist the victims of such crimes (other than compensation). The authorized programs are described in Appendix A. Formula funds should be devoted to programs that directly relate to drug control.

Allocation of Funds to the States

Eligible Applicants

State Government

All states are eligible to apply for and receive formula grants. Sec. 502 of the Act. State, as defined in the statute, means any state of the United States and includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa. Sec. 901(a)(2) of the Act.

Units of Local Government

Units of local government are eligible to receive subgrants from a participating state. Units of local government means any city, county, town, township, borough, parish, village or other general purpose political subdivision of a state and includes Indian tribes which perform law enforcement functions as determined by the Secretary of the Interior. Sec. 901(a)(3) of the Act.

Allocation

Sec. 506(a) of the Act provides that at least 80 percent of the total amount appropriated for this part shall be allocated for formula grants. The formula grant allocation is the balance of the appropriation remaining after a

set aside for discretionary programs of 20 percent of the total appropriation or $50,000,000, whichever is less. Each participating state shall receive a base amount of 0.25 percent of the total formula grant allocation or $500,000, whichever is greater. The remaining funds are allocated to each state on the basis of the state's relative share of total U.S. population. The FY 1990 allocations by state are found in Appendix B.

For the purposes of this Section, American Samoa and the Northern Mariana Islands shall be considered as one state, and 67 percent of the amount allocated shall be given to American Samoa and 33 percent to the Northern Mariana Islands. Sec. 901(a)(2) of the Act.

If BJA determines, on the basis of information available during any fiscal year, that a portion of the funds allocated to a state for that fiscal year will not be required or that a state will be unable to qualify or receive funds under the Formula Grant Program or that a state chooses not to participate in the program, then the state's portion of the funds shall be awarded by the Director of BJA to urban, rural and suburban units of local government or combinations thereof within the state, giving priority to those jurisdictions with greatest need. Sec. 506(e). Any funds allocated under the Formula Grant Program which are not distributed in accordance with Sec. 506 (a) and (b) shall be available for obligation under the Discretionary Grant Program. Sec. 506(f) of the Act.

Administrative Requirements

Distribution of Formula Funds Within the State

Variable Pass-through

Funds granted to the state are further subgranted by the state to state agencies and units of local government to carry out programs and projects contained in an approved application. Each state shall distribute to its local units of government, in the aggregate, a portion of the state's formula grant funds equal to the local government share of total state and local criminal justice expenditures for the previous fiscal year. Sec. 506(b)(1) of the Act. In determining the portion to be distributed to local units, the most recent and complete data (1988) available from the Bureau of Justice Statistics (BJS), OJP, of the U.S. Department of Justice shall be used unless the use of other data has been approved in advance by BJA. The portion of each state's allocation which must be passed through to local units of government is found in Appendix B.

To request approval of a distribution ratio other than that announced by BJA, the head of the State Office must certify in writing to BJA that the ratio it proposes is a correct reflection of the local share of total state and local criminal justice expenditures and that the state has notified its major local governments of the request and informed them of the opportunity to contact BJA within 30 days if they have any objections. The written request must also cite the expenditure data used to substantiate the proposed change, which shall be reviewed by BJS, prior to approval or rejection by BJA.

Distribution of Funds to State Agencies

Any funds not required to be passed through to local units of government may be used for programs administered by state agencies. Sec. 506(b)(3) of the Act. States may exceed the variable pass-through by providing funds not used at the state level to local units of government.

Priority to Jurisdictions With the Greatest Need

In distributing funds, the state shall give priority to those jurisdictions with the greatest need. Sec. 506(b)(2) of the Act.

45-Day Rule for Review of Local Government Applications

The state must make a decision on each complete application made by a local unit of government, or a combination of units of local government, within 45 days of receipt. An application shall be deemed approved by the state unless the state informs the applicant in writing within 45 days of the specific reasons for disapproval. The state shall not finally disapprove any application without first affording the applicant reasonable notice and opportunity for reconsideration. Sec. 508(a) of the Act. The state may establish program priorities for submission of the applications based on their strategy and criteria. The failure of an application to conform to the program priorities or to meet the criteria may constitute reason for disapproval.

45-Day Rule for Making Funds Available to Local Units of Government

Within 45 days following BJA's approval of a state's formula grant application and notice to and acceptance of conditions by the state, the state shall make funds available to local units of government, or combinations thereof, whose applications have been submitted to, approved and awarded by the state. The Director of BJA shall have the authority to waive the 45-day requirement upon a finding that the state cannot satisfy the requirement consistent with state statutes. Sec. 508(b) of the Act.

Matching Requirements

The requirement for states to provide a match of 25 percent of total project costs has been retained for FY 1990. Current law provides for the match to increase to 50 percent in any subsequent fiscal years.

Cash Match

The non-Federal share of expenditures shall be paid in cash. Sec. 504(e) of the Act. Funds required to pay the non-Federal portion of the cost of each program and project for which a grant is made shall be in addition to funds that would otherwise be made available for law enforcement by the recipients of the grant funds. Sec. 503(a)(3) of the Act.

Waiver of Matching Requirement for Indian Tribes

Funds subgranted to an Indian tribe which performs law enforcement functions (as determined by the Secretary of the Interior) shall be used to pay 100 percent of the cost of a program or project. Sec. 504(a)(2) of the Act.

Use of Proceeds Received Under the Equitable Sharing Program as Match

State and local units of government may use cash they received under the equitable sharing program to cover the non-Federal portion of costs of any OJP project or program.

Use of Proceeds from Asset Forfeitures as Match

A state or local unit of government may use forfeiture funds as match if state and local statutes allow for the collection and retention of such funds.

Administrative Costs

Given the increase in the formula grant allocation over previous years, states are encouraged to limit administrative costs to no more than five percent of their allocation. However, the Act allows up to 10 percent of grant funds to be used to pay for costs incurred in administering the formula grant program. Funds which are not used for administration of the program can be used to implement drug control efforts. Requests to use more than five percent of the funds for administration of the program should be justified in the formula grant application. There shall be a

presumption that funds specifically designated for preparation of the application for funds, including the drug strategy and administration of the award, are being used for the benefit of both state and local agencies and are expended in accordance with the variable pass-through requirement.

Undercover Operations

State agencies and local units of government may apply for and receive grants to conduct law enforcement undercover operations. The process by which these applications are reviewed and conducted must include provisions to protect the confidentiality of the operations. The standard of "need to know/right to know" is paramount when handling these types of applications. The following is provided as guidance:

- Information pertaining to the political jurisdictions and/or implementing agencies should be omitted on any documents submitted to BJA. The application should only include the program description, the funds involved and the number of projects.
- It is recommended that state agencies establish policies and procedures for special handling of undercover applications and grants. These should address:

—Limiting the need to provide confidential information by the applicant for review and funding decisions

—Minimizing the number of personnel having "need to know/right to know" status in performing application review and grant management functions

—Storing applications, grant awards and grant management documents in secure locations to prevent unauthorized access

Establishing/revising special management procedures relating to financial, monitoring and auditing activities in order to maintain confidentiality of the application and/or subgrant.

For the specific Office of Justice Programs (OJP) requirements governing the management of confidential funds, see OJP M 7100, Financial and Administrative Guide for Grants.

Allowable/Unallowable Expenses

General Salaries and Personnel Costs

Payment of personnel costs with grant funds is permitted if the costs are a part of an approved program or project. Sec. 501(b) of the Act.

Equipment and Hardware

Equipment and hardware expenses which are part of an approved program or project are allowable expenses. Sec. 501(b) of the Act.

Expenditures for Purchase of Evidence and Information

Formula grant funds which may be used for confidential expenditures are defined as funds used for the purchase of services, purchase of physical evidence and purchase of information including buy money, flash rolls etc. Guidelines related to confidential expenditures are found in OJP M7100, Financial and Administrative Guide for Grants (current edition). BJA has delegated to the State Office which administers the formula grant program authority to approve the allocation, use and expenditure of formula subgrant funds for confidential expenditures. Thus, the use of the term "Grantor Agency" as used in M7100 means the State Office for subgrants. All state applications containing projects which will utilize funds for confidential expenditures must contain an assurance that the guidelines found in M7100 will be followed.

Construction

Use of formula grant funds for construction projects is prohibited except when facilities to be constructed are penal or correctional institutions. Sec. 505(c) of the Act. Correctional institutions refer to prisons, jails, juvenile correctional institutions and residential community corrections facilities.

Land Acquisition

Acquisition of land with grant funds is prohibited. Sec. 505(c) of the Act.

Evaluation Cost

Expenses associated with conducting evaluations of programs/projects funded with formula grant funds are allowable expenses and may be paid with administrative funds, program funds or a combination of both. Sec. 504(d) of the Act.

Participation in Drug Enforcement Administration Task Forces

Formula grant funds may be used for expenses associated with participation of the state or units of local government, or combinations thereof, in the State and Local Task Force Program established by the Drug Enforcement Administration. Sec. 504(c) of the Act.

State Application Requirements

Application Submission

The Act requires that applications for funds be submitted within 60 days after the date that the appropriation for the program is enacted. Sec. 503(a) of the Act.

If a state fails to submit an application by the submission deadline as defined by the Act, BJA will provide the state with written notice that it intends to begin the process of making funds available to local units of government, or combinations thereof, within the state, within 30 days of the date of the notice. The state will be provided with an opportunity to submit its application and a justification for the late submission within the 30-day period. The Director of BJA will make a determination on adequacy of the justification prior to initiating review of the application.

An original and ten copies of the application should be mailed to: Bureau of Justice Assistance, Control Desk, 633 Indiana Avenue, NW., Washington, DC 20531.

Please note the number of copies which are being requested. This will assist BJA in the application review and award process.

Application Content

A complete formula grant application includes the following:

- Standard Form (SF) 424 "Federal Assistance" (revised 4–88)
- Executive Order 12372 Compliance
- Audit Requirements
- Civil Rights Requirements
- Certification Regarding Debarment
- Certification Regarding Drug-Free Workplace Requirements
- State Legislature Review
- Certified Assurances
- Statewide Strategy
- List of Program/Projects

Standard Form 424 (revised 4–88)

This form is the face sheet for the application. A copy of the current form is found in Appendix C. This document must be signed by a duly authorized official and dated. Note: Applications using an outdated version of the SF–424 will not be accepted.

Executive Order 12372 Compliance "Intergovernmental Review of Federal Programs"

Applicants must complete item 16 of SF–424 which requires information regarding compliance with Executive Order 12372. In accordance with the Executive Order and the Department of Justice's implementing regulation, 28

CFR part 30, states must submit formula grant applications to the state "Single Point of Contact" (SPOC), if one exists, and if the program has been selected for coverage by the state process. The state may submit its application to the SPOC at the same time the application is submitted to BJA. The state SPOC may take up to 60 days from the application submission date to comment on the application. If, at the time that BJA approves the state's application, the SPOC has not commented on the application, and the 60-day comment period has not expired, the award will be special conditioned to allow for comment prior to the award of subgrants by the state.

Applicants are encouraged to contact their state's SPOC as soon as possible to inform them of the prospective application and to receive instructions regarding the state process.

Audit Requirements

Each grantee accepting BJA formula grant funds must agree to comply with the requirements of the OMB Circular A-128. Applications must include:

- Date of the last audit
- Dates covered by the last audit
- Date of the next audit
- Dates to be covered by the next audit
- Date next audit will be forwarded to cognizant audit agency
- Designated Federal cognizant agency

Civil Rights Requirements

In addition to the nondiscrimination and Equal Employment Opportunity Plan (EEOP) requirements listed in the Certified Assurances, applicants must include in their application:

- Civil Rights contact person
- Title and address of contact person
- Telephone number of contact person
- Number of persons employed by the organizational unit responsible for administering the grant

The contact person will serve as liaison with the Office for Civil Rights, OJP.

Applicants who previously applied for and received block or formula grant funding from BJA and have an approved EEOP, need only submit a statistical update of the previously approved plan. The statistical update shall be for the preceding year. At a minimum, the update shall contain the requirements found at 28 CFR 42.304 (a), (b), (c) and (d), along with a narrative statement describing the progress made during the preceding year, remedial action(s) taken and the status and issues of all discrimination complaints filed against the applicant during that period.

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion

Executive Order 12549, Debarment and Suspension, 34 CFR Part 85, Section 85.510, Participants' Responsibilities, requires the grantee to obtain from each subgrantee applicant a *Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion.* Appendix C contains a copy of the Direct Recipient form which should be submitted by the state as part of the application. The Sub-Recipient form, also found in Appendix C, should be submitted to the state office as part of each subgrant application and should be kept on file by the State office.

Certification Regarding Drug-Free Workplace Requirements

Title V, Sec. 5153 of the Anti-Drug Abuse Act of 1988 requires all grantees of Federal funds, other than an individual, to certify to the granting agency that it will provide a drug free workplace. Appendix C contains the certification form. The drug-free workplace requirement applies to the direct grantees (e.g., Criminal Justice Planning Agency) and all recipient instrumentalities of the state (e.g., Corrections Departments).

State Legislature Review

As stated in the Act and the Certified Assurance, the application must be submitted for review to the state legislature or its designated body. The application must be submitted to the state legislature no later than the time of submission to BJA. BJA will not approve the use of funds until the state legislature or its designated body has reviewed the application or the 30-day review period has passed. A copy of the document which transmits the application to the state legislature should be included in the application submission packet.

Application Assurances

Many of the administrative requirements are met by the Chief Executive Officer of the state or his/her designee signing assurances regarding compliance. Documentation of compliance is retained by the state. A list of the assurances which must be signed and included in the application are found in Appendix C.

Statewide Strategy for Drug and Violent Crime Control

Each state is required to develop a statewide strategy to improve the functioning of the criminal justice system, with an emphasis on drug trafficking, violent crime and serious offenders. The strategy shall be prepared after consultation with state and local officials, particularly those whose duty it is to enforce drug and criminal laws and direct the administration of justice. The strategy should contain:

- A definition and analysis of the drug and violent crime problem in the state and an analysis of the problems in each of the counties and municipalities with major drug and violent crime problems.
- An assessment of the criminal justice resources being devoted to crime and drug control programs at the time of the application.
- A description of how the state is complying with coordination requirements, which should include a detailed description of the Federal LECC's role in assisting in the development of the statewide strategy.
- Identification of resource needs.
- The establishment of statewide priorities for crime and drug control activities and programs.
- An analysis of the relationship of the proposed state efforts to the *National Drug Control Strategy,* which should include a description of the state and local drug testing programs that include arrestees, prisoners, parolees, those out on bail, and others in the criminal justice system. The description should include an explanation of how drug test results are used in bail, sentencing, early release, probation, and parole decisions. If the state has not adopted comprehensive drug testing programs, information on timetables to do so should be provided.
- A plan for coordinating the programs to be funded under this program with other Federally funded programs, including state and local drug abuse education, treatment and prevention programs.

Programs to be Funded

Applications must set forth programs and projects which meet the purposes and criteria outlined in the Act. Sec. 506 (c) of the Act. Recommended program elements are highlighted on page 1. Since the Act identifies specific areas for funding, BJA deems some criminal justice system improvement programs as not appropriate for Federal funding (e.g., services for criminal defense and furlough programs for offenders who pose dangers to the community).

The application must designate which statutory purpose each program or project is intended to address and provide the name of the subgrantee, if known, and the estimated funding level for the program or project, including the amount and source of cash matching

funds. The application must also include a description of the program and how it contributes to the statewide drug strategy's implementation.

The application must contain a Program List which includes:

- The legislatively authorized purpose area
- The title of the program or project
- The implementation Agency
- The Federal amount allocated to the program or project
- The amount of the match
- The source of the match (state, local, or other)

The Program List must be followed by specific information on each program to be funded including: a description of the program, the statutory purpose it addresses, its objectives, the critical elements in the program design, the indicators which will be used to assess performance and how it contributes to the implementation of the statewide strategy.

BJA develops program briefs that describe programs which have been found, based on evaluation and research, to be effective in drug and violent crime control.

If a program/project identified for funding includes activities which partially fall outside of the purposes set forth in Sec. 501 of the Act, the applicant must describe the program/project and clearly delineate the percentage of the funded activity which will be involved with Sec. 501 purposes. The description, which should also follow the Program List, must indicate the prorated amount of costs being covered by the formula grant funds and contain an adequate justification.

Federal, State and Local Participation in Strategy Development

Section 503 (a)(1) of the Act requires that "the strategy shall be prepared after consultation with State and local officials with emphasis on those whose duty it is to enforce drug and criminal laws and direct the administration of justice. Section 503 (a)(1)(A) requires that the strategy contain "a definition and analysis of the drug and violent crime problem in the state, and an analysis of the problems in each of the counties and municipalities with major drug and violent crime problems." Section 506 (b)(2) requires that "in distributing funds received under this part among urban, rural and suburban units of local government and combinations thereof, the State shall give priority to those jurisdictions with the greatest need."

It is essential that Federal, state and local law enforcement, prosecutors, and other criminal justice personnel participate closely in developing the statewide drug strategy. State planning agencies should not draft the strategy and then submit the document for review, thereby depriving operational agencies from making substantive contributions at the beginning of the strategy development process. As noted above, states are also encouraged to contact and work with the Law Enforcement Coordinating Committee (LECC) of the United States Attorney(s) within the state. The LECC, which brings together Federal, state and local law enforcement and prosecutors, can serve as an important resource in the strategy development process.

Further, after completion, the applicant is encouraged to send a copy of the statewide strategy or a summary of the strategy to local governments, major operational agencies and LECCs. This should include an analysis of the areas of greatest need, the allocation of funds and the impact of the state strategy on areas with major drug problems.

Drug and Violent Crime Policy Board

Each state is strongly encouraged to establish a Drug and Violent Crime Policy Board to serve as a forum for communication and a structure for coordination. The Board should be responsible for the development of the state strategy and should facilitate coordination within the state. The Board members should include state and local officials and operational level representatives from all components of the criminal justice system (e.g., law enforcement, prosecution, courts and corrections), education and treatment.

The United States Attorney or the Chair of the Law Enforcement Coordinating Committee should also be included on the Board to facilitate coordination with Federal drug control efforts. Federal employees who serve as members of the Board should be non-voting members relative to state grant funding decisions.

The Board should be appointed by the Governor to establish its credibility as the Policy Board within the state and the importance of its mission. If a Board is established, the application for formula grant funds should include a description of the Board's roles, responsibilities, and activities and a list of Board members, their agency and level of government and the criminal justice function and/or other discipline (e.g., education or drug treatment) they represent. Payment of the costs associated with the operation of the Drug and Violent Crime Policy Board is an allowable use for the administrative funds.

Review of State Applications

45-Day Rule for BJA Review of Applications

BJA must approve or disapprove applications or amendments within 45 days of official receipt. Sec. 505 (b) of the Act. The application or amendment shall be considered approved unless BJA informs the applicant in writing of specific reasons for disapproval prior to the expiration of the 45-day period. Applications which are incomplete, as determined by BJA, shall not be considered officially received for purposes of the 45-day rule.

Rather than reject or return incomplete applications, BJA will notify the applicant that its application has been received and what needs to be accomplished for the application to be considered "complete" and, thus, officially received. Every effort will be made to notify states of any problems early in the review process. This procedure will allow a review of the submitted material to start. The 45-day review period will not commence until BJA has determined that the application is "complete". Any outstanding special conditions on formula grant awards from prior fiscal years must be satisfied before a new award will be made.

Written Notification and Reason for Disapproval

BJA shall notify the applicant in writing of the specific reasons for the disapproval of the application or amendment, in whole or in part. The applicant will be afforded an opportunity for reconsideration before a final determination of disapproval is made. Sec. 505 (d) of the Act.

Affirmative Finding

Prior to approval of the application or amendments, BJA must make an affirmative finding in writing that the program or project has been reviewed in accordance with the Act. Sec. 505 (a) (2) of the Act.

Appendix A

Authorized Program Areas

1. Demand reduction education programs in which law enforcement officers participate;
2. Multi-jurisdictional task force programs that integrate Federal, state and local drug law enforcement agencies and prosecutors for the purpose of enhancing interagency coordination and intelligence and facilitating multi-jurisdictional investigations;
3. Programs designed to target the domestic sources of controlled and illegal substances, such as precursor chemicals, diverted pharmaceuticals, clandestine laboratories and cannabis cultivations;

4. Providing community and neighborhood programs that assist citizens in preventing and controlling crime, including special programs that address the problems of crimes committed against the elderly and special programs for rural jurisdictions;

5. Disrupting illicit commerce in stolen goods and property;

6. Improving the investigation and prosecution of white-collar crime, organized crime, public corruption crimes and fraud against the government with priority attention to cases involving drug-related official corruption;

7. a. Improving the operational effectiveness of law enforcement through the use of crime analysis techniques, street sales enforcement, schoolyard violator programs, gang-related and low-income housing drug control programs;

b. Developing and implementing antiterrorism plans for deep draft ports, international airports and other important facilities;

8. Career criminal prosecution programs, including the development of model drug control legislation;

9. Financial investigative programs that target the identification of money laundering operations and assets obtained through illegal drug trafficking, including the development of proposed model legislation, financial investigative training and financial information sharing systems;

10. Improving the operational effectiveness of the court process, such as court delay reduction programs and enhancement programs;

11. Programs designed to provide additional public correctional resources and improve the corrections system, including treatment in prisons and jails, intensive supervision programs and long-range corrections and sentencing strategies;

12. Providing prison industry projects designed to place inmates in a realistic working and training environment which will enable them to acquire marketable skills and to make financial payments for restitution to their victims, for support of their own families and for support of themselves in the institution;

13. Providing programs which identify and meet the treatment needs of adult and juvenile drug-dependent and alcohol-dependent offenders;

14. Developing and implementing programs which provide assistance to jurors and witnesses and assistance (other than compensation) to victims of crime;

15. a. Developing programs to improve drug control technology, such as pretrial drug testing programs, programs which provide for the identification, assessment, referral to treatment, case management and monitoring of drug-dependent offenders and enhancement of state and local forensic laboratories;

b. Criminal justice information systems to assist law enforcement, prosecution, courts and corrections organizations (including automated fingerprint identification systems);

16. Innovative programs which demonstrate new and different approaches to enforcement, prosecution and adjudication of drug offenses and other serious crimes;

17. Addressing the problems of drug trafficking and the illegal manufacture of controlled substances in public housing;

18. Improving the criminal and juvenile justice system's response to domestic and family violence, including spouse abuse, child abuse and abuse of the elderly;

19. Drug control evaluation programs which state and local units of government may utilize to evaluate programs and projects directed at state drug control activities;

20. Providing alternatives to prevent detention, jail and prison for persons who pose no danger to the community; and

21. Programs of which the primary goal is to strengthen urban enforcement and prosecution efforts targeted at street drug sales.

Appendix B—Allocation of Funds

FORMULA GRANT PROGRAM ALLOCATION OF FUNDS

State	FY 1990 Estimated state allocations	Percentage to be passed through to local jurisdictions
Alabama	$6,593,000	51.28
Alaska	1,704,000	24.63
Arizona	5,755,000	61.23
Arkansas	4,260,000	57.78
California	39,676,000	64.37
Colorado	5,498,000	64.03
Connecticut	5,405,000	44.76
Delaware	1,890,000	28.47
District of Columbia	1,831,000	100.00
Florida	17,842,000	65.13
Georgia	9,653,000	58.16
Hawaii	2,488,000	47.09
Idaho	2,358,000	62.82
Illinois	16,857,000	66.51
Indiana	8,580,000	58.91
Iowa	4,860,000	46.27
Kansas	4,397,000	54.58
Kentucky	6,080,000	30.33
Louisiana	7,011,000	55.09
Maine	2,634,000	45.98
Maryland	7,303,000	43.14
Massachusetts	9,035,000	44.28
Michigan	13,613,000	57.43
Minnesota	6,873,000	70.93
Mississippi	4,568,000	57.17
Missouri	8,012,000	58.08
Montana	2,088,000	58.56
Nebraska	3,177,000	60.13
Nevada	2,428,000	61.93
New Hampshire	2,470,000	54.88
New Jersey	11,538,000	58.55
New Mexico	3,047,000	44.84
New York	25,459,000	64.53
North Carolina	9,854,000	39.31
North Dakota	1,899,000	60.24
Ohio	15,820,000	61.89

FORMULA GRANT PROGRAM ALLOCATION OF FUNDS—Continued

State	FY 1990 Estimated state allocations	Percentage to be passed through to local jurisdictions
Oklahoma	5,418,000	46.28
Oregon	4,769,000	49.38
Pennsylvania	17,366,000	67.76
Rhode Island	2,345,000	44.75
South Carolina	5,729,000	40.98
South Dakota	1,962,000	49.36
Tennessee	7,676,000	52.21
Texas	23,999,000	67.52
Utah	3,297,000	50.90
Vermont	1,749,000	28.20
Virginia	9,207,000	31.59
Washington	7,339,000	62.91
West Virginia	3,551,000	49.66
Wisconsin	7,622,000	67.39
Wyoming	1,642,000	55.41
Puerto Rico	5,485,000	0
Virgin Islands	1,129,000	0
American Samoa	717,570	0
Guam	1,169,000	0
N. Mariana Islands	353,430	0
	[1] 395,101,000	

[1] The estimated allocations assume enactment of the Budget Reconciliation Act, H.R. 3299, and of the Compact of Free Association with Palau, H.J. Res. 175.

Appendix C—Application Forms and Assurances

BILLING CODE 4410-01-M

OMB Approval No. 0348-0043

APPLICATION FOR FEDERAL ASSISTANCE

2. DATE SUBMITTED		Applicant Identifier
3. DATE RECEIVED BY STATE		State Application Identifier
4. DATE RECEIVED BY FEDERAL AGENCY		Federal Identifier

1. TYPE OF SUBMISSION:

Application	Preapplication
☐ Construction	☐ Construction
☐ Non-Construction	☐ Non-Construction

5. APPLICANT INFORMATION

Legal Name:	Organizational Unit:
Address (*give city, county, state, and zip code*):	Name and telephone number of the person to be contacted on matters involving this application (*give area code*)

6. EMPLOYER IDENTIFICATION NUMBER (EIN): ☐☐ – ☐☐☐☐☐☐☐

7. TYPE OF APPLICANT: (*enter appropriate letter in box*) ☐

A. State
B. County
C. Municipal
D. Township
E. Interstate
F. Intermunicipal
G. Special District
H. Independent School Dist.
I. State Controlled Institution of Higher Learning
J. Private University
K. Indian Tribe
L. Individual
M. Profit Organization
N. Other (Specify): _____

8. TYPE OF APPLICATION:

☐ New ☐ Continuation ☐ Revision

If Revision, enter appropriate letter(s) in box(es): ☐ ☐

A. Increase Award B. Decrease Award C. Increase Duration
D. Decrease Duration Other (*specify*):

_____

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: ☐☐ . ☐☐☐

TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. AREAS AFFECTED BY PROJECT (*cities, counties, states, etc.*):

13. PROPOSED PROJECT:		14. CONGRESSIONAL DISTRICTS OF:	
Start Date	Ending Date	a. Applicant	b. Project

15. ESTIMATED FUNDING:		
a. Federal	$	.00
b. Applicant	$	.00
c. State	$	.00
d. Local	$	.00
e. Other	$	.00
f. Program Income	$	.00
g. TOTAL	$	.00

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE _____

b. NO. ☐ PROGRAM IS NOT COVERED BY E.O. 12372

☐ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?

☐ Yes If "Yes," attach an explanation. ☐ No

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED

a. Typed Name of Authorized Representative	b. Title	c. Telephone number
d. Signature of Authorized Representative		e. Date Signed

Previous Editions Not Usable

Standard Form 424 (REV 4-88)
Prescribed by OMB Circular A-102

INSTRUCTIONS FOR THE SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item: Entry:

1. Self-explanatory.
2. Date application submitted to Federal agency (or State if applicable) & applicant's control number (if applicable).
3. State use only (if applicable).
4. If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.
5. Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.
6. Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.
7. Enter the appropriate letter in the space provided.
8. Check appropriate box and enter appropriate letter(s) in the space(s) provided:
   - "New" means a new assistance award.
   - "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.
   - "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation.
9. Name of Federal agency from which assistance is being requested with this application.
10. Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.
11. Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.

BILLING CODE 4410-01-C

Item: Entry:

12. List only the largest political entities affected (e.g., State, counties, cities).
13. Self-explanatory.
14. List the applicant's Congressional District and any District(s) affected by the program or project.
15. Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate *only* the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
16. Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.
17. This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
18. To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

Certified Assurances FY-1990—(Drug Control and System Improvement Formula Grant Program) FY-1990

(1) The applicant assures that Federal funds made available under this formula grant will not be used to supplant state or local funds but will be used to increase the amounts of such funds that would, in the absence of Federal funds, be made available for law enforcement activities.

(2) The applicant assures that matching funds required to pay the non-Federal portion of the cost of each program and project, for which grant funds are made available, shall be in addition to funds that would otherwise be made available for law enforcement by the recipients of grant funds and shall be provided on a project-by-project basis. (However, the state may request BJA to approve exceptions such as match on a program-by-program basis, statewide basis, unit of government basis or a combination of the above. The state must include any requests for approval of other than project-by-project match in its application to BJA).

(3) The applicant assures that the state application, and any amendment thereto, has been submitted for review to the state legislature or its designated body. (For purposes of this section, such application or amendment shall be deemed to be reviewed if the state legislature, or its designated body, does not review such application or amendment within the 30-day period beginning on the date such application or amendment is submitted thereto).

(4) The applicant assures that the state application and any amendment thereto are made public before submission to BJA and, to the extent provided under state law or established procedure, an opportunity to comment thereon was provided to citizens and to neighborhood and community groups.

(5) The applicant assures that following the first fiscal year covered by an application and each fiscal year thereafter, a performance evaluation and assessment report will be submitted to BJA.

(6) The applicant assures that fund accounting, auditing, monitoring, evaluation procedures and such records as BJA shall prescribe shall be provided to assure fiscal control, proper management and efficient disbursement of funds received.

(7) The applicant assures that it shall maintain such data and information and submit such reports in such form at such times and containing such data and information as BJA may reasonably require to administer the program.

(8) The applicant certifies that the programs contained in this application meet all the requirements of the Act and guidelines, that all information contained in the application is correct, that there has been appropriate coordination with affected agencies and that the applicant will comply with all provisions of the Act and all other applicable Federal laws, regulations and guidelines.

(9) The applicant assures that the state is undertaking initiatives to reduce, through the enactment of innovative penalties or increasing law enforcement efforts, the demand for controlled substances by holding accountable those who unlawfully possess or use such substances.

(10) The applicant assures that it will comply with Title V of the Anti-Drug Abuse Act of 1988 and regulations promulgated by the Federal Government to maintain a drug-free workplace.

(11) The applicant assures that it will comply, and all its subgrantees and contractors will comply, with the nondiscrimination requirements of the Omnibus Crime Control and Safe Streets Act of 1968, as amended; title VI of the Civil Rights Act of 1964; section 504 of the Rehabilitation Act of 1973, as amended; title IX of the Education Amendments of 1972; the Age Discrimination Act of 1975; the Department of Justice Nondiscrimination Regulations 28 CFR part 42, subparts C, D, E and G; and Executive Order 11246, as amended by Executive Order 11375, and their implementing regulations, 41 CFR part 60.1 *et seq.*, as applicable to construction contracts.

(12) The applicant assures that in the event a Federal or state court or administrative agency makes a finding of discrimination after a due process hearing on the grounds of race, color, religion, national origin or sex against a recipient of funds, the recipient will forward a copy of the finding to the Office for Civil Rights, OJP.

(13) The applicant assures that if required to formulate an Equal Employment Opportunity Program (EEOP), in accordance with 28 CFR 42.301 *et seq.*, it will maintain a current one on file. Further, the applicant will require every fund recipient required to formulate an EEOP, in accordance with the previously cited regulation, to submit a certification to the applicant that it has a current EEOP on file which meets the applicable requirements.

(14) The applicant assures that if required to maintain an EEOP and the applicant agency will directly utilize $500,000 or more in grant funds, it will submit a copy of the subject EEOP at the same time as the application submission, with the understanding that the statewide application for funds may not be awarded prior to approval of the applicant's EEOP by the Office for Civil Rights, OJP. Further, in those instances where a subgrantee is required to maintain an EEOP, the applicant will provide BJA a copy of said EEOP if the proposed subgrant is for $500,000 or more and not award a subgrant until the subgrantee's EEOP has been approved by the Office for Civil Rights, OJP.

(15) The applicant assures that it will comply with the provisions of OJP's M7100.1 Financial and Administrative Guide for Grants.

(16) The applicant assures that it will comply with the provisions of 28 CFR applicable to grants and cooperative agreement, including part II, Applicability of Office of Management and Budget Circulars; part 18, Administrative Review Procedures; part 20, Criminal Justice Information Systems; part 22, Confidentiality of Identifiable Research and Statistical Information Systems; part 23, Criminal Intelligence Systems Operating Policies; part 30, Intergovernmental Review of Department of Justice Programs and Activities; part 42, Nondiscrimination Equal Employment Opportunity Policies and Procedures; part 61, Procedures for Implementing the National Environmental Policy Act; and part 63, Floodplain Management and Wetland Protection Procedures.

(17) The grantee assures that it will submit for review and approval amendments to the application if as a result of compliance with Executive Order 12372, Intergovernmental Review of Federal Programs, and/or Sec. 503 (a)(5) of the Act Certified Assurance 4) comments are submitted to the grantee which the grantee feels are sufficiently valid to warrant such change.

Certification

I certify that the programs proposed in this application meet all the requirements of the Anti-Drug Abuse Act of 1988, Subtitle C—State and Local Narcotics Control and Justice Assistance Improvements of 1988, Pub. L. 100-690 (Nov. 18, 1988), that all the information presented is correct, that there has been appropriate coordination with affected agencies and that the application will comply with the provisions of the Act and all other Federal laws, regulations and guidelines. By appropriate language incorporated in each grant, subgrant or other document under which funds are to be disbursed, the undersigned shall assure the applicable conditions above apply to all recipients of assistance.

Authorized Official Date

BILLING CODE 4410-01-M

U.S. DEPARTMENT OF JUSTICE
OFFICE OF JUSTICE PROGRAMS
OFFICE OF THE COMPTROLLER

Certification Regarding Debarment, Suspension, and Other Responsibility Matters Primary Covered Transactions

(Direct Recipient)

_____
Application Number

This certification is required by the regulations implementing Executive Order 12549, Debarment and Suspension, 28 CFR Part 67, Section 67.510, Participants' responsibilities. The regulations were published as Part VII of the May 26, 1988 *Federal Register* (pages 19160-19211).

(BEFORE COMPLETING CERTIFICATION, READ INSTRUCTIONS ON REVERSE)

(1) The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals:

(a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;

(b) Have not within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(c) Are not presently indicted for or otherwise criminally or civilly charged by a government entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

(d) Have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State or local) terminated for cause or default.

(2) Where the prospective primary participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

_____
Name and Title of Authorized Representative

_____ _____
Signature Date

_____
Name and Address of Organization

Instructions for Certification

1. By signing and submitting this proposal, the prospective primary participant is providing the certification set out below.

2. The inability of a person to provide the certification required below will not necessarily result in denial of participation in this covered transaction. The prospective participant shall submit an explanation of why it cannot provide the certification set out below. The certification or explanation will be considered in connection with the department or agency's determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.

3. The certification in this clause is a material representation of fact upon which reliance was placed when the department or agency determined to enter into this transaction. If it is later determined that the prospective primary participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

4. The prospective primary participant shall provide immediate written notice to the department or agency to whom this proposal is submitted if at any time the prospective primary participant learns its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

5. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of the rules implementing Executive Order 12549.

6. The prospective primary participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency entering into this transaction.

7. The prospective primary participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions," provided by the department or agency entering into this covered transaction, without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

8. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may check the Nonprocurement List.

9. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

10. Except for transactions authorized under paragraph 6 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntary excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

U.S. DEPARTMENT OF JUSTICE
OFFICE OF JUSTICE PROGRAMS
OFFICE OF THE COMPTROLLER

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion Lower Tier Covered Transactions

(Sub-Recipient)

This certification is required by the regulations implementing Executive Order 12549, Debarment and Suspension, 28 CFR Part 67, Section 67.510, Participants' responsibilities. The regulations were published as Part VII of the May 26, 1988 *Federal Register* (pages 19160-19211).

(BEFORE COMPLETING CERTIFICATION, READ INSTRUCTIONS ON REVERSE)

(1) The prospective lower tier participant certifies, by submission of this proposal, that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.

(2) Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

Name and Title of Authorized Representative

Signature Date

Name of Organization

Address of Organization

OJP FORM 4061/1 (REV. 2/89) Previous editions are obsolete.

Instructions for Certification

1. By signing and submitting this proposal, the prospective lower tier participant is providing the certification set out below.

2. The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the prospective lower tier participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

3. The prospective lower tier participant shall provide immediate written notice to the person to which this proposal is submitted if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

4. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of rules implementing Executive Order 12549.

5. The prospective lower tier participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency with which this transaction originated.

6. The prospective lower tier participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions," without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

7. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may check the Nonprocurement List.

8. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

9. Except for transactions authorized under paragraph 5 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntary excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

U.S. DEPARTMENT OF JUSTICE
OFFICE OF JUSTICE PROGRAMS
OFFICE OF THE COMPTROLLER

Certification Regarding Drug-Free Workplace Requirements
Grantees Other Than Individuals

This certification is required by the regulations implementing the Drug-Free Workplace Act of 1988, 28 CFR Part 67, Subpart F. The regulations, published in the January 31, 1989 *Federal Register*, require certification by grantees, prior to award, that they will maintain a drug-free workplace. The certification set out below is a material representation of fact upon which reliance will be placed when the agency determines to award the grant. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or governmentwide suspension or debarment (see 28 CFR Part 67, Sections 67.615 and 67.620).

The grantee certifies that it will provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing a drug-free awareness program to inform employees about—
  (1) The dangers of drug abuse in the workplace;
  (2) The grantee's policy of maintaining a drug-free workplace;
  (3) Any available drug counseling, rehabilitation, and employee assistance programs; and
  (4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will—
  (1) Abide by the terms of the statement; and
  (2) Notify the employer of any criminal drug statute conviction for a violation occurring in the workplace no later than five days after such conviction;

(e) Notifying the agency within ten days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction;

(f) Taking one of the following actions, within 30 days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted—
  (1) Taking appropriate personnel action against such an employee, up to and including termination; or
  (2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

Place(s) of Performance: The grantee shall insert in the space provided below the site(s) for the performance of work done in connection with the specific grant (street address, city, county, state, zip code):

_____

_____

_____

_____ _____
Organization Name Application Number

_____
Name and Title of Authorized Representative

_____ _____
Signature Date

OJP FORM 4061/3 (2/89)

[FR Doc. 89-28961 Filed 12-11-89; 8:45 am]
BILLING CODE 4410-01-C

federal register

Tuesday
December 12, 1989

Part VI

Department of Health and Human Services

Food and Drug Administration

Advisory Committee Meeting

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

Meeting: The following advisory committee meeting is announced:

Oncologic Drugs Advisory Committee

Date, time, and place. December 14, 1989, 8:30 a.m., Ballroom, Holiday Inn, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open presentation of data, 9:30 a.m. to 10:30 a.m.; closed presentation of data, 10:30 a.m. to 12:30 p.m.; closed committee deliberations, 1:30 p.m. to 2:30 p.m.; open committee discussion, 2:30 p.m. to 3:30 p.m.; David F. Hersey, Center for Drug Evaluation and Research, Rm. 8B-45, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695.

General function of the committee: The committee reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in cancer.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before the meeting and submit of brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will evaluate a possible increased incidence of neurotoxicity with a high dose of a generic Ara-C (cytarabine).

Closed presentation of data. The committee will hear trade secret and/or confidential commercial information relevant to a generic drug product. This portio of the meeting will be closed to permit discussion of this informaiton (5 U.S.C. 552b(c)(4)).

Closed committee deliberations. The committee will review trade secret or confidential commerical information relevant to a generic drug product. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

FDA is giving less than 15 days public notice of this Oncologic Drugs Advisory Committee Meeting because of the serious nature of the problem and the need to determine, if possible, its cause and arrive at a solution. The next regularly scheduled meeting of the committee is February 1 and 2, 1990, and FDA did not believe it appropriate to wait that long. Attempts were made to schedule a meeting in later December so as to provide sufficient time for at least a 15-day public notice of the meeting. However, it was not possible to find a date on which a quorum of the members could meet. The agency decided that it was in the public interest to hold this scientific meeting on December 14, 1989, even if there was not sufficient time for the customary 15-day public notice.

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

Details on the agenda, questions to be addressed by the committee, and a current list of committee members are available from the contact person before and after the meeting. Transcripts of the open portion of the meeting will be available from the Freedom of Information Office (HFI-35), Food and Drug Administration, Rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting will be available from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner, with the concurrence of the Chief Counsel, has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a

clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure whould constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA as amended; and, notably deliberative sessions to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. App. I), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: December 8, 1989.

James S. Benson,

Acting Commissioner of Food and Drugs.

[FR Doc. 89-29150 Filed 12-11-89; 11:39 am]

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This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 523-6641. The text of laws is not published in the **Federal Register** but may be ordered in individual pamphlet form (referred to as "slip laws") from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone 202-275-3030).

H.R. 481/Pub. L. 101-199

To designate the building located at 2562 Hylan Boulevard, Staten Island, New York, as the "Walter Edward Grady United States Post Office Building". (Dec. 6, 1989; 103 Stat. 1793; 1 page) Price: $1.00

H.R. 3294/Pub. L. 101-200

To authorize distribution within the United States of the United States Information Agency film entitled "A Tribute to Mickey Leland". (Dec. 6, 1989; 103 Stat. 1794; 1 page) Price: $1.00

S. 892/Pub. L. 101-201

To exclude Agent Orange settlement payments from countable income and resources under Federal means-tested programs. (Dec. 6, 1989; 103 Stat. 1795; 1 page) Price: $1.00

S. 1960/Pub. L. 101-202

To authorize the food stamp portion of the Minnesota Family Investment Plan. (Dec. 6, 1989; 103 Stat. 1796; 9 pages) Price: $1.00