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[Two Sessions]

WHEN: March 12, 1996 at 9:00 am and March 26, 1996 at 9:00 am

WHERE: Office of the Federal Register Conference Room, 800 North Capitol Street, NW., Washington, DC (3 blocks north of Union Station Metro)

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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.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket 91–155–18]

Mediterranean Fruit Fly

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rules as final rule.

SUMMARY: We are adopting as a final rule, without change, the Mediterranean fruit fly regulations, as established and amended by a series of interim rules published in the Federal Register between November 1991 and August 1995. The regulations quarantine portions of California and restrict the interstate movement of regulated articles for those areas to help prevent the spread of the Mediterranean fruit fly into noninfested areas of the United States.

EFFECTIVE DATE: April 3, 1996.

FOR FURTHER INFORMATION CONTACT: Mr. Michael B. Stefan, Operations Officer, Domestic and Emergency Operations, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737–1236; (301) 734–8247.

SUPPLEMENTARY INFORMATION:

Background

The Mediterranean fruit fly, *Ceratitis capitata* (Wiedemann), is one of the world's most destructive pests of numerous fruits and vegetables. The Mediterranean fruit fly (Medfly) can cause serious economic losses. Heavy infestations can cause complete loss of crops, and losses of 25 to 50 percent are not uncommon. The short life cycle of this pest permits the rapid development of serious outbreaks.

In an interim rule effective November 5, 1991, and published in the Federal Register on November 13, 1991 (56 FR 57573–57579, Docket No. 91–155), we established the Mediterranean fruit fly (Medfly) regulations (7 CFR 301.78 through 301.78–10; referred to below as the regulations) and quarantined the Hancock Park area of Los Angeles County, CA. The regulations impose restrictions on the interstate movement of regulated articles from quarantined areas in order to prevent the spread of the Medfly to noninfested areas of the United States. We have published a series of interim rules amending these regulations by adding to or removing from the list of quarantined areas certain portions of Los Angeles, Santa Clara, Orange, Riverside, San Bernardino, San Diego, and Ventura Counties, CA, and by adding three treatments for fruit. Amendments affecting the quarantined areas in California were made effective on September 10 and November 12, 1992; and on January 19, July 16, August 3, September 15, October 8, November 22, and December 16, 1993; and on January 10, February 14, March 4, July 7, August 2, and October 12, 1994; and on August 1, 1995 (57 FR 42485–42486, Docket No. 91–155–2; 57 FR 54166–54169, Docket No. 91–155–3; 58 FR 6343–6346, Docket No. 91–155–4; 58 FR 39123–39124, Docket No. 91–155–5; 58 FR 42489–42491, Docket No. 91–155–6; 58 FR 49186–49190, Docket No. 91–155–7; 58 FR 53105–53109, Docket No. 91–155–8; 58 FR 63027–63031, Docket No. 91–155–9; 58 FR 67627–67630, Docket No. 91–155–10; 59 FR 2281–2283, Docket No. 91–155–11; 59 FR 7895–7896, Docket No. 91–155–12; 59 FR 11177–11180, Docket No. 91–155–13; 59 FR 35611–35612, Docket No. 91–155–14; 59 FR 40207–40209, Docket No. 91–155–15; and 59 FR 52405–52407, Docket No. 91–155–16; 60 FR 40053–40054, Docket No. 91–155–17).

Comments on these interim rules were required to be received on or before 60 days after the date of publication in the Federal Register. We did not receive any comments. The facts presented in the interim rules still provide a basis for these rules.

This action also affirms the information contained in the interim rules concerning Executive Orders 12291 and 12866 and Regulatory Flexibility Act, Executive Orders 12372 and 12778, and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived the review process required by Executive Order 12866.

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

PART 301—DOMESTIC QUARANTINE NOTICES

Accordingly, we are adopting as a final rule, without change, the regulations at 7 CFR 301.78 through 301.78–10, as amended by interim rules that were published at 56 FR 57573–57579 on November 13, 1991; 57 FR 42485–42486 on September 15, 1992; 57 FR 54166–54169 on November 17, 1992; 58 FR 6343–6346 on January 28, 1993; 58 FR 39123–39124 on July 22, 1993; 58 FR 42489–42491 on August 10, 1993; 58 FR 49186–49190 on September 22, 1993; 58 FR 53105–53109 on October 14, 1993; 58 FR 63027–63031 on November 30, 1993; 58 FR 67627–67630 on December 22, 1993; 59 FR 2281–2283 on January 14, 1994; 59 FR 7895–7896 on February 17, 1994; 59 FR 11177–11180 on March 10, 1994; 59 FR 35611–35612 on July 13, 1994; 59 FR 40207–40208 on August 8, 1994; and 59 FR 52405–52407 on October 18, 1994; 60 FR 40053–40054 on August 7, 1995.

Authority: 7 U.S.C. 150bb, 150dd, 150ee, 150ff, 161, 162, and 164–167; 7 CFR 2.22, 2.80, and 371.2(c).

Done in Washington, DC, this 26th day of February 1996.

Lonnie J. King,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–4951 Filed 3–1–96; 8:45 am]

BILLING CODE 3410–34–P

7 CFR Part 319

[Docket No. 93–119–2]

Importation of Citrus Fruits From Australia

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the Fruits and Vegetables regulations to allow oranges, lemons, limes, mandarins, and grapefruit from the Riverina and

Sunraysia districts of Australia to be imported into the United States. We are taking this action because we have determined that the citrus may be imported without presenting a significant risk of introducing injurious plant pests into the United States. This rule provides importers and consumers in the United States with an additional source of citrus fruit.

EFFECTIVE DATE: March 4, 1996.

FOR FURTHER INFORMATION CONTACT: Mr. Peter M. Grosser, Senior Operations Officer, Port Operations, PPQ, APHIS, 4700 River Road Unit 139, Riverdale, MD 20737–1236, (301) 734–8891.

SUPPLEMENTARY INFORMATION:

Background

The Fruits and Vegetables regulations in 7 CFR 319.56 through 319.56–8 (referred to below as ''the regulations'') prohibit or restrict the importation of fruits and vegetables to prevent the introduction and dissemination of injurious insects, including fruit flies, that are new to or not widely distributed in the United States. Paragraphs (e) and (f) of § 319.56–2 contain requirements for the importation of certain fruits and vegetables based on their origin in a definite area or district. The definite area or district must meet certain criteria, including criteria designed to ensure that the area or district is free from all or certain injurious insects. Section 319.56–2v contains provisions for importing citrus fruit from Australia.

On September 11, 1995, we published in the Federal Register (60 FR 47101–47103, Docket No. 93–119–1) a proposal to amend the regulations to allow oranges, lemons, limes, mandarins, and grapefruit from the Riverina and Sunraysia districts of Australia to be imported into the United States. We proposed to allow importation of the citrus fruit without cold treatment for fruit flies, provided that the districts remain free of fruit flies that attack citrus. If any such fruit flies were detected in the districts, we proposed to allow importation of the citrus fruit subject to the completion of an Animal and Plant Health Inspection Service authorized cold treatment and subject to all other applicable requirements of the regulations.

We solicited comments concerning our proposal for 30 days ending October 11, 1995. We received 12 comments by that date. They were from growers, packers, producers, shippers, grocery chains, and an independent distributor. Nine of the commenters completely supported the proposed rule. The remarks of the three remaining commenters are discussed below by topic. Two of the comments were on reciprocal trade agreements and were nearly identical.

Disease Risk

Comment: The proposed importation into the United States of citrus fruits from the Riverina and Sunraysia districts of Australia could introduce several serious citrus diseases, including Australian scab, citrus black spot, and diseases of the species *Guignardia,* into the United States. Disease surveys for these pathogens should be performed in the Riverina and Sunraysia districts of Australia prior to allowing citrus fruits from these districts to be imported into the United States. Additionally, provisions should be made for ongoing disease surveys in these districts before the proposed importation is allowed.

Response: We do not believe that citrus fruits from the Riverina and Sunraysia districts of Australia are likely to introduce serious diseases into the United States. Citrus black spot, *Guignardia citricarpa,* and Australian citrus scab, *Sphaceloma fawcetti* var. *scabiosa,* occur where abundant rainfall and a suitable temperature range favor development of infection, not in inland areas such as the arid, hot Riverina and Sunraysia districts. We do not believe that these pathogens could survive in the irrigated horticultural areas of the Riverina and Sunraysia districts. Additionally, no other species of *Guignardia* has been reported as the cause for a disease on citrus. These facts, plus the pest and disease monitoring system continuously maintained by the plant pest authorities in the Riverina and Sunraysia districts, convince us that the disease risk posed by citrus fruits from the Riverina and Sunraysia districts of Australia is insignificant. If either *Guignardia citricarpa* or *Sphaceloma fawcetti* var. *scabiosa* were detected in citrus fruits from the Riverina and Sunraysia districts of Australia, our importation program would cease immediately.

Reciprocal Trade Agreements

Comment: More than 3 years ago, Florida's citrus industry petitioned the Australian Quarantine and Inspection Service (AQIS) to allow Florida citrus fruits to be imported into Australia. AQIS should respond to Florida's petition before a decision is reached regarding the importation into the United States of citrus fruits from the Riverina and Sunraysia districts of Australia.

Response: Our proposal and decision to allow importation of citrus fruits from the Riverina and Sunraysia districts of Australia are based solely on whether these importations can be made without significant risk of pest introduction. We have no authority to base these decisions on the presence or absence of reciprocal arrangements.

Therefore, based on the rationale set forth in the proposed rule and in this document, we are adopting the provisions of the proposal as a final rule with a minor editorial change for clarity.

Effective Date

This is a substantive rule that 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 publication in the Federal Register.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

We are amending the Fruits and Vegetables regulations by allowing the importation of oranges, lemons, limes, mandarins, and grapefruit from the Riverina and Sunraysia districts of Australia.

According to a U.S. Department of Agriculture estimate, the total U.S. production of citrus fruits was approximately 11.172 million metric tons in 1992. Approximately 1.1 million metric tons of citrus fruits were exported from the United States in 1992, with about 9,741 metric tons exported to Australia.

According to an estimate offered by the Australian Office of the Counsellor, Australia produced approximately 592,000 metric tons of citrus fruits in 1992. Citrus production in Australia is oriented primarily to domestic consumption, with exports accounting for approximately 79,000 metric tons, or only about 13 percent of the total production, in 1992. Of the total quantity exported, 2,517 metric tons (about 3 percent) went to the United States.

The U.S. entities who will be most affected by this rule include citrus fruit producers, exporters, and importers. It is estimated that 93 percent of the U.S. farms that produce citrus fruit,

approximately 21,225 farms in all, qualify as small businesses. While this rule provides an additional supply of citrus fruit in the United States, domestic citrus fruit producers, including small entities, can expect a very insignificant decline in the price of citrus fruits. Due to the seasonal difference in availability, U.S. and Australian producers will not be in direct competition for the domestic citrus market. Both exporters and importers are expected to benefit from the rule. The projected benefit to exporters may accrue from the expanded export opportunities that may result from a favorable reciprocal trade treatment given by Australia. Importers may also benefit from the increased availability of citrus fruit, especially navel oranges, during the time of year when U.S. production is lowest. However, the economic benefits to importers and exporters are not expected to be significant.

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.

Executive Order 12778

This rule allows oranges, lemons, limes, mandarins, and grapefruit to be imported into the United States from the Riverina and Sunraysia districts of Australia. State and local laws and regulations regarding citrus fruit imported under this rule will be preempted while the fruit is in foreign commerce. Fresh citrus fruits are generally imported for immediate distribution and sale to the consuming public, and will remain in foreign commerce until sold to the ultimate consumer. The question of when foreign commerce ceases in other cases must be addressed on a case-by-case basis. No retroactive effect will be given to this rule, and this rule will not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*.).

List of Subjects in 7 CFR Part 319

Bees, Coffee, Cotton, Fruits, Honey, Imports, Incorporation by reference, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, 7 CFR part 319 is amended as follows:

PART 319—FOREIGN QUARANTINE NOTICES

1. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 150dd, 150ee, 150ff, 151–167, 450, 2803, and 2809; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.2(c).

2. Section 319.56–2v is revised to read as follows:

§ 319.56–2v Conditions governing the entry of citrus from Australia.

(a) The Administrator has determined that the irrigated horticultural areas within the following districts of Australia meet the criteria of § 319.56–2 (e) and (f) with regard to the Mediterranean fruit fly (*Ceratitis capitata* [Wiedemann]), the Queensland fruit fly (*Dacus tryoni* [Frogg]), and other fruit flies destructive of citrus:

(1) The Riverland district of South Australia, defined as the county of Hamley and the geographical subdivisions, called ''hundreds,'' of Bookpurnong, Cadell, Gordon, Holder, Katarapko, Loveday, Markaranka, Morook, Murtho, Parcoola, Paringa, Pooginook, Pyap, Stuart, and Waikerie;

(2) The Riverina district of New South Wales, defined as:

(i) The shire of Carrathool; and

(ii) The Murrumbidgee Irrigation Area, which is within the administrative boundaries of the city of Griffith and the shires of Leeton, Narrendera, and Murrumbidgee; and

(3) The Sunraysia district, defined as the shires of Wentworth and Balranald in New South Wales and the shires of Mildura, Swan Hill, Wakool, and Kerang, the cities of Mildura and Swan Hill, and the borough of Kerang in Victoria.

(b) Oranges (*Citrus sinensis* [Osbeck]); lemons (*C. limonia* [Osbeck] and *meyeri* [Tanaka]); limes (*C. aurantiifolia* [Swingle] and *latifolia* [Tanaka]); mandarins, including satsumas, tangerines, tangors, and other fruits grown from this species or its hybrids (*C. reticulata* [Blanco]); and grapefruit (*C. paradisi* [MacFad.]) may be imported from the Riverland, Riverina, and Sunraysia districts without treatment for fruit flies, subject to paragraph (c) of this section and all other applicable requirements of this subpart.

(c) If surveys conducted in accordance with § 319.56–2d(f) detect, in a district listed in paragraph (a) of this section, the Mediterranean fruit fly (*Ceratitis capitata* [Wiedemann]), the Queensland fruit fly (*Dacus tryoni* [Frogg]), or other fruit flies that attack citrus and for which a treatment is listed in the Plant Protection and Quarantine (PPQ) Treatment Manual, citrus fruit from that district will remain eligible for importation into the United States in accordance with § 319.56–2(e)(2), provided the fruit undergoes cold treatment in accordance with the PPQ Treatment Manual, which is incorporated by reference at § 300.1 of this chapter, and provided the fruit meets all other applicable requirements of this subpart. Entry is limited to ports listed in § 319.56–2d(b)(1) of this subpart if the treatment is to be completed in the United States. Entry may be through any port if the treatment has been completed in Australia or in transit to the United States. If no approved treatment for the detected fruit fly appears in the PPQ Treatment Manual, importation of citrus from the affected district or districts is prohibited.

Done in Washington, DC, this 28th day of February 1996.

Lonnie J. King,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–4952 Filed 3–1–96; 8:45 am]

BILLING CODE 3410–34–P

Commodity Credit Corporation

7 CFR Parts 1487, 1491, 1492 and 1495

Regulatory Reform Initiative

AGENCY: Commodity Credit Corporation (CCC), USDA.

ACTION: Final rule.

SUMMARY: In response to the President's Regulatory Reform Initiative, the Commodity Credit Corporation is issuing this final rule to amend its regulations to eliminate the following programs: Noncommercial Risk Assurance Program (GSM–101); CCC Intermediate Credit Export Sales Program for Breeding Animals (GSM–201); CCC Intermediate Credit Export Sales Program for Foreign Market Development Facilities (GSM–301); and Disposition of Agricultural Commodities under the CCC Barter Program (Barter Program). These programs are inactive or obsolete and have not been used in 15 years or more.

EFFECTIVE DATE: April 3, 1996.

FOR FURTHER INFORMATION CONTACT: L.T. McElvain, Director, CCC Operations Division, Foreign Agricultural Service, U.S. Department of Agriculture, AG Box 1035, Washington D.C., 20250–1035; Fax (202) 720–2949; Telephone (202) 720–6211. The U.S. Department of Agriculture (USDA) prohibits

discrimination in its programs on the basis of race, color, national origin, sex, religion, age, disability, political beliefs and marital or familial status. Persons with disabilities who require alternative means for communication of program information (braille, large print, audiotape, etc.) should contact the USDA Office of Communications at (202) 720–5881 (voice) or (202) 720–7808 (TDD).

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This final rule is issued in conformance with Executive Order 12866. It has been determined to be neither significant nor economically significant for the purposes of E.O. 12866 and, therefore, has not been reviewed by the Office of Management and Budget (OMB).

Regulatory Flexibility Act

It has been determined that the Regulatory Flexibility Act is not applicable to this final rule since CCC is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of rulemaking with respect to the subject matter of this rule.

Executive Order 12372

These programs are not subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. See notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115 (June 24, 1983).

Environmental Evaluation

It has been determined by an environmental evaluation that this action will not have a significant impact on the quality of the human environment. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

Paperwork Reduction Act

The amendment to 7 CFR parts 1487, 1491, 1492 and 1495 set forth in this final rule does not contain information collections that require clearance by the OMB under the provisions of 44 U.S.C. 35.

Executive Order 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. The final rule would not have preemptive effect with respect to any state or local laws, regulations, or policies which conflict with such provisions or which otherwise impede their full implementation. The rule would not have retroactive effect.

The Department of Agriculture is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion permits, the Department actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome, and are easy for the public to understand, use or comply with. In short, the Department is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations.

Background

CCC published a proposed rule in the Federal Register on December 13, 1995, in response to the President's Regulatory Reform Initiative, that would amend Title 7 of the Code of Federal Regulations to remove the following parts:

- Part 1487—Noncommercial Risk Assurance Program (GSM–101);
- Part 1491—CCC Intermediate Credit Export Sales Program for Breeding Animals (GSM–201);
- Part 1492—CCC Intermediate Credit Export Sales Program for Foreign Market Development Facilities (GSM–301); and
- Part 1495—Disposition of Agricultural Commodities under the CCC Barter Program (Barter Program).

Reasons for Removal

CCC proposed to remove these parts for the following reasons:

- GSM–101—This risk assurance program, implemented in 1979, covered only non-commercial or political risk and became obsolete when the CCC Export Credit Guarantee Program (GSM–102) was introduced in 1980 to cover political and commercial risk. The GSM–101 program was last used in 1981.
- GSM–201—This direct credit program has been used only once (a transaction for livestock exports to Spain in 1979). The terms available under the program—3 to 10 year direct credits—could be made available under a modified GSM–5 Program (7 CFR Part 1488) Financing of Sales of Agricultural Commodities Program.
- GSM–301—This direct credit program was intended to facilitate commodity exports which would be sold to generate funds to finance the construction of a market development project. The program was used only once (in connection with a bulk grain discharge and storage facility developed at Ashdod, Israel). That project began in 1978 and was completed in the early 1980's. For a number of years, funding has not been made available for this program.
- Barter Program—From 1950 through 1973, CCC exchanged CCC-owned agricultural commodities for strategic and critical materials for the National Defense Stockpile. The program could also be used to obtain foreign-produced supplies and services used in Department of Defense construction projects and Agency for International Development projects. The program was terminated in 1973 when CCC stocks were depleted. The National Defense Stockpile is now liquidating many strategic materials. Also, CCC has authority, which it has at times used, to enter into direct barter arrangements under the CCC Charter Act in order to obtain strategic materials for defense stock piles.

Comments

The deadline for submitting comments on the proposed rule was January 12, 1996. CCC did not receive any comments on this proposed rule. CCC has determined to make the changes to 7 CFR Part 1487, Part 1491, Part 1492, and Part 1495 as proposed.

List of Subjects

7 CFR Part 1487

Agricultural commodities, Exports, Insurance, Reporting and recordkeeping requirements.

7 CFR Part 1491 and 1492

Exports, Livestock, Loan programs—agriculture, Reporting and recordkeeping requirements.

7 CFR Part 1495

Agricultural commodities, Exports, Government procurement, Strategic and critical materials.

PARTS 1487, 1491, 1492, 1495—[REMOVED]

For the reasons set out in the preamble under the authority at 5 U.S.C. Section 552(a)(1)(E), 7 CFR Chapter XIV is amended by removing and reserving parts 1487, 1491, 1492 and 1495.

Signed at Washington, DC, on February 27, 1996.

Christopher E. Goldthwait,

General Sales Manager and Vice President, Commodity Credit Corporation.

[FR Doc. 96–4953 Filed 3–1–96; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 95–NM–118–AD; Amendment 39–9525; AD 96–05–01]

Airworthiness Directives; McDonnell Douglas Model DC–9–80 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain McDonnell Douglas Model DC–9–80 series airplanes, that currently requires inspection and replacement of certain suspect horizontal stabilizer primary trim motors. That AD was prompted by an analysis which revealed that certain incorrectly manufactured motor shafts could fail prematurely and, in turn, cause the primary trim motor to fail. The actions specified in that AD are intended to prevent such failures of the primary trim motor, which could ultimately result in reduced controllability of the airplane. This amendment expands the applicability of the existing AD to include additional affected airplanes.

DATES: Effective April 3, 1996.

The incorporation by reference of certain other publications listed in the regulations is approved by the Director of the Federal Register as of April 3, 1996.

The incorporation by reference of McDonnell Douglas MD–80 Alert Service Bulletin A27–342, dated August 4, 1994, was approved previously by the Director of the Federal Register as of April 3, 1996 (60 FR 15034, March 22, 1995).

ADDRESSES: The service information referenced in this AD may be obtained from McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Department C1–L51 (2–60); or from Sundstrand Aerospace, 4747 Harrison Avenue, P.O. Box 7002, Rockford, Illinois 61125–7002. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Walter Eierman, Aerospace Engineer, Systems and Equipment Branch, ANM–130L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712; telephone (310) 627–5336; fax (310) 627–5210.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 95–06–04, amendment 39–9174 (60 FR 15034, March 22, 1995), which is applicable to McDonnell Douglas Model DC–9–80 series airplanes, was published in the Federal Register on September 26, 1995 (60 FR 49525). That action proposed to continue to require the current inspections and replacement of certain suspect horizontal stabilizer primary trim motors. That action also proposed to expand the applicability of the current AD to include additional affected airplanes.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Three commenters support the proposal.

One commenter requests that the proposal be revised to allow operators to conduct a records search, rather than a visual inspection, to determine if the subject motor is installed on the airplane. This commenter, an operator of affected airplanes, states that it tracks the subject motors by the manufacturer's serial number, which enables it to identify quickly the location of any of the subject motors at any given time. Therefore, the commenter considers that, in lieu of requiring it (and possibly other operators) to apply for an alternative method of compliance with the AD, the final rule should provide for this alternative action.

The FAA concurs with the commenter's request. The final rule has been revised to provide for the option of conducting a records search to determine if the motor installed on the airplane is identified with one of the suspect serial numbers.

Two commenters request that the proposed AD be revised to preclude operators from having to reinspect for units that were previously modified and re-identified (i.e., in accordance with Sundstrand Service Bulletin 9590–27–012). One of these commenters points out that these units require an overhaul every 3,500 hours; at that time they are removed from the airplane and, after overhaul, may be installed on a different airplane or placed in spare status (pending installation on another airplane). One commenter points out that the proposed AD does not take into account the situation where a unit originally installed on an airplane subject to AD 95–06–04 may be removed from that airplane and later installed on another airplane that is subject to the proposed AD. If this situation occurs, the commenter is concerned that operators will be required to duplicate inspections and other actions unnecessarily.

The FAA concurs that some clarification is necessary. As for motors modified (and re-identified) in accordance with Sundstrand Service Bulletin 9590–27–012, the final rule allows for their installation on airplanes that are subject to either AD 95–06–04 or this new AD. If a modified unit is installed on any of these airplanes no further action, including any duplicating ''re-identification,'' is required by the AD. In order to make this eminently clear, the FAA has revised paragraphs (a) and (b) of the final rule to specify that, if the trim motor installed on the airplane has been modified previously in accordance with the applicable Sundstrand service bulletin, no further action is required.

As for the possibility of suspect units being installed as spares, the FAA is not certain that this possibility would occur, since the FAA has been advised that apparently all motors affected by AD 95–06–04 have been modified. However, the FAA has added paragraph (c) to the final rule to preclude the future installation, on any airplane, of a motor having one of the suspect serial numbers.

As for duplicating inspections, as discussed above, the FAA has revised the final rule to allow operators to conduct a records search, in lieu of a visual inspection, to determine if the suspect motor is installed. A records search would expedite the determination as to whether or not a suspect unit is installed; it would also be far less expensive to accomplish than a visual inspection of the airplane.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes previously described. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

There are approximately 142 Model DC–9–80 series airplanes of the affected design in the worldwide fleet. The FAA estimates that a total of 73 airplanes of

U.S. registry will be affected by this proposed AD.

The inspection of the horizontal stabilizer primary trim motor is expected to take approximately 1 work hour per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of this requirement is estimated to be $60 per airplane.

The inspection specified in this rule previously was required by AD 95–06–04, which was applicable to approximately 13 U.S.-registered airplanes. Based on the figures discussed above, the cost impact of the current inspection requirements of that AD on U.S. operators of those 13 airplanes is estimated to be $780. In consideration of the compliance time and effective date of AD 95–06–04, the FAA assumes that the operators of the 13 airplanes subject to that AD have already initiated the required actions. This new AD action will add no new costs associated with those airplanes.

This new AD is applicable to approximately 60 additional airplanes. Based on the figures discussed above, the new (inspection) costs to U.S. operators that will be imposed by this new AD are estimated to be $3,600. This figure is based on assumptions that no operator of these additional airplanes has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Should an operator elect to replace a suspect motor, that action will require 5 work hours to accomplish, at an average labor rate of $60 per work hour. Required parts will be provided by Sundstrand Electric Power Systems (the manufacturer of the horizontal stabilizer primary trim motors) at no charge to operators. Based on these figures, the cost impact on U.S. operators for the replacement of a suspect motor is estimated to be $300 per airplane.

Should an operator elect to modify a suspect motor, that action will require 4 work hours to disassemble, modify, reassemble, and test the motor (excluding removal and reinstallation of the motor from the airplane). The average labor rate is $60 per work hour. Required parts will be provided by Sundstrand at no charge to operators. Based on these figures, the cost impact on U.S. operators for the modification of a suspect motor is estimated to be $240 per airplane.

The regulations adopted herein will 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.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) 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. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–9174 (60 FR 15034, March 22, 1995), and by adding a new airworthiness directive (AD), amendment 39–9525, to read as follows:

96–05–01 McDonnell Douglas: Amendment 39–9525. Docket 95–NM–118–AD. Supersedes AD 95–06–04, Amendment 39–9174.

Applicability: Model DC–9–80 series airplanes; as listed in McDonnell Douglas MD–80 Alert Service Bulletin A27–342, dated August 4, 1994, and in McDonnell Douglas MD–80 Alert Service Bulletin A27–342, Revision 1, dated May 15, 1995; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

Note 2: Paragraph (a) of this AD merely restates the requirements of paragraph (a) of AD 95–06–04, amendment 39–9174. As allowed by the phrase, ''unless accomplished previously,'' if those requirements of AD 95–06–04 have already been accomplished, this AD does not require that those actions be repeated.

To prevent failure of the horizontal stabilizer primary trim motor, accomplish the following:

(a) For airplanes listed in McDonnell Douglas MD–80 Alert Service Bulletin A27–342, dated August 4, 1994: Within 6 months after April 21, 1995 (the effective date of AD 95–06–04, amendment 39–9174), conduct either a visual inspection of the horizontal stabilizer primary trim motor or a records search to determine if the motor is identified with one of the suspect serial numbers listed in McDonnell Douglas MD–80 Alert Service Bulletin A27–342, dated August 4, 1994, or Revision 1, dated May 15, 1995. If a visual inspection is conducted, it must be performed in accordance with the procedures specified in the service bulletin.

(1) If the horizontal stabilizer primary trim motor is not identified with a suspect serial number; or if the horizontal stabilizer primary trim motor has been modified previously in accordance with Sundstrand Service Bulletin 9590–27–012, dated August 8, 1995; no further action is required by this AD.

(2) If the horizontal stabilizer primary trim motor is identified with a suspect serial number and has not been modified previously in accordance with Sundstrand Service Bulletin 9590–27–012, dated August 8, 1995; prior to further flight, accomplish either paragraph (a)(2)(i) or (a)(2)(ii) of this AD.

(i) Replace the motor in accordance with the McDonnell Douglas alert service bulletin. Or

(ii) Modify the motor in accordance with Sundstrand Service Bulletin 9590–27–012, dated August 8, 1995; and install the modified motor in accordance with the McDonnell Douglas alert service bulletin.

(b) For airplanes listed in McDonnell Douglas MD–80 Alert Service Bulletin A27–342, Revision 1, dated May 15, 1995, and not subject to paragraph (a) of this AD: Within 6 months after the effective date of this AD, conduct either a visual inspection of the horizontal stabilizer primary trim motor or a records search to determine if the motor is identified with one of the suspect serial numbers listed in McDonnell Douglas MD–80 Alert Service Bulletin A27–342, Revision 1, dated May 15, 1995. If a visual inspection is conducted, it must be performed in accordance with the procedures specified in that service bulletin.

(1) If the horizontal stabilizer primary trim motor is not identified with a suspect serial number; or if the horizontal stabilizer primary trim motor has been modified previously in accordance with Sundstrand Service Bulletin 9590–27–012, dated August 8, 1995; no further action is required by this AD.

(2) If the horizontal stabilizer primary trim motor is identified with a suspect serial number and has not been modified previously in accordance with Sundstrand Service Bulletin 9590–27–012, dated August 8, 1995; prior to further flight, accomplish either paragraph (b)(2)(i) or (b)(2)(ii) of this AD.

(i) Replace the motor in accordance with the McDonnell Douglas alert service bulletin. Or

(ii) Modify the motor in accordance with Sundstrand Service Bulletin 9590–27–012, dated August 8, 1995; and install the modified motor in accordance with the McDonnell Douglas alert service bulletin.

(c) As of six months after the effective date of this AD, no person shall install, on any airplane, a horizontal stabilizer primary trim motor identified with one of the suspect serial numbers listed in McDonnell Douglas MD–80 Alert Service Bulletin A27–342, dated August 4, 1994, or Revision 1, dated May 15, 1995; unless that motor has been modified in accordance with Sundstrand Service Bulletin 9590–27–012, dated August 8, 1995.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(f) The inspection and replacement shall be done in accordance with McDonnell Douglas MD–80 Alert Service Bulletin A27–342, dated August 4, 1994; and McDonnell Douglas MD–80 Alert Service Bulletin A27–342, Revision 1, dated May 15, 1995, which contains the following list of effective pages:

Page No.	Revision level shown on page	Date shown on page
1–5, 7–10	1	May 15, 1995.
6	Original	Aug. 4, 1994.

The modification shall be done in accordance with Sundstrand Service Bulletin 9590–27–012, dated August 8, 1995. The incorporation by reference of McDonnell Douglas MD–80 Alert Service Bulletin A27–342, dated August 4, 1994, was approved previously by the Director of the Federal Register, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, as of April 21, 1995 (60 FR 15034, March 22, 1995). The incorporation by reference of McDonnell Douglas MD–80 Alert Service Bulletin A27–342, Revision 1, dated May 15, 1995; and Sundstrand Service Bulletin 9590–27–012, dated August 8, 1995; was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Department C1–L51 (2–60); or from Sundstrand Aerospace, 4747 Harrison Avenue, P.O. Box 7002, Rockford, Illinois 61125–7002. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(g) This amendment becomes effective on April 3, 1996.

Issued in Renton, Washington, on February 22, 1996.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–4508 Filed 3–1–96; 8:45 am]

BILLING CODE 4910–13–U

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14 CFR Part 39

[Docket No. 94–NM–122–AD; Amendment 39–9527; AD 96–05–02]

Airworthiness Directives; Fokker Model F28 Mark 0100 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Fokker Model F28 Mark 0100 series airplanes, that requires modification of a certain galley; repetitive inspections to detect damage and to determine the clearance of generator wires in the auxiliary power unit (APU); and repair or replacement of the damaged wires. This amendment is prompted by reports indicating that, during an unscheduled removal of a galley from the production line, the insulation of one of the generator wires of the APU was found damaged due to inadequate clearance with the adjacent structure. The actions specified by this AD are intended to prevent such damage, which could result in a short in the electrical wiring of the APU and, thus, pose a potential fire hazard.

DATES: Effective April 3, 1996.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of April 3, 1996.

ADDRESSES: The service information referenced in this AD may be obtained from Fokker Aircraft USA, Inc., 1199 North Fairfax Street, Alexandria, Virginia 22314. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tim Dulin, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (206) 227–2141; fax (206) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Fokker Model F28 Mark 0100 series airplanes was published in the Federal Register on December 9, 1994 (59 FR 236). That action proposed to require modification of a Nordskog Galley Model 1–871galley. It also proposed to require repetitive inspections to detect damage and determine the clearance of generator wires in the auxiliary power unit (APU); and repair or replacement of the damaged wires.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the single comment received.

The commenter requests that the rule be revised to delete proposed paragraph (a)(2)(i), which would require operators to conduct repetitive inspections if the initial inspection shows that no damage to the feeder cables exists and that the cables adequately clear the adjacent structure. This commenter, an operator, states that it has conducted a boroscope inspection of the APU generator cables on all of its airplanes, and has found nothing anywhere near the cables that could cause damage to them. This operator notes that its initial inspection, which was conducted using a flexible boroscope from the cockpit, provided an excellent view of both the cables and the drain enclosure. The inspection revealed that there is a clearance between the wiring and adjacent structure (drain screws) on the order of six inches.

The FAA concurs with the commenter's request. According to the Rijksluchtvaartdienst (RLD), which is the airworthiness authority for the Netherlands, the clearance between the drain screws and the APU feeder cable (generator wires) found on airplanes on the production line was on the order of one inch. This amount of clearance was considered to be inadequate, such that chafing or damage of the wire installation could occur. Also, according to the RLD, the reason that the referenced service bulletin specifies that the inspection be accomplished with a mirror is because the manufacturer considered that a mirror would give a better estimate of the clearance than could a boroscope inspection. However, the FAA, in consultation with the RLD, recently has concluded that, since the clearance between the drain screws and the wires has been determined to be on the order of 6 inches on all affected airplanes that have not already been modified in accordance with this AD, there is little reason to believe that chafing would occur. In light of this, the FAA finds that there is no need for a repetitive inspection of the wires. Therefore, the FAA has revised paragraph (a)(2)(i) of the final rule to indicate that, if no wires are found damaged as a result of the inspection and they adequately clear the adjacent structure (positive clearance), no further inspections are required.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the change previously described. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

The FAA estimates that 52 airplanes of U.S. registry will be affected by this proposed AD, that it will take approximately 2 work hours per airplane to accomplish the required actions, and that the average labor rate is $60 per work hour. Required parts will cost approximately $1,000 per airplane. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $58,240, or $1,120 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

The regulations adopted herein will 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.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) 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. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

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

96–05–02 Fokker: Amendment 39–9527. Docket 94–NM–122–AD.

Applicability: Model F28 Mark 0100 series airplanes; as listed in Fokker Service Bulletin SBF100–24–029, dated June 28, 1993; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent a short in the electrical wiring of the auxiliary power unit (APU) and a potential fire hazard, accomplish the following:

(a) Within 250 flight hours after the effective date of this AD, accomplish paragraphs (a)(1) and (a)(2) of this AD.

(1) Modify Nordskog Galley Model 1–871, in accordance with paragraphs 2.A., 2.B., and 2.C. of the Accomplishment Instructions of Fokker Service Bulletin SBF100–24–029, dated June 28, 1993.

(2) Perform an inspection to detect damage of and to determine the adequacy of clearance of the generator wires, having part numbers (P/N) AJC0001A, AJ0001B, and AJC0001C, of the auxiliary power unit (APU), in accordance with Fokker Service Bulletin SBF100–24–029, dated June 28, 1993.

(i) If no wires are found damaged and they adequately clear the adjacent structure (positive clearance), no further action is required by this paragraph.

(ii) If no wires are found damaged, but they do not adequately clear the adjacent structure, repeat the inspection thereafter at intervals not to exceed 250 flight hours.

(iii) If any wire is found damaged, prior to further flight, modify the Nordskog Galley Model 1–871 in accordance with paragraph (b) of this AD, and repair or replace the damaged wire in accordance with the service bulletin. However, the modification and repair/replacement actions may be postponed for a maximum of 10 days after detection of the damage, provided that the APU generator is rendered inoperative in accordance with the Master Minimum Equipment List (MMEL), and that modification and repair/replacement actions are accomplished prior to reactivation of the APU generator.

(b) At the next removal of the Nordskog Galley Model 1–871, or within 9,000 flight hours after the effective date of this AD, whichever occurs first, modify the Nordskog Galley in accordance with Fokker Service Bulletin SBF100–24–029 (reference Nordskog Engineering Change Order 43589 Attachment), dated June 28, 1993. Accomplishment of this modification constitutes terminating action for the repetitive inspection requirements of this AD.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(e) The actions shall be done in accordance with Fokker Service Bulletin SBF100–24–029, dated June 28, 1993, including Nordskog Engineering Change Order 43589 Attachment. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Fokker Aircraft USA, Inc., 1199 North Fairfax Street, Alexandria, Virginia 22314. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on April 3, 1996.

Issued in Renton, Washington, on February 23, 1996.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–4669 Filed 3–1–96; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 157

[Docket No. RM81–19–000]

Project Cost and Annual Limits

Issued: February 27, 1996.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule.

SUMMARY: Pursuant to the authority delegated by 18 CFR 375.307(e)(1), the Director of the Office of Pipeline Regulation computes and publishes the project cost and annual limits specified in Table I of § 157.208(d) and Table II of § 157.215(a) for each calendar year.

EFFECTIVE DATE: January 1, 1996.

FOR FURTHER INFORMATION CONTACT: Michael J. McGehee, Division of Pipeline Certificates, OPR, (202) 208–2257.

SUPPLEMENTARY INFORMATION:

Order of the Director, OPR

Section 157.208(d) of the Commission's Regulations provides for project cost limits applicable to construction, acquisition, operation and miscellaneous rearrangement of facilities (Table I) authorized under the blanket certificate procedure (Order No. 234, 19 FERC ¶ 61,216). Section 157.215(a) specifies the calendar year dollar limit which may be expended on underground storage testing and development (Table II) authorized under the blanket certificate. Section 157.208(d) requires that the ''limits specified in Tables I and II shall be adjusted each calendar year to reflect the 'GNP implicit price deflator' published by the Department of Commerce for the previous calendar year.''

Pursuant to § 375.307(e)(1) of the Commission's Regulations, the authority for the publication of such cost limits, as adjusted for inflation, is delegated to the Director of the Office of Pipeline Regulation. The cost limits for calendar years 1982 through 1996, as published in Table I of § 157.208(d) and Table II of § 157.215(a), are hereby issued.

Note that these inflation adjustments are based on the Gross Domestic Product (GDP) Implicit Price Deflator, and include the Commerce Department's estimated fourth quarter GDP Implicit Price Deflator rather than the annual GDP Implicit Price Deflator or Gross National Product (GNP) Implicit Price Deflator, which are not yet available for 1995. The Commerce Department advises that in recent years the annual change has been virtually the same for both indices. Further adjustments will be made, if necessary.

List of Subjects in 18 CFR Part 157

Natural Gas.

Kevin P. Madden,

Director, Office of Pipeline Regulation.

Accordingly, 18 CFR Part 157 is amended as follows:

PART 157—[AMENDED]

1. The authority citation for Part 157 continues to read as follows:

Authority: 15 U.S.C. 717–717w, 3301–3432; 42 U.S.C. 7101–7352.

§ 157.208 [Amended]

2. Table I in § 157.208(d) is revised to read as follows:

TABLE I

Year	Limit	
	Auto. proj. cost limit (col. 1)	Prior notice pro. cost limit (col. 2)
1982	$4,200,000	$12,000,000
1983	4,500,000	12,800,000
1984	4,700,000	13,300,000
1985	4,900,000	13,800,000
1986	5,100,000	14,300,000
1987	5,200,000	14,700,000
1988	5,400,000	15,100,000
1989	5,600,000	15,600,000
1990	5,800,000	16,000,000

TABLE I—Continued

Year	Limit	
	Auto. proj. cost limit (col. 1)	Prior notice pro. cost limit (col. 2)
1991	6,000,000	16,700,000
1992	6,200,000	17,300,000
1993	6,400,000	17,700,000
1994	6,600,000	18,100,000
1995	6,700,000	18,400,000
1996	6,900,000	18,800,000

§ 157.215 [Amended]

3. Table II in § 157.215(a) is revised to read as follows:

TABLE II

Year	Limit
1982	$2,700,000
1983	2,900,000
1984	3,000,000
1985	3,100,000
1986	3,200,000
1987	3,300,000
1988	3,400,000
1989	3,500,000
1990	3,600,000
1991	3,800,000
1992	3,900,000
1993	4,000,000
1994	4,100,000
1995	4,200,000
1996	4,300,000

[FR Doc. 96–4925 Filed 3–1–96; 8:45 am]

BILLING CODE 6717–01–M

RAILROAD RETIREMENT BOARD

20 CFR Part 368

RIN 3220–AB20

Prohibition of Cigarette Sales to Minors

AGENCY: Railroad Retirement Board.

ACTION: Interim final rule.

SUMMARY: The Railroad Retirement Board (Board) adds regulations to implement the Prohibition of Cigarette Sales to Minors in Federal Buildings and Lands Act which prohibits the sale of tobacco through vending machines and the distribution of free tobacco samples on Federal property.

DATES: *Effective Date:* This regulation will be effective March 4, 1996.

Comment Date: Comments due on or before April 3, 1996.

ADDRESSES: Comments may be mailed to the Secretary to the Board, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611.

FOR FURTHER INFORMATION CONTACT: Thomas W. Sadler, Assistant General

Counsel, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611, telephone (312) 751–4513, TTD (312) 751–4701.

SUPPLEMENTARY INFORMATION: The Board conducts its business in real property owned or leased by the General Services Administration. All property occupied or reserved for Board use must comply with Public Law 104–52. Tobacco products may not be sold in vending machines and free samples of tobacco products may not be distributed in or around property occupied and maintained by the Board. The Board will permit the sale of tobacco products to individuals 18 and older by staffed concession stands on property occupied and maintained by the Board.

Because of the importance of the subject matter of this rule, the Board is publishing it as an interim final rule rather than as a proposed rule. However, any person wishing to comment on this rule may do so within 30 days of the date of this publication in the Federal Register.

The agency has determined that this is not a significant regulatory action for purposes of Executive Order 12866; therefore, no regulatory impact analysis is required. There are no information collections associated with this rule.

List of Subjects in 20 CFR Part 368

Railroad retirement, Smoking, Tobacco.

Title 20 CFR, chapter II is amended by adding a new part 368 to read as follows:

PART 368—PROHIBITION OF CIGARETTE SALES TO MINORS

Sec.
368.1 Introduction.
368.2 Definitions.
368.3 Vending machines.
368.4 Concession stands.
368.5 Free tobacco samples.

Authority: Sec. 636, Pub. L. 104–52, 109 Stat. 507 (40 U.S.C. 486nt).

§ 368.1 Introduction.

This part implements Public Law 104–52, the ''Prohibition of Cigarette Sales to Minors in Federal Buildings and Lands Act,'' which prohibits the sale of tobacco products through vending machines and the distribution of free samples of tobacco products on Federal property.

§ 368.2 Definitions.

As used in this part—

Federal property includes any building and real property occupied and maintained by the Board.

Minor means an individual under the age of 18 years.

Tobacco product means cigarettes, cigars, little cigars, pipe tobacco, smokeless tobacco, snuff, and chewing tobacco.

§ 368.3 Vending machines.

The sale of tobacco products in vending machines is prohibited in or around Federal property occupied and maintained by the Railroad Retirement Board.

§ 368.4 Concession stands.

Tobacco products may be sold on property occupied and maintained by the Railroad Retirement Board only as authorized by the Railroad Retirement Board or the General Services Administration or other Federal agency. Concession stands may not sell tobacco products to minors.

§ 368.5 Free tobacco samples.

The distribution of free samples of tobacco products is prohibited in or around Federal property occupied and maintained by the Railroad Retirement Board.

Dated: February 21, 1996.

By Authority of the Board.

For the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 96–4676 Filed 3–1–96; 8:45 am]

BILLING CODE 7905–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Issuance of Notices Relating to Debarment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority to FDA officials in the Center for Drug Evaluation and Research (CDER), the Center for Veterinary Medicine (CVM), and the Center for Biologics Evaluation and Research (CBER) by adding a new delegations section concerning the issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment. Additionally, FDA is amending the regulations regarding petitions so that certain officials of CDER, CVM, and CBER are authorized to respond to petitions concerning debarment and refusal to terminate debarment. This action will make the process of issuing such notices and responses to petitions more efficient.

EFFECTIVE DATE: March 4, 1996.

FOR FURTHER INFORMATION CONTACT: Ellen Rawlings, Division of Management Systems and Policy (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4976.

SUPPLEMENTARY INFORMATION: New section 306 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 335a), created by the Generic Drug Enforcement Act of 1992, authorizes the Secretary of Health and Human Services and, by previous delegation, the Commissioner of Food and Drugs (the Commissioner) to take actions relating to debarment proposals and orders as well as proposals and orders to deny an application to terminate a debarment order. Certain aspects of this authority are being redelegated in new § 5.98 from the Commissioner to the Directors of CDER, CVM, and CBER, to the Deputy Directors of CDER and CVM, and the Associate Director for Policy Coordination and Public Relations, CBER, as appropriate. In addition, FDA is amending § 5.31 (21 CFR 5.31) by delegating authority to the Directors of CDER, CVM, and CBER, to the Deputy Directors of CDER and CVM, and the Associate Director for Policy Coordination and Public Relations of CBER to respond to petitions concerning actions they are authorized to take under new § 5.98. The redelegations will make the process of issuing such notices and responses to petitions more efficient.

Further redelegation of the authority delegated is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282,

3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701–1706, 2101, 2125, 2127, 2128 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1, 300aa–25, 300aa–27, 300aa–28); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591; secs. 312, 313, 314 of the National Childhood Vaccine Injury Act of 1986, Pub. L. 99–660 (42 U.S.C. 300aa–1 note).

2. Section 5.31 is amended by adding new paragraphs (f)(1)(vi), (f)(2)(x), and (f)(8) to read as follows:

§ 5.31 Petitions under part 10.

* * * * *

(f) * * *

(1) * * *

(vi) Section 5.98 *Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.*

(2) * * *

(x) Section 5.98 *Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.*

* * * * *

(8) The Director and Deputy Director, CVM, are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter concerning actions they are authorized to take under § 5.98 *Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.*

3. New § 5.98 is added to subpart B to read as follows:

§ 5.98 Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.

The Director and Deputy Director, Center for Drug Evaluation and Research (CDER), the Director and Deputy Director, Center for Veterinary Medicine (CVM), and the Director and Associate Director for Policy Coordination and Public Relations, Center for Biologics Evaluation and Research (CBER) are authorized to issue the following notices under section 306 of the Federal Food, Drug, and Cosmetic Act (the act) which relate to the assigned functions of their organizations:

(a) Notices of opportunity for hearing on proposals for mandatory or permissive debarment.

(b) Notices ordering debarment when opportunity for a hearing has been waived.

(c) Notices ordering debarment where the person notifies the agency that the person acquiesces to debarment under section 306(c)(2)(B) of the act.

(d) Notices of opportunity for hearing on proposals denying an application to terminate debarment under section 306(d)(3) of the act.

(e) Orders denying an application to terminate debarment under section 306(d)(3) of the act when opportunity for a hearing has been waived.

Dated: February 26, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–4914 Filed 3–1–96; 8:45 am]

BILLING CODE 4160–01–F

UNITED STATES INFORMATION AGENCY

22 CFR Part 514

Exchange Visitor Program

AGENCY: United States Information Agency.

ACTION: Statement of policy and notice to sponsors.

SUMMARY: Public Law 104–72 directs the Agency to continue its oversight of au pair activities in the United States until September 30, 1997. This announcement sets forth the Agency's intended implementation of this law.

EFFECTIVE DATE: This policy statement is effective March 4, 1996.

FOR FURTHER INFORMATION CONTACT: Stanley S. Colvin, Assistant General Counsel, United States Information Agency, 301 4th Street SW., Washington, DC 20547; telephone, (202) 619–6829.

SUPPLEMENTARY INFORMATION: Au pair programs, whereby European youths are placed with American host families seeking child care, have been overseen by the Agency since 1986. Originally begun as a pilot project, the au pair program has expanded over the past ten years to now encompass eight Agency-designated sponsors who facilitated the entry of some 11,000 au pair participants in 1995. Congress, in enacting Public Law 104–72, extended temporarily the Agency's authority to oversee this activity. As discussed below, the Congress also addressed two long-standing programmatic matters of concern to the Agency.

Since begun in 1986, au pair participants have only been selected from the countries of Western Europe. This limitation was set forth in initial pilot-project guidelines but remained in place pursuant to subsequent legislation that directed the Agency to continue its oversight of au pair activities under the ''same terms and conditions'' of the pilot guidelines. Public Law 104–72 removes this programmatic limitation by directing the Agency to oversee au pair activities conducted on a ''world-wide basis.''

Accordingly, the Agency has advised au pair sponsors that, unless otherwise prohibited by law, au pair participants may be recruited from all world countries. The Agency construes ''world-wide'' basis to not include nationals of countries lacking diplomatic relations with the United States. Further, the Agency is of the opinion that ''World wide basis'' would allow a national of one country, resident in another, to be recruited and issued a visa in the country of residence.

The Agency concludes that Public Law 104–72 renders inoperative, the ''same terms and conditions'' requirement of prior legislation. Accordingly, the Agency will accept applications from United States organizations seeking designation as an au pair sponsor. Due to the time-limited authority given the Agency in Public-Law 104–72, all designated au pair sponsors will continue to be given temporary, not permanent, program designations. Such designations will be made by the Agency under the authority of Public Law 104–72 and not under the Agency's Fulbright-Hays Act authorities as set forth at 22 U.S.C. 1474 et seq.

Finally, the Agency hereby gives notice of its intent to limit the number of au pair participants to not more than 22,720. The Agency does not believe that currently designated sponsors, and those organizations receiving new designations, will be affected by this numerical limitation. This belief is based upon the past history of au pair activities and the Agency's knowledge of the growth rates of similar programs overseen by the Agency.

The Agency specifically reserves the right to limit the number of participants sponsored by an individual organization. Participant levels for newly designated au pair sponsors will be determined by the Agency in consultation with the sponsor. The organization's prior experience, organizational capacity, and resources will be specifically considered in determining participant levels.

List of Subjects in 22 CFR Part 514

Cultural exchange programs.

Dated: February 28, 1996.

Les Jin,

General Counsel.

[FR Doc. 96–4973 Filed 3–1–96; 8:45 am]

BILLING CODE 8230–01–M

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 535

Iranian Assets Control Regulations; Shams Pahlavi Assets Unblocked

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule; amendment to the list of persons whose assets are subject to blocking.

SUMMARY: The Office of Foreign Assets Control of the U.S. Department of the Treasury is amending section 535.217 of the Iranian Assets Control Regulations, 31 CFR § 535.217, to remove the name Shams Pahlavi from § 535.217(b). Shams Pahlavi, sister of Mohammed Reza Pahlavi, the former Shah of Iran, previously was identified in § 535.217(b) as a person who had been served as a defendant in litigation brought by Iran in a court within the United States seeking the return of property alleged to belong to Iran. She therefore was identified as a person whose United States assets were blocked pursuant to the provisions of § 535.217(a). Reference to Shams Pahlavi is now removed from § 535.217(b) based upon the final termination of all pertinent litigation against her. Accordingly, her United States assets are no longer blocked pursuant to § 535.217(a).

EFFECTIVE DATE: March 1, 1996.

FOR FURTHER INFORMATION CONTACT: Regarding the status of blocked assets, Loren L. Dohm, Blocked Assets Division (tel.: 202/622–2440); regarding legal questions, William B. Hoffman, Chief Counsel (tel.: 202/622–2410); Office of Foreign Assets Control, Department of the Treasury, Washington, D.C. 20220.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document is available as an electronic file on *The Federal Bulletin Board* the day of publication in the Federal Register. By modem, dial 202/515–1387 and type ''/GO FAC,'' or call 202/512–1530 for disks or paper copies. This file is available for downloading without charge in WordPerfect, ASCII, and Adobe Acrobat™ readable (*.PDF) formats. The document is also accessible for downloading in ASCII format without charge from Treasury's Electronic Library (''TEL'') in the ''Business, Trade and Labor Mall'' of the FedWorld bulletin board. By modem dial 703/321–3339, and select the appropriate self–expanding file in TEL. For Internet access, use one of the following protocols: Telnet = fedworld.gov (192.239.93.3); World Wide Web (Home Page) = http://www.fedworld.gov; FTP = ftp.fedworld.gov (192.239.92.205).

Background

The Office of Foreign Assets Control is amending § 535.217(b) of the Iranian Assets Control Regulations, 31 CFR part 535, to reflect changes in the status of litigation brought by Iran against close relatives of the former Shah of Iran seeking the return of property alleged to belong to Iran. In 1991, Shams Pahlavi was identified in § 535.217(b) based on proof of service upon her in litigation of the type described in § 535.217(a). Pursuant to that provision, all property and assets located in the United States within the control of Shams Pahlavi were blocked until all pertinent litigation against her was finally terminated. Because that litigation has been finally terminated, reference to Shams Pahlavi is deleted from § 535.217(b).

Because the Regulations involve a foreign affairs function, Executive Order 12866 and the provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act, 5 U.S.C. 601–612, does not apply. Wherever possible, however, it is the practice of the Office of Foreign Assets Control to receive written submissions or hold informal consultations with interested parties before the issuance of any rule or other public document.

List of Subjects in 31 CFR Part 535

Administrative practice and procedure, Banking, Banks, Blocking of assets, Currency, Foreign investment in the United States, Iran, Penalties, Reporting and recordkeeping requirements, Securities.

For the reasons set forth in the preamble, 31 CFR part 535 is amended as follows:

PART 535—IRANIAN ASSETS CONTROL REGULATIONS

1. The authority citation for Part 535 continues to read as follows:

Authority: 50 U.S.C. 1701–1706; E.O. 12710, 44 FR 65729, 3 CFR, 1979 Comp., p. 457; E.O. 12205, 45 FR 24099, 3 CFR, 1980 Comp., p. 248; E.O. 12211, 45 FR 26685, 3 CFR, 1980, Comp., p. 253; E.O. 12276, 46 FR 7913, 3 CFR, 1981 Comp., p. 104; E.O. 12279, 46 FR 7919, 3 CFR 1981 Comp., p. 109; E.O. 12280, 46 FR 7921, 3 CFR 1981 Comp., p. 110; E.O. 12281, 46 FR 7923, 3 CFR, 1981 Comp., p. 112; E.O. 12282, 46 FR 7925, 3 CFR, 1981 Comp., p. 113; E.O. 12282, 46 FR 7927, 3 CFR, 1981 Comp., p. 113; E.O. 12283, 46 FR 7927, 3 CFR 1981 Comp., p. 114; and E.O. 12294, 46 FR 14111, 3 CFR, 1981 Comp., p. 139.

Subpart B—Prohibitions

2. Section 535.217 is amended by revising paragraph (b) to read as follows:

§ 535.201 Blocking of property of the former Shah of Iran and of certain Iranian nationals.

* * * * *

(b) [No persons presently listed].

* * * * *

Dated: February 1, 1996.

R. Richard Newcomb,

Director, Office of Foreign Assets Control.

Approved: February 8, 1996.

Dennis M. O'Connell,

Acting Deputy Assistant Secretary (Regulatory, Tariff & Law Enforcement).

[FR Doc. 96–4899 Filed 3–1–96; 8:45 am]

BILLING CODE 4810–25–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07–96–003]

RIN 2115–AE46

Special Local Regulations: Manatee River, Palmetto, FL

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: Special local regulations are being adopted for the A.P.B.A. (American Power Boat Association) Green Bridget Regatta. This event will be held on Saturday, March 23, and Sunday, March 24, 1996 between 10 a.m. and 6 p.m. edt (eastern daylight time). This event will attract large spectator crowds and create congestion. Therefore, these regulations are needed to provide for the safety of life on navigable waters during the event.

EFFECTIVE DATE: This rule is effective from 9 a.m. to 7 p.m. edt on March 23 and 24, 1996.

ADDRESSES: Unless otherwise indicated, documents referred to in this preamble are available for inspection or copying at U.S. Coast Guard Group ST. Petersburg, 600 8th Avenue SE., St. Petersburg, FL 33701–5099, between 8 a.m. and 3 p.m. edt, Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: LTJG J.W. Nelson, U.S. Coast Guard Group St. Petersburg, FL at (813) 824–7533.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a notice of proposed rulemaking has not been published for these regulations. The permit application was not received until late January. Following normal rulemaking procedures would have been impracticable, as there was insufficient time to publish the proposed rule in advance of the event or to provide for a delayed effective date.

Discussion of Regulations

This rule is needed to provide for the safety of life on navigable waters, to protect the vessels participating in the races, and to protect marine mammals during the A.P.B.A. (American Power Boat Association) Green Bridge Regatta. There will be approximately 50–75 power boats, 21 to 50 feet in length, engaged in a power boat race, and no spectator craft are expected. A regulated area is established between daybecacons #1 (27°30.6N, 82°34.6W, LLNR 19525) and #21A (27°30.5N, 82°34.7W, LLNR 19570) in the Manatee River. All coordinates referenced are datum: NAD 83. The Manatee River will be closed to all inbound and outbound vessel traffic, other than spectator craft, at various times between the hours of 10 a.m. and 6 p.m. edt, March 23 and 24, 1996. Vessel traffic will be allowed to transit the area during intermissions.

Regulatory Evaluation

These regulations are not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has not been reviewed by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. Entry into the area is prohibited for only 10 hours each day of the event.

Since the impact of these regulations is to be minimal, the Coast Guard certifies that it will not have a significant economic impact on a substantial number of small entities.

Collection of Information

These regulations contain no collection-of-information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that these regulations do not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard has considered the environmental impact of this action consistent with Section 2.B.2. of Commandant Instruction M16475.1B (as revised by 59 FR 38654, July 29m, 1994). In accordance with that section, this action has been environmentally assessed (EA completed), and the Coast Guard has determined that it will not significantly affect the quality of the human environment. An environmental assessment and finding of no significant impact have been prepared and are available for inspection and copying at the address listed under **ADDRESSES.** Specifically, the Coast Guard has consulted with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service regarding the environmental impact of this event, and it was determined that the event does not jeopardize the continued existence of protected species. As a condition to this permit, the applicant is required to educate the operators of spectator craft and race participants regarding the possible presence of manatees and the appropriate precautions to take if the animals are sighted.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

Temporary Final Regulations

In consideration of the foregoing, Part 100 of Title 33, Code of Federal Regulations, is amended as follows:

PART 100—[AMENDED]

1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35.

2. A temporary § 100.35–T07–003 is added to read as follows:

§ 100.35–T07–003 Manatee River, Palmetto, FL.

(a) *Regulated area.* A regulated area is established in the Manatee River with the northwest corner point at Pt Ogden, position 27°30′41″ N, 82°34′47″ W, extending to the northeast corner point at northern approach to Green Bridge, position 27°30′35″ N, 82°34′22″ W, then extending to the southeast corner point at southern approach to Green Bridge, position 27°29′58″ N, 82°34′17″ W, and then to the southwest corner point at Point Pleasant, position 27°30′07″ N, 82°34′42″ W. All coordinates referenced use Datum: NAD 83.

(b) *Special local regulations* (1) In accordance with these regulations, the regulated area is designated as a no entry zone. Vessel traffic is permitted into the area during intermission, but is prohibited from entering the course area described in paragraph (b)(2) of this section during the race.

(2) Inside the no entry zone is a designated area surrounding the race course. The course consists of two ½ mile straight-aways and two ⅓ mile turns. The course is bounded by a line connecting the northeast corner point at position 27°30′10″ N, 82°34′30″ W, a southeast corner point at position 27°30′10″ N, 82°34′27″ W, a southwest corner point at position 27°30′15″ N, 82°34′38″ W, and a northwest corner point at position 27°30′30″ N, 82°34′40″ W. All coordinates referenced use Datum: Nad 83.

(c) *Effective dates.* This section is effective at 9 a.m. and terminate at 7 p.m. edt on March 23 and 24, 1996.

Dated: February 20, 1996.

Roger T. Rufe, Jr.,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 96–4917 Filed 3–1–96; 8:45 am]

BILLING CODE 4910–14–M

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33 CFR Part 100

[CGD07–96–004]

RIN 2115–AE46

Special Local Regulations; City of Augusta, GA

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: Temporary special local regulations are being adopted for the Augusta Port Authority Invitational Rowing Regatta. The event will be held from 7 a.m. to 5 p.m. edt (Eastern Daylight Time) on March 21–24, 1996 on the Savannah River at August, GA. These regulations are necessary to

provide for the safety of life on navigable waters during the event.

EFFECTIVE DATE: This rule is effective from 6:30 a.m. to 5:30 p.m. edt on March 21–24, 1996.

ADDRESSES: Unless otherwise indicated, documents referred to in this preamble are available for copying and inspection at U.S. Coast Guard Group Charleston, 196 Tradd Street, Charleston, SC 29401–1817, between 8 a.m. and 3 p.m. edt, Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: ENS M. Daponte, U.S. Coast Guard Group Charleston, SC at (803) 724–7621.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for these regulations. Following normal rulemaking procedures would have been impracticable. The information necessary to hold the event was not received until January 10 1996, and there was not sufficient time remaining to publish proposed rules in advance of the event or to provide for a delayed effective date.

Discussion of Regulations

There will be 1000 participants racing 4 and 8 man rowing shells on a fixed course. The event will take place on the portion of the Savannah River at Augusta, Georgia between U.S. Highway 1/78/278 Bridge, at mile marker 199.45, and mile marker 197, on March 21–24, 1996. This rule is required to provide for the safety of life on the navigable waters during the running of the Invitational Rowing Regatta.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(f) of that order. It has not been reviewed review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. The regulated area encompasses less than 1.5 nautical miles on the Savannah River between U.S. Highway 1/78/278 Bridge, at mile marker 199.45, and mile marker 197, entry into which is prohibited only for eleven hours on each day of the event.

Since the impact of this proposal is expected to be minimal, the Coast Guard certifies that, if adopted, it will not have a significant economic impact on a substantial number of small entities.

Collection of Information

These regulations contain no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this rule in accordance with the principles and criteria contained in Executive Order 12612 and has determined that this regulation does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard has considered the environmental impact of this action consistent with Section 2.B.2. of Commandant Instruction M16475.1B. In accordance with that section, this action has been environmentally assessed (EA completed), and the Coast Guard has determined that it will not significantly affect the quality of the human environment. An environmental assessment and finding of no significant impact have been prepared and are available for inspection and copying at the address listed under **ADDRESSES**. As a condition to the permit, the applicant is required to educate the operators of spectator craft and parade participants regarding the possible presence of manatees and the appropriate precautions to take if the animals are sighted.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

Temporary Final Regulations

In consideration of the foregoing, part 100 of title 33, Code of Federal Regulations, is amended as follows:

PART 100—[AMENDED]

1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233, 49 CFR 1.46 and 33 CFR 100.35.

2. A temporary § 100.35–07–004 is added as follows:

§ 100.35–07–004 Special Local Regulations; Savannah River at Augusta, GA.

(a) *Regulated area.* A regulated area is established on that portion of the Savannah River at Augusta, Georgia between U.S. Highway 1/78/278 Bridge, at mile marker 199.45, and mile marker 197. The regulated area encompasses the width of the Savannah River between these two points.

(b) *Special local regulations.* (1) Entry into the regulated area by other than event participants is prohibited, unless otherwise authorized by the Patrol Commander. After termination of the Augusta Invitational Rowing Regatta on March 24, 1996, all vessels may resume normal operation.

(2) Four temporary overhead cables will be used to delineate the course's racing lanes, and floats will be used on the surface of the river to mark lane separations.

(c) *Effective dates.* This section is effective from 6:30 a.m. to 5:30 p.m. est on March 21–24, 1996.

Dated: February 20, 1996.

Roger T. Rufe, Jr.,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 96–4920 Filed 3–1–96; 8:45 am]

BILLING CODE 4910–14–M

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33 CFR Part 100

[CG11–96–002]

RIN 2115–AE46

Special Local Regulations; Parker 500 Enduro

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation.

SUMMARY: This notice implements 33 CFR 100.1102, ''Marine Events on the Colorado River, between Davis Dam (Bullhead City, Arizona) and Headgate Dam (Parker, Arizona),'' for the Parker 500 Enduro'' listed as ''Parker Enduro.''

This event consists of circle races and a marathon race by powerboats 12 to 22 feet in length. These regulations will be effective in the area of the Colorado River known as Parker Strip from Headgate Dam to Badenochs Marina approximately 2.5 miles north. This is a smaller area than that published in 33 CFR 100.1102. Implementation of section 33 CFR 100.1102 is necessary to control vessel traffic in the regulated areas during the event to ensure the safety of participants and spectators.

EFFECTIVE DATE: Section 33 CFR 100.1102 is effective from 11 a.m., on March 9, 1996 and until 6 p.m. on March 10, 1996, unless cancelled earlier by the San Diego Activities Commander.

FOR FURTHER INFORMATION CONTACT: QMC Paul Appleton, U.S. Coast Guard Activities San Diego, California; Tel: (619) 683–6309.

Discussion of Notice

The Parker 500 Enduro is scheduled to occur on March 9 and 10, 1996. These

Special Local Regulations permit Coast Guard control of vessel traffic in order to ensure the safety of spectators and participant vessels. In accordance with the regulations in 33 CFR 100.1102, no spectators shall anchor, block, loiter in, or impede the through transit of participants or official patrol vessels in the regulated area during the effective dates and times, unless cleared for such entry by or through an official patrol vessel.

Dated: February 16, 1996.

R.A. Appelbaum,

Rear Admiral, U.S. Coast Guard, Commander, Eleventh Coast Guard District.

[FR Doc. 96–4922 Filed 3–1–96; 8:45 am]

BILLING CODE 4910–14–M

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33 CFR Part 165

[CGD07–96–009]

RIN 2115–AE84

Regulated Navigation Area Regulations; Fort Pierce, FL

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary regulated navigation area at the Peter P. Cobb bridge in Fort Pierce, Florida. This regulated navigation area is needed to protect all vessels from a safety hazard created by damage to the Peter P. Cobb bridge and associated debris in the surrounding area. Entry into this zone is prohibited unless authorized by the Captain of the Port, Miami, Florida.

EFFECTIVE DATE: This regulation is effective from 12 p.m. on February 24, 1996 and terminates at 12 p.m. on March 31, 1996.

FOR FURTHER INFORMATION CONTACT: BMC J. L. Belk, Port Management and Response Department, USCG Marine Safety Office Miami, Florida at (305) 536–5693.

SUPPLEMENTARY INFORMATION:

Background and Purpose

At approximately 4 p.m. on November 7, 1995, a vessel allided with the east side of the fender system of the Peter P. Cobb Bridge (also known as the South Bridge) on the Indian River South Section at Fort Pierce, Florida. The center section of the east fender system was destroyed leaving the bridge support piling unprotected. Construction crews are replacing the fender system which was destroyed.

A regulated navigation area has been established on the Indian River South Section which includes the area under the main span of the bridge extending 100 feet either side of the bridge within the main channel. A previous regulated navigation area (CGD07–95–073) was established for this area. This regulation will terminate at 12 p.m. on February 24, 1996. Since repairs on the Peter P. Cobb bridge have not been completed, a new regulation is needed to continue the repairs without creating unusual hazards on the waterway for vessels traversing the area. This area will have the following restrictions and conditions for vessel traffic.

All barge traffic must obtain permission from the Captain of the Port or his designated representative prior to transiting. Any barges allowed to transit the zone by the Captain of the Port will be required to meet the following conditions: the barge must be assisted by two tugs made fast fore and aft; tugs must be of adequate horse power to fully maneuver the barge; and the zone shall be transited by barge traffic at slack water only. All other vessel traffic shall stay clear of the damaged section of the bridge and the repair work underway.

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days after Federal Register publication. Publication of notice of proposed rulemaking and delay of effective date would be contrary to public interest because immediate action is necessary to prevent vessels from alliding with the bridge support pilings, causing potential danger to the public.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this rule will have a significant economic impact on a substantial number of small entities. ''Small entities'' include independently owned and operated businesses that are not dominant in their field and that otherwise qualify as ''small business concerns'' under section 3 of the Small Business Act (15 U.S.C. 632).

For reasons set forth in the above Regulatory Evaluation, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This rule contains no information collection requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*)

Federalism

The action has been analyzed under the principles and criteria contained in executive order 12612 and has determined that the rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard has considered the environmental impact of this action and has determined pursuant to Section 2.B.2. of Commandant Instruction M16475.1B that this action is categorically excluded from further environmental documentation. A categorical exclusion checklist and categorical exclusion determination have been completed and are available for inspection and copying.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (waters), Reporting and recordkeeping requirements, Safety measures, Waterways.

Final Regulations

For the reasons set out in the preamble the Coast Guard amends 33 CFR Part 165 as follows:

PART 100—[AMENDED]

1. The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; 49 CFR 1.46.

2. A new temporary § 165.T07–009 is added to read as follows:

§ 165.T07–009 Regulated Navigation Area; Indian River South Section, Peter P. Cobb Bridge, Fort Pierce, FL.

(a) *Location.* The following area is a regulated navigation area:

All waters under the main bridge span extending 100 feet either side of the bridge within the main channel.

(b) *Regulations.* In accordance with general regulations in § 165.11 of this

part, no vessel may operate within the regulated navigation area contrary to this regulation. All barge traffic must obtain permission from the Captain of the Port or his designated representative prior to transiting. Any barges allowed to transit the zone by the Captain of the Port will be required to meet the following conditions: the barge must be assisted by two tugs made fast fore and aft; tugs must be of adequate horsepower to fully maneuver the barge; and the zone shall be transited by barge traffic at slack water only. All other vessel traffic shall stay clear of the damaged section of the bridge and repair work underway. The Captain of the Port will notify the public of changes in the status of this zone by Marine Safety Radio Broadcast on VHF Marine Band Radio, Channel 22 (157.1 MHz).

(c) *Effective dates.* This section is effective at 12 p.m. on February 24, 1996 and terminates at 12 p.m. on March 31, 1996.

Dated: February 23, 1996.

Roger T. Rufe, Jr.,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 96–4916 Filed 3–1–96; 8:45 am]

BILLING CODE 4910–14–M

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33 CFR Part 165

[CGD 05–96–007]

RIN 2115–AA97

Safety Zone: Atlantic Intracoastal Waterway, Vicinity of Marine Corps Base Camp Lejeune, NC

AGENCY: Coast Guard, DOT.

ACTION: Temporary rule.

SUMMARY: The Coast Guard Captain of the Port, Wilmington, has established a safety zone in the Atlantic Intracoastal Waterway (AICW) along Marine Corps Base Camp Lejeune (Marine Corps Base), North Carolina. The safety zone encompasses the waters of the Atlantic Intracoastal Waterway between lighted dayboards 64 and 65A. The safety zone is needed to protect people, vessels, and property from safety hazards associated with the launching of insert line charges in support of amphibious assault training. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port.

EFFECTIVE DATE: This rule is effective from 8 a.m. March 8 to 6 a.m. March 14 1996 unless sooner terminated by the Captain of the Port.

FOR FURTHER INFORMATION CONTACT: LTJG K.J. DELOOFF, USCG, Project Officer, c/o Commanding Officer, U.S. Coast Guard Marine Safety Office, 272 North Front Street, Wilmington, North Carolina 28401–3907. Phone: (910) 343–4895, Extension 108.

SUPPLEMENTARY INFORMATION:

Discussion of Regulation

Marine Corps Base Camp Lejeune will conduct training assaults on a simulated mined beach. Up to three exercises will be held each day and each exercise will last 30–45 minutes. Each assault involves firing an inert line charge which clears the simulated minefield. The inert charge is propelled by a 5 foot solid fuel rocket from which the inert explosives trail. The rocket is typically prevented from flying its full flight by a cable attached to the firing point. If this cable breaks, the rocket motor, and possibly the inert line charge could impact in the Atlantic Intracoastal Waterway. The Coast Guard is establishing a safety zone to prevent damage or injury which could result from this training exercise and will prevent vessels from transiting during the firing of the line charge.

The safety zone will be effective from 8 a.m. on March 8, 1996 to 6 a.m. on March 14, 1996 unless terminated sooner by the Captain of the Port Wilmington (COTP). The actual times the waterway will be closed will be approximately 30–45 minute periods one to three times per day. Before firing the inert line charge, the COTP will announce via VHF channel 16 that this section will be enforced and the waterway will be closed to traffic. Vessels from either the U.S. Coast Guard or U.S. Navy will patrol each end of the safety zone to inform and control vessel traffic.

The safety zone includes:

The waters of the Atlantic Intracoastal Waterway from lighted dayboard number 64 at approximately 34°33′ 59.7″ North, 077°16′ 50.5″ West to lighted dayboard 65A at approximately 34°32′ 40.0″ North, 077°19′ West.

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making this regulation effective in less than 30 days after Federal Register publication. Publishing a NPRM and delaying the effective date would be contrary to the public interest since immediate action is needed to protect mariners from potential hazards associated with potential flight of an rocket propelled inert line charge over navigable waters. The final schedule for this event and other related activities was not finalized and communicated to the Coast Guard in sufficient time to allow for a period for comments.

Assessment

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has not been reviewed by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979).

The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Collection of Information

This rule contains no information collection requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 12612 and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that, under paragraph 2.B.2.e(34) of Commandant Instruction M16475.1B (amended by 59 FR 38654), this rule is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons set out in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—[AMENDED]

1. The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; and 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; 49 CFR 1.46.

2. A new temporary § 165.T05.007 is added to read as follows:

§ 165.T05.007 Safety Zone: Atlantic Intracoastal Waterway, Marine Corps Base Camp Lejeune, North Carolina.

(a) *Location.* The following area is a safety zone:

(1) The waters of the Atlantic Intracoastal Waterway from lighted dayboard number 64 at approximately 34°33′59.7″ North, 077°16′50.5″ West to lighted dayboard 65A at approximately 34°32′40.0″ North, 077°19′ West.

(b) This section is effective from 8 a.m., March 8, 1996 to 6 a.m., March 14, 1996, unless terminated earlier by the Captain of the Port (COTP), Wilmington, NC.

(c) No person or vessel may enter the safety zone without the permission of the COTP or his designated representative.

(d) The COTP or his designated representative will announce times during which this section will be enforced.

(e) The COTP or his designated representative may be contacted at the Marine Safety Office, Wilmington, NC by telephone at (910) 343–4895 or by radio on VHF–FM channel 16.

Dated: February 12, 1996.

T.L. Rice,

Captain, U.S. Coast Guard, Captain of the Port, Wilmington, NC.

[FR Doc. 96–4918 Filed 3–1–96; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 80

[FRL–5433–8]

RIN 2060–AD55

Prohibition on Gasoline Containing Lead or Lead Additives for Highway Use

AGENCY: Environmental Protection Agency (EPA).

ACTION: Partial withdrawal of direct final rule.

SUMMARY: On February 2, 1996, EPA published a direct final rule (61 FR 3832) revising EPA regulations to reflect the Clean Air Act's statutory prohibition of the introduction into commerce of gasoline containing lead or lead additives for use as a motor vehicle fuel after December 31, 1995. This action was published without prior proposal. Because EPA has received adverse comment with respect to paragraph 40 CFR 80.24(b) of this action, EPA withdraws this paragraph from the direct final rule. The withdrawal of this paragraph does not otherwise affect the February 2, 1996 direct final rule, for which all other actions will become effective March 4, 1996.

EFFECTIVE DATE: March 4, 1996.

FOR FURTHER INFORMATION CONTACT: Richard Babst, U.S. Environmental Protection Agency, Office of Air and Radiation, (202) 233–9473.

SUPPLEMENTARY INFORMATION: On February 2, 1996, EPA published in the Federal Register a direct final rule revising its regulations in accordance with the Clean Air Act prohibition of the introduction of gasoline containing lead or lead additives into commerce for use as a motor vehicle fuel after December 31, 1995. Among other actions, the direct final rule would have revised paragraph 40 CFR 80.24(b), which contains a specification regarding gasoline tank filler inlets for motor vehicles. The direct final rule was published without prior proposal in the Federal Register with a provision for a 15 day comment period. In addition, EPA published a proposed rule, also on February 2, 1996 (61 FR 3894). EPA announced in both rules that, should EPA receive adverse comment on the direct final rule, the Agency would withdraw the direct final rule and address the comments received in a subsequent final rule based on the related proposed rule. EPA received adverse comment within the prescribed comment period specifically addressing a revision that would have been made to 40 CFR 80.24(b). With this document, EPA is withdrawing revisions to 40 CFR 80.24(b) from the February 2, 1996 direct final rule (61 FR 3832). The withdrawal of this paragraph does not affect the other actions in the February 2, 1996 direct final rule, and all other actions will become effective March 4, 1996 as indicated in the direct final rule. The adverse comment received will be addressed in a subsequent final rule based on the related proposed rule (61 FR 3894).

List of Subjects in 40 CFR Part 80

Environmental protection, Air pollution control, Fuel additives, Gasoline, Leaded gasoline, Unleaded gasoline, Motor vehicle pollution.

For the reasons set forth in the preamble, the amendment revising 40 CFR 80.24(b) published at 61 FR 3838 (February 2, 1996) is withdrawn.

Dated: February 27, 1996.

Carol M. Browner,

Administrator.

[FR Doc. 96–4958 Filed 3–1–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 167

[OECA; FRL–5433–4]

Pesticide Reports for Pesticide-Producing Establishments; (EPA Form 3540–16); Additional Time To Report

AGENCY: Environmental Protection Agency (EPA).

ACTION: Time extension for submission of reports.

SUMMARY: Because of delays in completing and distributing reporting packages, EPA is announcing that it will extend the due date for submission of annual pesticide production reports (EPA Form 3540–16) for calendar year 1995 until two months after reporting packages are mailed by EPA. These reports under Section 7 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and supporting regulations at 40 CFR Part 167 would otherwise be due on or before March 1, 1996.

DATES: Annual pesticide production reports for calendar year 1995 will be due May 1, 1996.

FOR FURTHER INFORMATION CONTACT: Carol L. Buckingham, (202) 564–5008, fax (202) 564–0085, Environmental Protection Agency, Mail Code 2225A, 401 M Street, SW., Washington, D.C. 20460.

SUPPLEMENTARY INFORMATION:

Background

Section 7 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the supporting regulations at 40 CFR Part 167 requires certain facilities who manufacture, prepare, propagate, compound, or process any pesticide, including any pesticide produced pursuant to Section 5 of the Act, any active ingredient, or device, or to package, repackage, label, relabel, or otherwise change the container of any pesticide or device to report annually on the amounts and types, etc. of pesticides produced.

Each year prior to the reporting deadline (March 1) EPA develops and sends to facilities a reporting package containing the current pesticide reporting forms (EPA Form 3540–16), and instructions for reporting.

Because of delays in development of the reporting package, it will not be distributed to the pesticide-producing establishments in time to meet the March 1 reporting date. Therefore, EPA is extending the reporting deadline to two (2) months after the packages are mailed out.

This allowance of additional time for reporting applies only to the FIFRA section 7 and 40 CFR Part 167 reporting

obligations for pesticide reports otherwise due on March 1, 1996, covering calendar year 1995. Nothing in this Notice shall be construed to apply to any other FIFRA reporting obligations, or to any pesticide reports (EPA Form 3540–16) due for past or future reporting years. Further, this allowance of additional time for reporting applies only to the Federal FIFRA section 7 and 40 CFR Part 167 reporting obligation; it does not apply to independent obligations under State laws which may require pesticide-production type reports.

To the extent that this action might be construed as rulemaking subject to section 553 of the Administrative Procedures Act, for the reasons stated above, EPA has determined that notice and an opportunity for public comment are impracticable and unnecessary. Providing for public comment might further delay reporting, and, because there is no substantive change in the reporting obligation, the public will continue to receive the same information, though slightly delayed.

List of Subjects in 40 CFR Part 167

Registration of pesticide and active ingredient producing establishments, Submission of pesticide reports.

Dated: February 23, 1996.

Steven A. Herman,

Assistant Administrator, Office of Enforcement and Compliance Assurance.

[FR Doc. 96–4829 Filed 3–1–96; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 61

RIN 3067–AC42

National Flood Insurance Program; Insurance Rates

AGENCY: Federal Insurance Administration, FEMA.

ACTION: Final rule.

SUMMARY: This final rule increases the National Flood Insurance Program (NFIP) chargeable (subsidized) rates, which apply to all structures located in communities participating in the Emergency Program of the NFIP and to certain structures in communities in the Regular Program of the NFIP. The rule is promulgated in order to bring subsidized premiums more in line with the risk. This rule will help the NFIP increase the capability to build reserves for catastrophic loss years.

EFFECTIVE DATE: April 30, 1996.

FOR FURTHER INFORMATION CONTACT: Charles M. Plaxico, Jr., Federal Emergency Management Agency, Federal Insurance Administration, 500 C Street SW., Washington, DC 20472, (202) 646–3422.

SUPPLEMENTARY INFORMATION: FEMA published a proposed rule (60 FR 56552, November 9, 1995) to increase the National Flood Insurance Program (NFIP) chargeable (subsidized) rates. Comments were solicited from the public with the comment period ending January 8, 1996. During this period, no comments were received. As a result, this final rule contains no changes from the proposed rule.

This rule increases the NFIP chargeable (subsidized) rates. The increase results from an ongoing review and reappraisal of the NFIP and of continuing efforts to maintain a business-like approach to its administration by emulating successful property insurance programs in the private sector and, at the same time, to achieve greater administrative and fiscal effectiveness in its operations. The amendments in the rates will help the NFIP increase the capability to build reserves for catastrophic loss years. Coverage changes and optional deductibles, in addition to rate increases, are part of the ongoing effort to achieve these goals.

The chargeable (subsidized) rates, to which this rule applies, are the rates applicable to structures located in communities participating in the Emergency Program of the NFIP and to certain structures in communities in the Regular Program of the NFIP.

These rates are countrywide rates for two broad building type classifications which, when applied to the amount of insurance purchased and added to the expense constant and Federal policy fee, produce a premium income less than the expense and loss payments that can be expected on the flood insurance policies issued on that basis. Funds needed to supplement the inadequate premium income are provided by the National Flood Insurance Fund. The subsidized rates are promulgated by the Administrator for use under the Emergency Program (added to the NFIP by the Congress in Section 408 of the Housing and Urban Development Act of 1969) and for use in the Regular Program on construction or substantial improvement started before the effective date of the initial Flood Insurance Rate Map (FIRM) or on or before December 31, 1974 (this additional grandfathering was added to the NFIP by Congress in section 103 of the Flood Disaster Protection Act of 1973), whichever is later.

It should be noted that over the NFIP's history, the Program has not been subjected to a truly catastrophic flood event. Thus, the historical average is substantially less than could be expected over the long term when the influence of the extremely infrequent, truly catastrophic flood would result in a significant increase in the average historical year's losses. It is because of these fortuitous conditions, the lack of market penetration in areas suffering very large floods, and relatively high market penetration in the southeastern part of the United States, which has not suffered a catastrophic flood event recently, that the Program remained self-supporting since 1986 relying only on policyholder funding. However, the chargeable (subsidized) rates are significantly less than those that would be charged on a full risk basis.

Using current subsidized rates and projected full risk loss costs at 1995 levels, it is expected that the average annual shortfall in the risk portion of premiums needed to fund loss expenses, including the catastrophic potential, is over $400.00 for each subsidized policyholder.

The statutory mandate to establish chargeable rates requires the Federal Emergency Management Agency (FEMA) to balance the need for providing reasonable rates to encourage potential insureds to purchase flood insurance with the requirement that the NFIP be a flexible program that minimizes cost and distributes burdens equitably among those who will be protected by flood insurance and the general public.

In the past, appropriations were required to replenish the program's borrowing authority when income was not sufficient due to the subsidy. Since 1986, FEMA has not asked Congress to appropriate any taxpayer funds to pay for this subsidy. Recent years have been extremely high loss years starting with Hurricane Hugo in 1989, Hurricanes Andrew and Iniki in 1992, the great Midwest flooding of 1993, and several other major flooding events, including the recent flooding in Louisiana. The Louisiana flooding has resulted in the most losses the Program has ever had and will result in the biggest payout the Program has ever had from a single event. Because of this mounting loss experience, we must reduce the subsidy.

Section 1308(e) of the National Flood Insurance Act of 1968, as amended, contains an annual rate increase limitation of 10 percent. The rates to accomplish the increase are in the following table. It should be noted that

although the rates in the table have been increased more than 10 percent, the entire premium, which also includes an expense constant, increases only by 10 percent.

Type of structure	Rates per year per $100 coverage on	
	Structure	Contents
(1) Residential	$0.68	$0.79
(2) All other (including hotels and motels with normal occupancy of less than 6 months in duration) ...	.79	1.58

For comparison, the subsidized rates being replaced by the preceding rates are as follows:

Type of structure	Rates per year per $100 coverage on	
	Structure	Contents
(1) Residential	$0.60	$0.70
(2) All other (including hotels and motels with normal occupancy of less than 6 months in duration) ...	.70	1.40

The increase is balanced between the provisions of the statute for chargeable rates that are less than actuarial rates, consistent with the objective of making flood insurance available at reasonable rates so as to encourage prospective insureds to purchase flood insurance, and the need to decrease the subsidy.

The projected average annual premium for subsidized policies using the revised chargeable rates and purchasing 1995 amounts of insurance is $441.00, a $40.00 increase over the present average. Despite this increase, the new rates produce only an estimated 39 percent of the premium that would have to be charged if these policies were actuarially rated (i.e., not subsidized).

National Environmental Policy Act

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4371 *et seq.*, and the implementing regulations of the Council on Environmental Quality, 40 CFR parts 1500–1508, FEMA prepared an environmental assessment for this rule. The assessment concludes that there will be no significant impact on the human environment as a result of the issuance of the proposed rule. This final rule is not a major Federal action significantly affecting the quality of the human environment. An Environmental Impact Statement has not been prepared. Copies of the environmental assessment are available for inspection through the Rules Docket Clerk, Federal Emergency Management Agency, room 840, 500 C Street SW., Washington, DC 20472.

Executive Order 12866, Regulatory Planning and Review

This rule is not a significant regulatory action as defined under Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735, October 4, 1993. To the extent possible, this rule adheres to the principles of regulation as set forth in Executive Order 12866. This rule has not been reviewed by the Office of Management and Budget under the provisions of Executive Order 12866.

Paperwork Reduction Act

This rule does not contain a collection of information and is therefore not subject to the provisions of the Paperwork Reduction Act of 1995.

Executive Order 12612, Federalism

This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform

This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778, Civil Justice Reform.

List of Subjects in 44 CFR Part 61

Flood insurance.

Accordingly, 44 CFR part 61 is amended as follows:

PART 61— INSURANCE COVERAGE AND RATES

1. The authority citation for part 61 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq.; Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR, 1978 Comp., p. 329; E.O. 12127 of Mar. 31, 1979, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

2. Section 61.9 is revised to read as follows:

§ 61.9 Establishment of chargeable rates.

(a) Pursuant to section 1308 of the Act, chargeable rates per year per $100 of flood insurance are established as follows for all areas designated by the Administrator under part 64 of this subchapter for the offering of flood insurance.

RATES FOR NEW AND RENEWAL POLICIES

Type of structure	Rates per year per $100 coverage on	
	Structure	Contents
(1) Residential	$0.68	$0.79
(2) All other (including hotels and motels with normal occupancy of less than 6 months in duration	.79	1.58

(b) The contents rate shall be based upon the use of the individual premises for which contents coverage is purchased.

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance'').

Dated: February 27, 1996.

Elaine A. McReynolds,

Administrator, Federal Insurance Administration.

[FR Doc. 96–4930 Filed 3–1–96; 8:45 am]

BILLING CODE 6718–03–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 285

[I.D. 010496B]

Atlantic Tuna Fisheries; Bluefin Tuna Adjustments

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Fishery closure; catch limit adjustment.

SUMMARY: As of February 25, 1996, reported recreational fishery landings of Atlantic bluefin tuna (ABT) larger than 73 inches (185 cm) totalled 3.7 metric tons (mt). The annual quota allocated to recreational catch of large medium and giant ABT is 4 mt. Therefore, landing large medium and giant ABT under the Angling category is prohibited effective at 11:30 p.m. on February 28, 1996. This action is being taken to prevent overharvest of this category. In addition, the daily catch limit for ABT is adjusted to one fish per vessel, which may be from the school, large school, or small medium size class. This action is being taken to lengthen the fishing season and ensure reasonable fishing opportunities in all geographic areas.

EFFECTIVE DATES: The closure is effective 11:30 p.m., local time, February 28,

1996, through December 31, 1996, or until the effective date of any future adjustment, which will be published in the Federal Register. The daily catch limit adjustment is effective 11:30 p.m., local time, March 11, 1996, through December 31, 1996, or until the effective date of any future adjustment, which will be published in the Federal Register.

FOR FURTHER INFORMATION CONTACT: William Hogarth, 301–713–2347.

SUPPLEMENTARY INFORMATION: Regulations implemented under the authority of the Atlantic Tunas Convention Act (16 U.S.C. 971 *et seq.*) governing the harvest of ABT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 285.

Implementing regulations for the Atlantic tuna fisheries at 50 CFR 285.22 provide for a total annual quota of 4 mt of large medium and giant ABT to be harvested from the regulatory area by vessels permitted in the Angling category or the Charter/Headboat category. NMFS is required, under § 285.20(b)(1), to monitor the catch and landing statistics and, on the basis of these statistics, to project a date when the catch of ABT will equal the quota applicable to any period.

As of February 25, 1996, reported recreational fishery landings of Atlantic bluefin tuna (ABT) larger than 73 inches (185 cm) totaled 3.7 metric tons (mt). Information on fishing effort available to NMFS indicates that the remaining quota is likely to be taken within the next few days. Therefore, fishing for, retention, possessing, or landing large medium or giant ABT by vessels in the Angling category or Charter/Headboat category must cease at 11:30 p.m., local time, February 28, 1996. This action is to prevent overharvest of the quota established for this category. Recreational anglers may continue to fish for large medium and giant ABT under the NMFS tag and release program (§ 285.27).

The Angling category fishery for school, large school, and small medium size ABT remains open. Implementing regulations for the Atlantic tuna fisheries at § 285.24 allow for inseason adjustments to the daily catch limits in order to lengthen the fishing season and ensure reasonable fishing opportunities for all geographic areas. The Assistant Administrator for Fisheries, NOAA, may increase or reduce the per angler catch limit for any size class bluefin tuna or may change the per angler limit to a per boat limit or a per boat limit to a per angler limit.

Based on a review of daily landing trends, availability of ABT on the fishing grounds, and anticipated fishing effort, the daily catch limit is adjusted as follows: No more than one bluefin tuna may be retained each day per Angling category vessel, which may be from the school, large school, or small medium size class. Notice of adjustments must be published at least 5 calendar days prior to a change in daily catch limit becoming effective. Therefore, the catch limit adjustment shall take effect at 11:30 p.m., local time on March 11, 1996.

Subsequent adjustments to the daily catch limit, if any, shall be announced through publication in the Federal Register. Charter/Headboat and General category vessels, when engaged in recreational fishing for school ABT, are subject to the same rules as Angling category vessels.

Classification

This action is taken under 50 CFR 285.20(b) and 50 CFR 285.22 and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 971 *et seq.*

Dated: February 27, 1996.

Richard W. Surdi,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 96–4876 Filed 2–27–96; 4:44 pm]

BILLING CODE 3510–22–F

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50 CFR Part 290

[Docket No. 960221042–6042–01; I.D. 122195B]

RIN 0648–A159

Fishery Marketing Cooperatives; Issuance of Cease and Desist Orders; Removal of Regulation

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS amends the Code of Federal Regulations (CFR) to remove a regulation that is no longer needed concerning the issuance of cease and desist orders to associations of aquatic products. This action is consistent with the President's Regulatory Reform Initiative.

EFFECTIVE DATE: March 4, 1996.

FOR FURTHER INFORMATION CONTACT: Bruce C. Morehead, (301)713-2358.

SUPPLEMENTARY INFORMATION: On March 4, 1995, as part of the President's Regulatory Reform Initiative, the President directed agencies to conduct a page-by-page review of all regulations and eliminate or revise those that are outdated or otherwise in need of reform. After conducting a review of 50 CFR part 290, it was determined that it was no longer needed and could be removed.

Part 290 of title 50 CFR provides a remedy under the authority of The Act of June 25, 1934 (48 Stat. 1213) (Act), whereby an association of producers of aquatic products (association) authorized by the Act may be ordered by the Secretary of Commerce (Secretary) to cease and desist from monopolizing or restraining trade to such an extent the price of any aquatic product is unduly enhanced. The regulation provides for a proceeding initiated by the filing of a complaint against an association with the Secretary. Since the establishment of NOAA 25 years ago under Reorganization Plan No. 4 of 1970 (84 Stat. 2090), no such complaints have been filed and NMFS is unaware of any such complaints that may be filed. Therefore, 50 CFR part 290 is no longer needed and is being removed.

Classification

Because this rule merely removes a regulation that is no longer necessary, no useful purpose would be served by providing prior notice and opportunity for public comment. Accordingly, under 5 U.S.C.553(b)(3)(B), for good cause, the Assistant Administrator for Fisheries, NOAA (AA) finds that it is unnecessary to provide prior notice and an opportunity for public comment for this rule. Also, because this rule merely removes a regulation that is no longer needed, the AA finds that no useful purpose would be served by delaying the rule's effective date for 30 days. Therefore, this rule is made effective upon publication.

This final rule has been determined to be not significant for the purpose of E.O. 12866.

List of Subjects in 50 CFR Part 290

Administrative practice and procedure, Antitrust, Cooperatives, Fisheries

Dated: February 26, 1996.

Gary Matlock,

Program Management Officer, National Marine Fisheries Service.

For the reasons set out in the preamble, under the authority of 70 Stat. 1121, as amended; 16 U.S.C. 742 (c), as amended; and Reorganization No. 4 of 1970, 50 CFR part 290 is removed and Subchapter J is vacated.

[FR Doc. 96–4841 Filed 3–1–96; 8:45 am]

BILLING CODE 3510–22–F

Proposed Rules

Federal Register
Vol. 61, No. 43
Monday, March 4, 1996

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.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 916 and 917

[Docket No. FV95–916–5–PR]

Nectarines and Peaches Grown in California; Relaxation of Quality Requirements for Fresh Nectarines and Peaches

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would relax, for the 1996 season only, the quality requirements for California nectarines and peaches. This proposal would establish a California Tree Fruit Agreement (CTFA) Utility quality requirement. California nectarines and peaches are currently subject to a minimum requirement of a modified U.S. No. 1 grade. The CTFA Utility quality requirement would be the same as a U.S. No. 2 except that misshapened fruit and fruit with serious damage due to scarring would be permitted. This proposed rule would also require that containers of nectarines and peaches meeting the CTFA Utility quality requirement be clearly marked ''CTFA Utility.'' This proposed rule is intended to allow more nectarines and peaches into fresh market channels.

DATES: Comments must be received by April 3, 1996.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent in triplicate to the Docket Clerk, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, Room 2523–S, Washington, DC 20090–6456; or by facsimile at 202–720–5698. All comments should reference the docket number and the date and page number of this issue of the Federal Register and will be made available for public inspection at the office of the Docket Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT: Kenneth Johnson, Marketing Specialist, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, Room 2523–S, Washington, DC 20090–6456; telephone: (202) 720–2861; or Terry Vawter, Marketing Specialist, California Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, 2202 Monterey Street, Suite 102B, Fresno, California, 93721; telephone: (209) 487–5901.

SUPPLEMENTARY INFORMATION: This proposed rule is issued under Marketing Agreement and Marketing Order Nos. 916 and 917 [7 CFR Parts 916 and 917] regulating the handling of nectarines and peaches grown in California, hereinafter referred to as the orders. The orders are effective under the Agricultural Marketing Agreement Act of 1937, as amended [7 U.S.C. 601–674], hereinafter referred to as the Act.

The Department of Agriculture (Department) is issuing this proposed rule in conformance with Executive Order 12866.

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. This proposed rule is not intended to have retroactive effect. This proposed rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction in equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after the date of the entry of the ruling.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are about 300 California nectarine and peach handlers subject to regulation under the orders covering nectarines and peaches grown in California, and about 1,800 producers of these fruits in California. Small agricultural producers have been defined by the Small Business Administration [13 CFR 121.601] as those having annual receipts of less than $500,000, and small agricultural service firms are defined as those whose annual receipts are less than $5,000,000. A majority of these handlers and producers may be classified as small entities.

The Department is proposing to establish, for the 1996 season only, a California Tree Fruit Agreement (CTFA) Utility quality requirement and a container marking requirement for shipments of fruit meeting CTFA Utility.

Minimum grade requirements for fresh nectarines and peaches grown in California are in effect under § 916.356 and § 917.459, respectively. This rule would amend §§ 916.356 and 917.459 by revising paragraph (a)(1) under each section, to permit shipments of fruit meeting CTFA Utility. CTFA Utility quality requirements are the same as the U.S. No. 2 grade requirements as set forth in the U.S. Standards for Grades of Nectarines [7 CFR 51.3145 through 51.3160] and the U.S. Standards for Grades of Peaches [7 CFR 51.1210 through 51.1223], except that misshapened fruit and fruit with serious damage due to scarring would be permitted. All other applicable size and maturity requirements would remain in effect. CTFA Utility fruit would be inspected by the Federal-State Inspection Service as meeting the CTFA Utility quality requirements. CTFA

Utility fruit would be subject to assessment and all other requirements of the orders. This rule would also amend §§ 916.350 and 917.442 by adding a paragraph to each section to specify that each package or container of nectarines and peaches shipped, meeting the requirements of the newly established CTFA Utility quality requirements, must be conspicuously marked with the words ''CTFA Utility''.

Shipments of California nectarines and peaches are subject to minimum grade, size, and maturity requirements under the provisions of Federal Marketing Orders 916 (section 916.356) during the period April 1 through October 31 each year and 917 (section 917.459) during the period April 1 through November 23 each year. Currently, nectarine shipments are required to meet the requirements of U.S. No. 1 except less scarring is permitted than the U.S. No. 1 Grade but the tolerance for fruit not well formed is greater than the U.S. No. 1 Grade. Different minimum size requirements are in effect for different groupings of nectarine varieties. Currently peach shipments are required to meet the requirements of U.S. No. 1 Grade except there is an additional tolerance for fruit damage caused by open sutures. Also, different minimum size requirements are in effect for different groupings of peach varieties. Both the nectarine and peach regulations allow the shipment of fruit one size smaller than the specified minimum if the fruit meets higher maturity requirements. Both nectarine and peach shipments are subject to container, pack, and container marking requirements.

Prior to the 1995 shipping season the Nectarine Administrative and Peach Commodity Committees (Committees) considered recommending a change in the nectarine and peach regulations to allow a utility grade for these fruits (Utility grade is a lower quality fruit than U.S. No. 1). During the 1995 season, changes were made to allow use of the utility grade for California plums which are regulated under a State program. The plum utility grade was based on the California Agricultural Code requirements. The Committees voted not to recommend a utility grade for nectarines and peaches in the 1995 season. The Committees did, however, hire Dr. Dennis Nef, California State University, Fresno, to conduct a research project to study the impact of a utility grade for nectarines and peaches. The Committees also believed that the industry experiences from the plum utility grade would be helpful in making future recommendations for a utility grade for nectarines and peaches. The report prepared by Dr. Nef was presented to the Nectarine and Peach Grade and Size Subcommittees in October 1995. The report found that about 22 percent of the peaches sampled in packinghouse cull bins in 1995 would have met California agricultural code requirements. Of the nectarines sampled from packinghouse culls in that year, about 6 percent would have met California agricultural code requirements and an additional 14 percent failed marketing order quality requirements but would have met U.S. No. 1 Grade (as indicated previously, the nectarine grade requirements under the marketing order permit less fruit scarring than allowed under U.S. No. 1). The report pointed out that these findings were based on a crop season which was marked by unusual crop and weather conditions. After reviewing the report, the nectarine and peach subcommittees voted to not recommend to the full Committees that a utility grade be implemented in 1996 for nectarines and peaches citing the unusual weather conditions that resulted in below normal crops. They believed that Dr. Nef's research project should be continued for another year to allow for the collection of data based on a more normal year.

On November 29, 1995, the Department wrote to the Committees recommending that a utility grade be adopted for nectarines and peaches for the 1996 season beginning April 1, 1996. These Committees met on December 6–7, 1995, to discuss possible implementation of a utility grade for nectarines and peaches for the 1996 season. Committee members and others in attendance at the meetings expressed views in opposition to and in support of implementing a utility grade.

Commenters in opposition to a utility grade for nectarines and peaches stated that the 1995 season was not a normal season for plums, nectarines, or peaches and should not be used as a basis for recommending a utility grade. They also said that the tree fruit industry is facing competition in both domestic and in foreign markets. One commenter stated that utility grade fruit would damage the reputation of California-produced tree fruit and another stated that poor quality California plums had been shipped to Hong Kong last year and that these plums had damaged the reputation of California plums. One commenter stated that allowing a utility grade would result in inspections of fruit which only serve to verify that the fruit in the container is poor quality. Others stated that lower quality fruit is not wasted and may be used for cattle feed. Another stated that the results of the recent grower referendum indicated support for the continuation of the program and the continuation of the quality standards.

One commenter in support of a utility grade for nectarines stated that the implementation of a utility grade for plums in 1995 resulted in a $10 million increase in plum grower revenue. Commenters noted that less than 10 percent of the plum pack was utility grade. One commenter stated that while less than one percent of his organization's plum pack was utility grade, this lower grade should be available for use by nectarine and peach handlers if a market exists. Others commented that the Department had recommended a utility grade for nectarines and peaches for one year only—1996.

Data on recent production of California nectarines and peaches in relation to season average producer prices appears to indicate that lesser quality fruit could be marketed successfully without interfering with sales of higher quality fruit. The limited quantity expected to be available would be expected to have a minimal effect on consumer purchases and season average producer prices for California nectarines and peaches. Sales of lesser quality fruit to a niche market could increase producer revenue and promote consumer satisfaction.

The Department's proposal to implement the ''CTFA Utility'' quality requirement for the 1996 season would authorize fruit meeting this requirement to be shipped to market and provide actual information on consumer and retailer acceptability of such fruit. This information could then be used to supplement information collected by Dr. Nef and assist the respective industries in developing their quality requirements for the 1997 season.

Based on the foregoing, the Department proposes that a utility grade for nectarines and peaches should be implemented on an experimental basis for the 1996 season. The Department proposes, for purposes of this regulation, to define ''CTFA Utility'' to mean fruit which meets the requirements of U.S. No. 2 Grade defined in the United States Standards for Grades of Nectarines (7 CFR 51.3145 through 51.3160) and the United States Standards for Grades of Peaches (7 CFR 51.1210 through 51.1223) except that misshapened fruit and fruit with serious damage due to scarring would be permitted.

Committee members and others who commented at the December 6–7 Committee meetings indicated that a niche market may exist for utility grade

fruit and that the opportunity should be made available to market lower quality fruit to meet demand. This proposal could allow more fruit to be marketed.

In order to prevent confusion in the marketplace and to clearly differentiate shipments of ''CTFA Utility'' fruit from better quality fruit, this proposal requires that containers of ''CTFA Utility'' fruit be conspicuously marked with the words ''CTFA Utility''. In addition, shipments of such fruit would be required to meet the same container, pack, and container marking requirements in effect for shipments of higher quality fruit.

This proposed rule reflects the Department's appraisal of the need to revise the quality and container requirements for California nectarines and peaches as specified. The Department believes that this rule may have a beneficial impact on producers, handlers, and consumers of California nectarines and peaches.

Based on available information, the Administrator of the AMS has determined that this action would not have a significant economic impact on a substantial number of small entities.

A 30-day comment period is provided to allow interested persons to respond to this proposal. All written comments timely received will be considered before a final determination is made on these matters.

List of Subjects

7 CFR Part 916

Marketing agreements, Nectarines, Reporting and recordkeeping requirements.

7 CFR Part 917

Marketing agreements, Peaches, Pears, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR Parts 916 and 917 are proposed to be amended as follows:

PART 916—NECTARINES GROWN IN CALIFORNIA

1. The authority citation for 7 CFR Part 916 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. Section 916.350 is amended by adding a new paragraph (d) to read as follows:

§ 916.350 California Nectarine Container and Pack Regulation.

* * * * *

(d) During the period April 1 through October 31, 1996, each container or package when packed with nectarines meeting CTFA Utility requirements, shall bear the words ''CTFA Utility'' marked on all containers and packages, along with all other required container markings, in letters of ¾ inch minimum height on the principal display panel. Consumer bags or packages must also be clearly marked on the bag or package as ''CTFA Utility'' along with other required markings.

3. Section 916.356 is amended by revising paragraph (a)(1) to read as follows:

§ 916.356 California Nectarine Grade and Size Regulation.

(a) * * *

(1) Any lot or package or container of any variety of nectarines unless such nectarines meet the requirements of U.S. No. 1 grade: Provided, that nectarines 2 inches in diameter or smaller, shall not have fairly light colored, fairly smooth scars which exceed an aggregate area of a circle ⅜ inch in diameter, and nectarines larger than 2 inches in diameter shall not have fairly light colored, fairly smooth scars which exceed an aggregate area of a circle ½ inch in diameter: Provided further, That an additional tolerance of 25 percent shall be permitted for fruit that is not well formed but not badly misshapen. Provided further, that, during the period April 1 through October 31, 1996, any handler may handle nectarines if such nectarines meet CTFA Utility quality requirements. The term CTFA Utility means nectarines that have been inspected by the Federal or Federal-State Inspection Service and meet the requirements of the U.S. No. 2 grade as defined in the United States Standards for Grades of Nectarines [7 CFR 51.3145 through 51.3160], except that misshapened fruit and fruit with serious damage due to scarring would be permitted. The Federal or Federal-State Inspection Service shall make final determinations on maturity through the use of color guides or such other tests as determined appropriate by the inspection agency.

* * * * *

PART 917—FRESH PEARS AND PEACHES GROWN IN CALIFORNIA

1. The authority citation for 7 CFR Part 917 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. Section 917.442 is amended by adding and reserving a new paragraph (c) and adding paragraph (d) to read as follows:

§ 917.442 California Peach Container and Pack Regulation.

* * * * *

(d) During the period April 1 through November 23, 1996, each container or package when packed with peaches meeting CTFA Utility requirements, shall bear the words ''CTFA Utility'' marked on all containers and packages, along with all other required container markings, in letters of ¾ inch minimum height on the principal display panel. Additional consumer bags or packages must also be clearly marked on the bag or package as ''CTFA Utility'' along with other required markings.

3. Section 917.459 is amended by revising paragraph (a)(1) to read as follows:

§ 917.459 California Peach Grade and Size Regulation.

(a) * * *

(1) Any lot or package or container of any variety of peaches unless such peaches meet the requirements of U.S. No. 1 grade: Provided, that an additional 25 percent tolerance shall be permitted for fruit with open sutures which are damaged, but not seriously damaged. Provided, that, during the period April 1 through November 23, 1996, any handler may handle peaches if such peaches meet CTFA Utility quality requirements. The term CTFA Utility means peaches that have been inspected by the Federal or Federal State Inspection Service and meet the requirements of the U.S. No. 2 grade as defined in the United States Standards for Grades of Peaches [7 CFR 51.1210 through 51.1223], except that misshapened fruit and fruit with serious damage due to scarring would be permitted. The Federal or Federal-State Inspection Service shall make final determinations on maturity through the use of color chips or other tests as determined appropriate by the inspection agency.

* * * * *

Dated: February 26, 1996.

Sharon Bomer Lauritsen,

Deputy Director, Fruit and Vegetable Division.

[FR Doc. 96–4871 Filed 3–1–96; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD01–95–168]

RIN 2115–AE46

Special Local Regulation: World's Fastest Lobster Boat Race, Moosabec Reach, Jonesport, ME

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a permanent special local regulation for the World's Fastest Lobster Boat Race. The event will be held annually on the observed Independence Day in the waters of Moosabec Reach, Jonesport, ME. This regulation is needed to protect the boating public from the hazards associated with high speed powerboat racing in confined waters.

DATES: Comments must be received on or before May 3, 1996.

ADDRESSES: Comments should be mailed to Commander (b), First Coast Guard District, Captain John Foster Williams Federal Building, 408 Atlantic Ave., Boston, MA 02110–3350, or may be hand delivered to Room 428 at the same address, between 8 a.m. and 4 p.m., Monday through Friday, except federal holidays. Comments will become part of this docket and will be available for inspection or copying at the above address.

FOR FURTHER INFORMATION CONTACT: Lieutenant (jg) B.M. Algeo, Chief, Boating Affairs Branch, First Coast Guard District, (617) 223–8311.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their names and addresses, identify this notice (CGD01–95–168), the specific section of the proposal to which each comment applies, and give reasons for each comment. The Coast Guard requests that all comments and attachments be submitted in an 8½″ x 11″ unbound format suitable for copying and electronic filing. If that is not practical, a second copy of any bound material is requested. Persons requesting acknowledgment of receipt of comments should enclose a stamped, self-addressed postcard or envelope.

The Coast Guard will consider all comments received during the comment period. It may change this proposal in view of the comments. The Coast Guard plans no public hearing. Persons may request a public hearing by writing to Commander (b), First Coast Guard District at the address under **ADDRESSES**. The request should include reasons why a hearing would be beneficial. If it is determined that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the Federal Register.

Discussion of Proposed Amendments

The World's Fastest Lobsterboat Race is a local, traditional event that has been held for many years in Jonesport, ME. In the past, the Coast Guard has promulgated individual regulations for each year's running of the race. Given the recurring nature of the event, the Coast Guard desires to establish a permanent regulation for this event. The proposed regulation would establish a regulated area on Moosabec Reach and would provide specific guidance to control vessel movement during the race.

This event includes up to 60 power-driven lobster boats competing in heats on a marked course at speeds approaching 25 m.p.h. The Coast Guard will assign a patrol to the event, and the race course will be marked. However, due to the speed, large wakes, and proximity of the participating vessels, it is necessary to establish a special local regulation to control spectator and commercial vessel movement within this confined area. Spectator craft are authorized to watch the race from any area as long as they remain outside the designated regulated area.

The proposed section will be effective annually on the observed Independence Day holiday or as published in a Coast Guard Notice to Mariners. A rain date may be established and announced in a Coast Guard Notice to Mariners. In emergency situations, the Coast Guard patrol commander may establish escort procedures for vessels requiring transit through the regulated area.

Regulatory Evaluation

This proposal is not a significant regulatory action under section 3(f) of Executive Order 12866, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact to be so minimal that a full Regulatory Evaluation, under paragraph 10e of the regulatory policies and procedures of DOT, is unnecessary. This conclusion is based on the limited duration of the race, the extensive advisories that will be made to the affected maritime community, and the minimal restrictions the regulation places on vessel traffic.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider the economic impact on small entities of a rule for which a general notice of proposed rulemaking is required. ''Small entities'' may include (1) small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields and (2) governmental jurisdictions with populations of less than 50,000. For the reasons discussed in the Regulatory Evaluation, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposal will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This proposal contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this proposal in accordance with the principles and criteria contained in Executive Order 12612 and has determined that this proposal does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard has considered the environmental impacts of this proposal and concluded that, under paragraph 2.B.2.e.34(h) of COMDTINST 16475.1B (as revised by 59 FR 38654, July 29, 1994), this proposal is a regulation issued in conjunction with an annually issued regatta or marine parade permit and is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

Proposed Regulation

For the reasons set out in the preamble, the Coast Guard proposes to amend 33 CFR part 100 as follows:

PART 100—[AMENDED]

1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35.

2. A permanent section, § 100.110, is added to read as follows:

§ 100.110 World's Fastest Lobster Boat Race, Jonesport, ME.

(a) *Regulated Area.* The regulated area includes all waters of Moosabec Reach within the following points (NAD 83):

Latitude	*Longitude*
44°31′36″ N	067°36′54″ W
44°31′48″ N	067°34′42″ W
44°31′36″ N	067°34′42″ W
44°31′18″ N	067°36′54″ W

(b) *Special local regulations.* (1) The Coast Guard patrol commander may delay, modify, or cancel the race as conditions or circumstances require.

(2) No person or vessel may enter, transit, or remain in the regulated area unless participating in the event or unless authorized by the Coast Guard patrol commander.

(3) Vessels encountering emergencies which require transit through the regulated area should contact the Coast Guard patrol commander on VHF Channel 16. In the event of an emergency, the Coast Guard patrol commander may authorize a vessel to transit through the regulated area with a Coast Guard designated escort.

(4) All persons and vessels shall comply with the instructions of the on-scene Coast Guard patrol commander. On-scene patrol personnel include commissioned, warrant, and petty officers of the U.S. Coast Guard. Upon hearing five or more short blasts from a U.S. Coast Guard vessel, the operator of a vessel shall proceed as directed. Members of the Coast Guard Auxiliary will also be present to inform vessel operators of this regulation and other applicable laws.

(c) *Effective period.* This section is in effect from 10 a.m. to 1 p.m. annually on the observed Independence Day holiday, unless otherwise specified in a Coast Guard Notice to Mariners.

Dated: February 20, 1996.

J.L. Linnon,

Rear Admiral, U.S. Coast Guard Commander, First Coast Guard District.

[FR Doc. 96–4919 Filed 3–1–96; 8:45 am]

BILLING CODE 4910–14–M

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33 CFR Part 100

[CGD 09–95–017]

RIN 2115–AE46

Special Local Regulation; Detroit Grand Prix, Detroit River, Fleming Channel and Scott Middle Ground, MI

AGENCY: Coast Guard, DOT.

ACTION: Notice of termination.

SUMMARY: This rulemaking project was initiated to adopt regulations requiring a ''NO STOPPING ZONE'' in the Fleming Channel, and a ''CAUTION AREA'' in the Scott Middle Ground of the Detroit River during the annual Detroit Grand Prix held on Belle Isle. The project is no longer necessary due to a further review of the event by the Coast Guard that determined mariners observing the Inland Navigation Rules will be able to safely watch the event. The Coast Guard is therefore terminating further rulemaking under docket number CGD09–95–017.

FOR FURTHER INFORMATION CONTACT:

Marine Science Technician Second Class Jeffrey M. Yunker, Ninth Coast Guard District, Aids to Navigation Branch, 1240 East Ninth Street, Cleveland, Ohio 44199–2060, (216) 522–3990.

SUPPLEMENTARY INFORMATION:

Regulatory History

On July 26, 1995, the Coast Guard published a Notice of Proposed Rulemaking entitled Special Local Regulation; Detroit Grand Prix, Detroit River, Fleming Channel and Scott Middle Ground, MI in the Federal Register (60 FR 38291). The deadline for the submission of comments was September 25, 1995. The Coast Guard received one comment on the proposal. The proposal recommended both the ''NO-STOPPING ZONE'' and ''CAUTION AREA'' be made into anchorage areas. The recommended size of the anchorage area in the Scott Middle Ground would also be greatly decreased. Further review of the event's history was conducted by Coast Guard Group Detroit and Coast Guard Station Belle Isle. It was determined that no regulated areas are required for this event. Mariners will be able to safely watch the event while adhering to the Inland Navigation Rules. Regulations were first written for this event in 1992. The event was expected to draw an estimated 2000 spectator craft which could pose hazards to navigation in the area. A large number of spectator craft has not been encountered during the event due to the poor visibility of the event from the water. Because there is no further need for regulations during the Detroit Grand Prix, the Coast Guard is terminating further rulemaking under docket number CGD09–95–017.

Dated: February 15, 1996.

G. F. Woolever,

Rear Admiral, U.S. Coast Guard, Commander, Ninth Coast Guard District.

[FR Doc. 96–4921 Filed 3–1–96; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 122, 123, 403, and 501

[FRL–5432–8]

National Pollutant Discharge Elimination System Permit Application Requirements for Publicly Owned Treatment Works and Other Treatment Works Treating Domestic Sewage

AGENCY: Environmental Protection Agency.

ACTION: Extension of comment period.

SUMMARY: The Environmental Protection Agency (EPA) announces that the public comment period for the National Pollutant Discharge Elimination System (NPDES) Permit Application Requirements for Publicly Owned Treatment Works and Other Treatment Works treating Domestic Sewage proposed rulemaking (60 FR 62546, December 6, 1995) will be extended from March 6, 1996 to March 29,1996 due to the effects of the recent Federal government shutdown. EPA is proposing to revise its NPDES permit application requirements and to develop a new permit application form, Form 2A, in order to streamline the permit application process for POTWs and improve the quality of permits issued to those facilities. The Agency is also proposing permit application requirements and an application form, Form 2S, for Treatment Works Treating Domestic Sewage to provide permit writers with the information necessary to issue effective permits for these facilities. In developing these proposed forms and application requirements, the Agency has consulted with State and municipal representatives and has addressed their concerns. As a result, the proposed forms and applications would minimize the burden on permittees and permitting authorities and result in greater environmental protection through more effective NPDES permits.

DATES: In order to be considered, comments must be received on or before March 29, 1996.

ADDRESSES: Comments should be addressed to Municipal and Sludge Application Rule Comment Clerk, Water Docket MC–4101; United States Environmental Protection Agency, 401 M Street SW., Washington, DC, 20460. Commenters are also requested to submit an original and 3 copies of their written comments as well as an original and 3 copies of any attachments, enclosures, or other documents referenced in the comments.

Commenters who want receipt of their comments acknowledged should include a self-addressed, stamped envelope. All comments must be postmarked or delivered by hand by March 29, 1996. No facsimiles (faxes) will be accepted.

EPA will also accept comments electronically. Comments should be addressed to the following Internet address: ow-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Electronic comments will be transferred into a paper version for the official record. EPA will attempt to clarify electronic comments if there is an apparent error in transmission. Comments provided electronically will be considered timely if they are submitted electronically by 11:59 p.m. (Eastern time) March 29, 1996. EPA is experimenting with electronic commenting, therefore commenters may want to submit both electronic comments and duplicate paper comments. This document has also been placed on the Internet for public review and downloading at the following location: gopher.epa.gov.

FOR FURTHER INFORMATION CONTACT: For information on Form 2A and municipal wastewater permitting issues in this notice, contact Robin Danesi, (202) 260–2991, Permits Division (4203), United States Environmental Protection Agency, 401 M Street S.W., Washington, D.C., 20460.

For information on Form 2S and sewage sludge permitting issues in this notice, contact Wendy Bell, (202) 260–9534, Permits Division (4203), United States Environmental Protection Agency, 401 M Street S.W., Washington, D.C., 20460. Copies of the proposed rulemaking can be obtained from the National Center for Environmental Publications and Information, Cincinnati, Ohio, (800) 553–6847, document number 833–Z–95–006.

Dated: February 26, 1996.

Robert Perciasepe,

Assistant Administrator for Water.

[FR Doc. 96–4831 Filed 3–1–96; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 96–15, RM–8748]

Radio Broadcasting Services; Barron, WI

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Barron Broadcasting Corporation requesting the allotment of Channel 256A at Barron, Wisconsin, as that community's first local FM broadcast service. Canadian concurrence will be requested for this allotment at coordinates 45–24–00 and 91–51–12.

DATES: Comments must be filed on or before April 22, 1996, and reply comments on or before May 7, 1996.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, as follows: Steven T. Moravec, Barron Broadcasting Corporation, 1407 Sumner Street, Suite 200, St. Paul, Minnesota 55116–2645.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rule Making,* MM Docket No. 96–15, adopted February 5, 1996, and released February 28, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 2100 M Street, NW., Suite 140, Washington, DC 20037, (202) 857–3800.

Provisions of the Regulatory Flexibility Act of l980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 96–4877 Filed 3–1–96; 8:45 am]

BILLING CODE 6712–01–F

47 CFR Part 73

[MM Docket No. 96–14, RM–8746]

Television Broadcasting Services; Memphis, TN

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition by Cossitt Library d/b/a Memphis Shelby County Public Library seeking the allotment of UHF TV Channel 56 to Memphis, Tennessee, and its reservation for noncommercial educational use. Channel *56 can be allotted to Memphis in compliance with the minimum distance separation requirements of Sections 73.610 and 73.698 of the Commission's Rules without the imposition of a site restriction. The coordinates for *56 are 35–08–58 and 90–02–56. Memphis is not affected by the Commission's temporary freeze on new television allotments in certain metropolitan areas.

DATES: Comments must be filed on or before April 22, 1996, and reply comments on or before May 7, 1996.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Matthew H. McCormick, Reddy, Begley & McCormick, 1001 22nd Street, NW., Suite 350, Washington, DC 20037 (Counsel for petitioner).

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Notice of Proposed Rule Making,* MM Docket No. 96–14, adopted February 5, 1996, and released February 28, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, ITS, Inc., (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Television broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 96–4875 Filed 3–1–96; 8:45 am]

BILLING CODE 6712–01–F

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 192, 193, and 195

[Docket No. PS–143]

RIN 2137–AC74

Periodic Updates to the Pipeline Safety Regulations

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

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: This NPRM proposes to update the references to voluntary specifications and standards to reflect more recently published editions of each document. Many referenced standards currently cited in the code are outdated. This NPRM would enable pipeline operators to utilize current technology, materials, and practices, thereby reducing costs and enhancing economic growth. This is consistent with the President's goals of regulatory reinvention and improvement of customer service to the American people. In addition, this NPRM proposes to eliminate the requirements for odorization of hydrogen transmission lines. The purpose of this proposal is to eliminate unnecessary regulatory burdens without compromising safety.

DATES: Comments to this NPRM are due on or before April 3, 1996.

ADDRESSES: Written comments regarding this NPRM should be sent to the RSPA dockets office, attention Verdell Simpkins, room 8421, U.S. Department of Transportation, 400 7th Street SW., Washington, DC. 20590.

FOR FURTHER INFORMATION CONTACT: Eben M. Wyman, (202) 366–0918, regarding the subject matter of this Notice; or the Dockets Unit, (202) 366–4453, for copies of this Notice or other material in the docket.

SUPPLEMENTARY INFORMATION:

Background

Regulatory Reinvention Initiative

In March of 1995, President Clinton issued a memorandum to heads of departments and agencies calling for a review of all agency regulations and elimination or revision of those that are outdated or in need of reform. The ''Regulatory Reinvention Initiative'' (RRI) was a Presidential directive requiring Federal regulatory agencies, among other things, to conduct a page-by-page review of all agency regulations, cutting or revising those that were obsolete, intrusive, or better handled by parties other than the Federal government (i.e., private business, State or local government).

RSPA has reviewed the pipeline safety regulations and is making changes and revisions where deemed appropriate. In addition, RSPA conducted three outreach meetings in 1995 in Dallas, TX, Lakewood CO, and Houston, TX in support of the President's goal of enhancing partnership with the pipeline industry. Comments received in these outreach meetings and in the RRI docket have resulted in the proposals in this NPRM.

Incorporations by Reference

RSPA has reviewed the voluntary consensus standards currently referred to in the pipeline safety regulations and in its appendices, and proposes to update the various voluntary consensus standards that are cited throughout 49 CFR Parts 192, 193, and 195. The respective organizations responsible for producing these standards often update or revise them to better suit the needs of changing pipeline systems.

Parts 192, 193, and 195 incorporate by reference all or portions of over 40 different documents or their equivalent containing practices, codes, standards, and specifications developed and published by technical organizations, including the American Petroleum Institute, American Gas Association, American Society of Mechanical Engineers, American Society of Civil Engineers, American Concrete Institute, American Society of Testing and Materials, International Conference of Building Officials, Manufacturers Standardization Society of the Valve and Fittings Industry, and National Fire Protection Agency. Many of the editions currently referenced are now out of print or obsolete. Later published editions of these documents utilize or focus on up-to-date technology. Pipeline operators could be unnecessarily burdened with design and construction requirements that are referred to in earlier editions.

To avoid these burdens and allow operators to benefit from various technological improvements in materials and methods, this NPRM proposes to update references to these outdated documents where the latest editions have been reviewed and accepted by OPS. The later editions referenced are set forth by name and date in the proposed amendments to appendices A and B of Part 192, appendix A of Part 193, and Part 195 (§ 195.3). The order and appearance in the CFR of the consensus standards would remain unchanged. Only the year representing the edition of the document would be revised. In addition to the proposed incorporating of current standards, some minor conforming amendments are also proposed.

The address for the American Society for Testing and Materials (ASTM) has changed. The correct address is: 100 Barr Harbor Drive, Conshohocken, PA, 19428. Parts 192 and 195 will be amended to reflect this change.

Section 192.63(a)(1) would be revised to refer to the 1995 edition of ASTM D 2513, replacing the 1987 edition.

Section 192.189(c) would be amended by correcting the reference to the National Electric Code. The ''C1'' nomenclature identifies the electrical code committee within the American National Standards Institute (ANSI), but is in no way related to identifying the code itself. The correct reference is ''ANSI/NFPA 70'', and would be so amended under the proposed rulemaking.

Requirement to Odorize Hydrogen Transmission Pipelines

In support of the President's goal to eliminate obsolete and unnecessary regulations, RSPA proposes to amend 49 CFR 192.625 to eliminate the odorization requirement for hydrogen transmission lines in cases where the odorization interferes with industrial end uses. Hydrogen pipelines that were operating without an odorant before May 5, 1975, are already exempt from the odorization requirement.

The requirement to odorize hydrogen in new and existing hydrogen transmission lines that do not fall under this ''grandfather clause'' may impose unreasonable costs on industry without any quantifiable safety benefit. This is because odorization renders hydrogen, which is primarily an industrial process feedstock, unfit for its uses without expensive deodorization. RSPA recognized that problems with the odorization requirements could be expected to occur after the ''grandfather'' date, but stated that it ''* * * prefers to address these problems on an individual basis in the waiver process.'' 40 FR 20279 at 20,280–281 (May 9, 1971).

There appears to be no advantage to continuing to use a waiver procedure. The potential advantages of odorization for hydrogen pipelines appear to be negligible, while the costs to industry for removal of the odorant may be unreasonably large. Also, the magnitude of any hazard from hydrogen pipeline leaks appear to be small. Hydrogen is not only much less dense than air, and thus tends to dissipate rapidly, but also has relatively low energy content for a given volume compared to natural gas. In addition, it appears that the ignition energy of hydrogen is so low that even static electricity can ignite the gas, making a build-up of gas unlikely. In addition, hydrogen is not generally used as a fuel, but rather as an industrial feedstock. Odorization renders hydrogen unfit for most of its industrial uses. Odorant can poison or reduce the reactivity of catalysts, make the end product unfit for the purpose for which it is intended, or reduce the percentage completion of a chemical reaction. This means that the odorant needs to be removed, an expensive process, prior to its use in manufacture.

The proposed language adds a paragraph to Section 192.625 to except from odorization requirements transmission lines if the gas is intended for an industrial plant using hydrogen in a manufacturing process.

Rulemaking Analyses

Executive Order 12866 and DOT Regulatory Policies and Procedures

This proposed rule is not considered a significant regulatory action under section 3(f) of Executive Order 12866 and, therefore, was not subject to review by the Office of Management and Budget (OMB). The notice is also not considered significant under the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034).

Executive Order 12612

The proposed rule has been analyzed with the principles and criteria in Executive Order 12612 (''Federalism''), and does not have sufficient federalism impacts to warrant the preparation of a federalism assessment.

Regulatory Flexibility Act

Based on the facts available, I certify that this proposal will not, if promulgated, have a significant economic impact on a substantial number of small entities. This certification is subject to modification as a result of a review of comments received in response to this proposal.

Paperwork Reduction Act

The cumulative effect of the proposals in this NPRM will be no change in the current information collection burden requirements for gas, hazardous liquid, and carbon dioxide pipeline operators.

List of Subjects

49 CFR Part 192

Incorporation by reference, Natural gas, Pipeline safety.

49 CFR Part 193

Incorporation by reference, Liquefied natural gas (LNG), Pipeline safety.

49 CFR Part 195

Anhydrous ammonia, Carbon dioxide, Incorporation by reference, Petroleum, Pipeline safety.

In consideration of the foregoing, RSPA proposes to amend 49 CFR parts 192, 193, and 195 as follows:

PART 192—[AMENDED]

1. The authority citation for part 192 continues to read as follows:

Authority: 49 U.S.C. 60101 *et seq.*; 49 CFR 1.53.

2. Paragraph (a)(1) of § 192.63 would be revised to read as follows:

§ 192.63 Marking of materials.

(a) * * *

(1) As prescribed in the specification or standard to which it was manufactured, except that thermoplastic fitting must be marked in accordance with the 1995 edition of ASTM D 2513; or

* * * * *

3. Paragraph (c) of § 192.189 would be revised to read as follows:

§ 192.189 Vaults: Drainage and waterproofing.

* * * * *

(c) Electrical equipment in vaults must conform to the applicable requirements of Class 1, Group D, of the National Electric Code, ANSI/NFPA 70.

4. Section 192.625 would be amended by revising paragraphs (b)(2)(iv)(C) and (b)(3) and by adding paragraph (b)(4) to read as follows:

§ 192.625 Odorization of gas.

* * * * *

(b) * * *

(2) * * *

(iv) * * *

(C) Reduces the percentage completion of a chemical reaction;

(3) In the case of a lateral line which transports gas to a distribution center, at least 50 percent of the length of that line is in a Class 1 or Class 2 location; or

(4) The combustible gas is hydrogen intended for use as a feedstock in a manufacturing process.

* * * * *

5. Appendix A of part 192 would be amended by revising paragraphs *I.* D, *II.* A 1, 3, and 4, *II.* B, *II.* C 3–6, and *II.* E to read as follows:

Appendix A to Part 192—Incorporated by Reference

I. List of Organizations and Addresses

* * * * *

D. American Society for Testing and Materials (ASTM), 100 Barr Harbor Drive, Conshohocken, PA 19428.

* * * * *

II. Documents Incorporated by Reference. (Numbers in Parentheses Indicate Applicable Editions.)

A. * * *

1. API Specification 5L ''Specification for Line Pipe (41st edition, 1995).

* * * * *

3. API Specification 6D ''Specification for Pipeline Valves (Gate, Plug, Ball, and Check Valves)'' (21st edition, 1994).

4. API Standard 1104 ''Welding of Pipelines and Related Facilities'' (18th edition, 1994).

B. American Society for Testing and Materials (ASTM):

1. ASTM Designation: A53 ''Standard Specification for Pipe, Steel, Black and Hot-Dipped, Zinc-Coated Welded and Seamless'' (A53–94).

2. ASTM Designation A106 ''Standard Specification for Seamless Carbon Steel Pipe for High-Temperature Service'' (A106–94).

3. ASTM Designation: A333/A333M ''Standard Specification for Seamless and Welded Steel Pipe for Low-Temperature Service'' (A333/A333M–94).

4. ASTM Designation: A372/A372M ''Standard Specification for Carbon and Alloy Steel Forgings for Thin-Walled Pressure Vessels'' (A372/A372M–95).

5. ASTM Designation: A381 ''Standard Specification for Metal-Arc-Welded Steel Pipe for Use With High-Pressure Transmission Systems'' (A 381–93).

6. ASTM Designation: A671 ''Standard Specification for Electric-Fusion-Welded

Steel Pipe for Atmospheric and Lower Temperatures'' (A 671–94).

7. ASTM Designation: A672 ''Standard Specification for Electric-Fusion-Welded Steel Pipe for High-Pressure Service at Moderate Temperatures'' (A672–94).

8. ASTM Designation A691 ''Standard Specification for Carbon and Alloy Steel Pipe, Electric-Fusion-Welded for High-Pressure Service at High Temperatures'' (A691–93).

9. ASTM Designation D638 ''Standard Test Method for Tensile Properties of Plastics'' (D638–94b).

10. ASTM Designation D2513 ''Standard Specification for Thermoplastic Gas Pressure Pipe, Tubing and Fittings'' (D2513–95a).

11. ASTM Designation D2517 ''Standard Specification for Reinforced Epoxy Resin Gas Pressure Pipe and Fittings'' (D2517–94).

C. * * *

3. ASME Boiler and Pressure Vessel Code, Section I ''Power Boilers'' (1995 edition with addenda).

4. ASME Boiler and Pressure Vessel Code, Section VIII, Division 1 ''Pressure Vessels'' (1995 edition with addenda).

5. ASME Boiler and Pressure Vessel Code, Section VIII, Division 2 ''Pressure Vessels: Alternative Rules'' (1995 edition with addenda).

6. ASME Boiler and Pressure Vessel Code, Section IX ''Welding and Brazing Qualifications'' (1995 edition with addenda).

* * * * *

E. National Fire Protection Association (NFPA):

1. ANSI/NFPA 30 ''Flammable and Combustible Liquids Code'' (1995).

2. ANSI/NFPA 58 ''Standard for the Storage and Handling of Liquefied Petroleum Gases'' (1995).

3. ANSI/NFPA 59 ''Standard for the Storage and Handling of Liquefied Petroleum Gases at Utility Gas Plants'' (1995).

4. ANSI/NFPA 70 ''National Electrical Code'' (1996).

PART 193—[AMENDED]

1. The authority citation for part 193 continues to read as follows:

Authority: 49 U.S.C. 60101 *et seq.*; 49 CFR 1.53.

2. Appendix A to part 193 would be amended by revising paragraphs *II.* C, *II* D .1 and 3, *II.* E, *II.* F, and *II.* G, to read as follows:

Appendix A to Part 193—Incorporation by Reference

* * * * *

II. Documents Incorporated by Reference. (Numbers in Parentheses Indicate Applicable Editions.)

* * * * *

C. American Society of Civil Engineers (ASCE):

1. ASCE 7–88 ''Minimum Design Loads for Buildings and Other Structures'' (1995)

D. * * *

1. API Specification 6D ''Specification for Pipeline Valves (Gate, Plug, Ball, and Check Valves)'' (21st edition, 1994).

* * * * *

3. API Standard 1104 ''Welding of Pipelines and Related Facilities'' (18th edition, 1994).

E. American Society of Mechanical Engineers (ASME):

1. ASME/ANSI B31.3 ''Chemical Plant and Petroleum Refinery Piping'' (1993).

2. ASME/ANSI B31.5 ''Refrigeration Piping'' (1992).

3. ASME/ANSI B31.8 ''Gas Transmission and Distribution Piping Systems'' (1995).

4. ASME Boiler and Pressure Vessel Code, Section I ''Power Boilers'' (1995 edition with Addenda).

5. ASME Boiler and Pressure Vessel Code, Section IV, ''Heating Boilers'' (1995 edition with Addenda).

6. ASME Boiler and Pressure Vessel Code, Section VIII, Division 1 ''Pressure Vessels'' (1995 edition with Addenda).

7. ASME Boiler and Pressure Vessel Code, Section VIII, Division 2, ''Pressure Vessels: Alternative Rules'' (1995 edition with Addenda).

8. ASME Boiler and Pressure Vessel Code, Section IX, ''Welding and Brazing Qualifications'' (1995 edition with Addenda).

F. International Conference of Building Officials (ICBU):

1. ''Uniform Building Code'' (UBC) (1994).

G. National Fire Protection Association (NFPA):

1. ANSI/NFPA 30 ''Flammable and Combustible Liquids Code'' (1993)

2. ANSI/NFPA 37 ''Standard for the Installation and Use of Stationary Combustion Engines and Gas Turbines'' (1994).

3. ANSI/NFPA 51B ''Standard for Fire Prevention in Use of Cutting and Welding Processes'' (1994).

4. ANSI/NFPA 59A ''Standard for the Production, Storage, and Handling of Liquefied Natural Gas (LNG)'' (1994).

5. ANSI/NFPA 70 ''National Electrical Code'' (1996).

PART 195—[AMENDED]

1. The authority citation for part 195 continues to read as follows:

Authority: 49 U.S.C. 60101 *et seq.*; 49 CFR 1.53.

2. Section 195.3 would be amended by revising paragraph (b)(6) and paragraphs (c) (2)–(5) to read as follows:

§ 195.3 Matter incorporated by reference.

* * * * *

(b) * * *

(6) American Society for Testing and Materials (ASTM), 100 Barr Harbor Drive, Conshohocken, PA 19428.

(c) * * *

(2) American Petroleum Institute (API):

(i) API Specification 5L ''Specification for Line Pipe'' (41st edition, 1995).

(ii) API Specification 6D ''Specification for Pipeline Valves (Gate, Plug, Ball, and Check Valves)'' (21st Edition, 1994).

(iii) API Specification 1104 ''Welding of Pipelines and Related Facilities'' (18th edition, 1994).

(3) American Society of Mechanical Engineers (ASME):

(i) ASME/ANSI B16.9 ''Factory-Made Wrought Steel Buttwelding Fittings'' (1993).

(ii) ASME/ANSI B31.4 ''Liquid Transportation Systems for Hydrocarbons, Liquid Petroleum Gas, Anhydrous Ammonia, and Alcohols'' (1992 edition with 1994 addenda).

(iii) ASME/ANSI B31.8 ''Gas Transmission and Distribution Piping Systems'' (1995)

(iv) ASME/ANSI B31G ''Manual for Determining the Remaining Strength of Corroded Pipelines'' (1991).

(v) Boiler and Pressure Vessel Code, Section VIII, Division 1 ''Pressure Vessels'' (1995 with Addenda).

(vi) ASME Boiler and Pressure Vessel Code, Section IX ''Welding and Brazing Qualifications'' (1995 with Addenda).

(4) Manufacturers Standardization Society of the Valve and Fittings Industry, Inc. (MSS):

(i) MSS SP–75 ''Specification for High Test Wrought Butt Welding Fittings'' (1993).

(ii) [Reserved]

(5) American Society for Testing and Materials (ASTM):

(i) ASTM Designation: A 53 ''Standard specification for Pipe, Steel, Black and Hot-Dipped, Zinc-Coated Welded and Seamless'' (A 53–94).

(ii) ASTM Designation: A 106 ''Standard Specification for Seamless Carbon Steel Pipe for High-Temperature Service'' (A 106–94).

(iii) ASTM Designation: A 333/A 333M ''Standard Specification for Seamless and Welded Steel Pipe for Low-Temperature Service''(A 333/A 333M–94).

(iv) ASTM Designation: A 381 ''Standard Specification for Metal-Arc-Welded Steel Pipe for Use With High-Pressure Transmission Systems'' (A 381–93).

(v) ASTM Designation: A 671 ''Standard Specification for Electric-Fusion-Welded Steel Pipe for Atmospheric and Lower Temperatures'' (A 671–94).

(vi) ASTM Designation: A 672 ''Standard Specification for Electric-Fusion-Welded Steel Pipe for High-Pressure Service at Moderate Temperatures'' (A 672–94).

(vii) ASTM Designation: A 691 ''Standard Specification for Carbon and Alloy Steel Pipe Electric-Fusion-Welded for High-Pressure Service at High Temperatures'' (A 691–93).

Issued in Washington, DC on February 23, 1996.

Richard B. Felder,

Associate Administrator for Pipeline Safety.

[FR Doc. 96–4622 Filed 3–1–96; 8:45 am]

BILLING CODE 4910–60–P

Notices

Federal Register
Vol. 61, No. 43
Monday, March 4, 1996

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 AGRICULTURE

Forest Service

Formulation of the Prerevision Review Process for the Cibola National Forest Land and Resource Management Plan Revision

AGENCY: Forest Service, USDA.

SUMMARY: The Cibola National Forest requests comments on draft Prerevision review topics that have been developed through the monitoring of the current Forest Plan and interdisciplinary team review. This is an invitation to the public and representatives of government entities to express their ideas and suggestions on what needs to be changed in the current Forest Plan. Upon completion of the prerevision review, the Regional Forester shall initiate the forest plan revision process by publishing a Notice of intent to revise the forest plan and to prepare the draft environmental impact statement.

DATES: This notice is effective March 6, 1996. Comments must be submitted in writing on or before April 15, 1996.

ADDRESSES: Direct comments to: Jeanine A. Derby, Forest Supervisor, Cibola National Forest, 2113 Osuna Road NE, Suite A, Albuquerque, New Mexico, 87110.

FOR FURTHER INFORMATION CONTACT: Barney Lyons, Forest Planner, Cibola National Forest at 505–761–4650.

Background

The Land and Resource Management Plan defines the long-term direction for managing the Cibola National Forest and the Kiowa, Rita Blanca, Black Kettle, and McClellan Creek National Grasslands. The Forest Plan will take an ecological approach to achieve multiple-use management of the National Forest and National Grasslands. It means that we must blend the needs of people and environmental values in such a way that the National Forest and Grasslands represent diverse, healthy, productive, and sustainable ecosystems. The present Cibola National Forest Plan was approved in 1985 and has been amended six times. Revision of a forest plan should occur about every 10 years, but no later than 15 years from the date of approval of the original plan or the latest plan revision.

A prerevision review of the forest plan has been conducted to identified changed conditions and/or new information which appears to indicate a need to change direction in the current plan. The Cibola National Forest developed criteria to separate between Revision Topics, Implementation Topics, Legislative Topics, Topics for other Government Entities, and Research Topics. Other information required by the National Forest Management Act will also be evaluated with the topics that indicate a need for change, such as roadless areas and wild and scenic rivers. This review was a combination of interdisciplinary team efforts and Forest plan monitoring. We are seeking comments on these topics as well as any other topics that might surface.

The revision topics that surfaced during the prerevision review are: balancing land capability with resource demand; watershed condition assessment and water uses, rights, quality and availability assessment; biological diversity; Native American collaboration; Land Grant Community collaboration; land uses; oil and gas leasing; population growth and social demographics; rural community economics; Scenery Management System; urban interface; wilderness management; recreation management; fire management; response to legal mandates; access management; and Range Management.

Implementation Topics were topics that needed additional emphasis but the present plan provide adequate direction for implementation. These topics are: infrastructure; balanced heritage resource management; land line location; limiting factors for wildlife; monitoring; resource inventories; small products as a vegetation management tool; planning coordination with local governments; Recreation Opportunity Spectrum, roadless areas and other special areas; public information and education; Research Natural Areas; budget constraints and workforce reductions; and law enforcement.

Several topics will be referred to other agencies for their consideration and input. These are:

Clean Air Act implementation; State wildlife departments regulations and hunting seasons; State forestry's responsibility for forestry practices on state and private lands; State's water quality management under the Clean Water Act; and the Department of Energy/Department of Defense responsibilities on land withdrawals.

Some of the research topics include:

Social impact on ecosystems; bats and their habitat; recreation uses and acceptable limits; grassland ecosystems and disturbances; pinyon-juniper treatment thresholds; medicinal plants and other forest products; bio-solid effects and applications; stream channel/wet meadow restoration, and health effects of smoke from prescribed burning.

No legislative topics have surfaced to date.

A copy of the draft Prerevision Review Topics is available at the Cibola National Forest Supervisor's Office, 2113 Osuna Road NE, Suite A, Albuquerque, New Mexico 87110, 505–761–4650.

Dated: February 26, 1996.

Kenneth D. Knarr,

Acting Forest Supervisor.

[FR Doc. 96–4937 Filed 3–1–96; 8:45 am]

BILLING CODE 3410–11–M

Klamath Provincial Advisory Committee (PAC)

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Klamath Provincial Advisory Committee will meet on March 27 and March 28, 1996 at the Best Western Ponderosa Inn Conference Room, 2220 Pine Street, Redding, California. The meeting will begin at 10:00 a.m. on March 27 and adjourn at 5:30 p.m. The meeting will reconvene at 8:00 a.m. on March 28 and continue until 4:00 p.m. Agenda items to be covered include: (1) Province-wide forest health work group discussion/presentation; (2) salvage timber sale monitoring; (3) Regional Ecosystem Office monitoring proposal; (4) Guidance for salvage sale activity in sensitive areas; (5) standing committee reports; and (6) public comment

periods. All PAC meetings are open to the public. Interested citizens are encouraged to attend.

FOR FURTHER INFORMATION CONTACT: Connie Hendryx, USDA, Klamath National Forest, 1312 Fairlane Road, Yreka, California 96097; telephone 916–842–6131, (FTS) 700–467–1309.

Dated: February 22, 1996.

Barbara Holder,

Designated Federal Official.

[FR Doc. 96–4869 Filed 3–1–96; 8:45 am]

BILLING CODE 3410–11–M

Natural Resources Conservation Service

PTE–26b Brady Canal Hydrologic Restoration Project, Terrebonne Parish, Louisiana; Finding of No Significant Impact

AGENCY: Natural Resources Conservation Service, USDA.

ACTION: Notice of a Finding of No Significant Impact.

SUMMARY: Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR Part 1500); and the Natural Resources Conservation Service Guidelines (7 CFR Part 650); the Natural Resources Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Brady Canal Hydrologic Restoration Project, Terrebonne Parish, Louisiana.

FOR FURTHER INFORMATION CONTACT: Donald W. Gohmert, State Conservationist, Natural Resources Conservation Service, 3737 Government Street, Alexandria, Louisiana 71302; telephone (318) 473–7751.

SUPPLEMENTARY INFORMATION: The environmental assessment of the federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Donald W. Gohmert, State Conservationist, has determined that the preparation and review of an environmental impact statement is not needed for this project.

This plan proposes to maintain and enhance wetland loss on 7,653 acres of combination marsh in Terrebonne Parish, Louisiana. Project measures include 315 linear feet of rock plug, 15,000 linear feet of earthen embankment, maintenance of 21,600 linear feet of overflow embankment, replacement of three fixed crest weirs with variable crest sections, replacement of one fixed crest weir, construction of one fixed crest weir with a barge bay, and two stabilized channel rock cross-sections.

The notice of a Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various federal, state, and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting Donald W. Gohmert.

No administrative action in implementation of the proposal will be taken until 30 days after the date of this publication in the Federal Register.

Donald W. Gohmert,

State Conservationist.

[FR Doc. 96–4863 Filed 3–1–96; 8:45 am]

BILLING CODE 3410–16–M

Rural Telephone Bank

Determination of the 1995 Fiscal Year Interest Rates on Rural Telephone Bank Loans

AGENCY: Rural Telephone Bank.

ACTION: Technical correction to Notice of 1995 fiscal year interest rates determination.

SUMMARY: The Rural Telephone Bank (Bank) hereby announces a technical amendment to a footnote regarding the Bank's calculation of the interest rate to be applied to loan advances made from the financing account during fiscal year 1995.

FOR FURTHER INFORMATION CONTACT: Barbara L. Eddy, Deputy Assistant Governor, Rural Telephone Bank, room 4056, South Building, U.S. Department of Agriculture, Washington, DC 20250, telephone number (202) 720–9556.

SUPPLEMENTARY INFORMATION: In accordance with 7 CFR 1610.10, on November 9, 1995, the Bank published its fiscal year 1995 interest rates for advances on liquidating and financing account loans (60 FR 56561). Interest rates for advances on liquidating and financing account loans are based on the Bank's cost of money. the cost of money rate methodology is the same for both accounts. It develops a weighted average rate for the Bank's cost of money considering total fiscal year loan advances; the excess of fiscal year loan advances over amounts received in the fiscal year from the issuances of Class A, B, and C stocks, debentures and other obligations; and the costs to the Bank of obtaining funds from these sources.

The interest rate for advances during fiscal year 1995 on financing account loans was established as shown in Table 1b, Financing Account, Cost of Money Rate, of the aforementioned notice (60 FR 56563). One component of the calculation to determine the cost of money rate for fiscal year 1995 was the issuance of debentures and other obligations.

As indicated in footnote number 2 to Table 1b, obligations incurred by the Bank, that is, funds borrowed for fiscal year 1995 financing account loan advances, were in excess of its borrowers' demands by approximately $90.4 million. In conformance with the established practice of the Bank, these excess funds would therefore be carried over to make advances in the next fiscal year (fiscal year 1996).

Subsequent to the Bank establishing its costs of money rate for fiscal year 1995, the practice of carrying over funds from one fiscal year to another was discontinued. The $90.4 million in excess funds will therefore not be used to make advances in fiscal year 1996 as previously indicated in footnote number 2 to Table 1b (60 FR 56563).

The Bank's fiscal year 1995 cost of money rates previously established at 6.04% and 6.88% for advances from the liquidating account and financing account, respectively, remain unchanged (60 FR 56561).

Dated: February 26, 1996

Wally Beyer,

Governor, Rural Telephone Bank.

[FR Doc. 96–4872 Filed 3–1–96; 8:45 am]

BILLING CODE 3410–15–M

Rural Utilities Service

Notice of Request for Reinstatement of a Previously Approved Information Collection for Which Approval Has Expired

AGENCY: Rural Utilities Service, USDA.

ACTION: Proposed collection; comments requested.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended), this notice announces the Rural Utilities Service's (RUS) intentions to reinstate a previously approved information collection for which approval has expired.

DATES: Comments on this notice must be received by May 3, 1996.

FOR FURTHER INFORMATION CONTACT: Dawn D. Wolfgang, Management Analyst, Program Support Staff, Rural Utilities Service, U.S. Department of

Agriculture, 14th & Independence Ave., SW., AG Box 1522, Washington, DC 20250–1522. Telephone: (202) 720–0812. FAX: (202) 720–4120.

SUPPLEMENTARY INFORMATION:

Title: Certification of Authority.

OMB Control Number: 0572–0074.

Type of Request: Reinstatement, with change, of a previously approved information collection for which approval has expired.

Abstract: The Rural Utilities Service (RUS) manages loan programs in accordance with the Rural Electrification Act of 1936 (7 U.S.C. 901 *et seq.*), as amended. A major factor in managing loan programs is controlling the advance of funds. One reason to control funds is so that the actual borrowers get their money. The use of RUS Form 675 allows this control to be achieved by providing a list of authorized signatures against which signatures requesting funds are compared. RUS Form 675 provides an effective control against the unauthorized release of funds by providing a list of authorized signatures. OMB Circular A–123, Management Accountability and Control, states that information should be maintained on a current basis and that cash should be protected from unauthorized use. This form allows borrowers to keep RUS up-to-date of any changes in signature authority and controls the release of funds only to authorized borrower representatives.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.1 of an hour per response.

Respondents: Small business or organization.

Estimated Number of Respondents: 490

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 49.

Copies of this information collection, and related form and instructions, can be obtained from Dawn Wolfgang, Program Support Staff, at (202) 720–0812.

Comments are invited on: (a) Whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments may be sent to: F. Lamont Heppe, Jr., Deputy Director, Program Support Staff, Rural Utilities Service, U.S. Department of Agriculture, 14th & Independence Ave., SW., AG Box 1522, Washington, DC 20250–1522. FAX: (202) 720–4120.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Dated: February 23, 1996.

Wally Beyer,

Administrator, Rural Utilities Service.

[FR Doc. 96–4962 Filed 3–1–96; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 803]

Grant of Authority for Subzone Status Mercedes-Benz U.S. International, Inc. (Motor Vehicles), Tuscaloosa County, Alabama

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, by an Act of Congress approved June 18, 1934, an Act ''To provide for the establishment . . . of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' as amended (19 U.S.C. 81a–81u) (the Act), the Foreign-Trade Zones Board (the Board) is authorized to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs ports of entry;

Whereas, the Board's regulations (15 CFR Part 400) provide for the establishment of special-purpose subzones when existing zone facilities cannot serve the specific use involved;

Whereas, an application from the City of Birmingham, Alabama, grantee of Foreign Trade Zone 98, for authority to establish special-purpose subzone status at the motor vehicle manufacturing plant of Mercedes-Benz U.S. International, Inc., in Tuscaloosa County, Alabama, was filed by the Board on February 16, 1995, and notice inviting public comment was given in the Federal Register (FTZ Docket 6–95, 60 FR 11070, 3–1–95); and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations are satisfied, and that approval of the application is in the public interest;

Now, therefore, the Board hereby authorizes the establishment of a subzone (Subzone 98A) at the Mercedes-Benz U.S. International, Inc., plant, in Tuscaloosa County, Alabama, at the location described in the application, subject to the FTZ Act and the Board's regulations, including § 400.28.

Signed at Washington, DC, this 21st day of February 1996.

Susan G. Esserman,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

Attest:

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 96–4980 Filed 3–1–96; 8:45 am]

BILLING CODE 3510–DS–M

[Docket 14–96]

Foreign-Trade Zone 94—Laredo, Texas, Application for Expansion

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the City of Laredo, Texas, grantee of Foreign-Trade Zone 94, requesting authority to expand its zone in Laredo, Texas, within the Laredo Customs port of entry. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the Board (15 CFR Part 400). It was formally filed on February 21, 1996.

FTZ 94 was approved on November 22, 1983 (Board Order 235, 48 FR 53737, 11/29/83) and expanded on March 26, 1990 (Board Order 468, 55 FR 12696, 4/5/90) and December 29, 1992 (Board Order 620, 58 FR 3533, 1/11/93). The zone project currently consists of four sites in the Laredo area: *Site 1* (500 acres)—within the 1,600-acre city-owned Laredo International Airport Industrial Park; *Site 2* (20 acres)—owned by the Texas-Mexican Railway, along Highway 359 in Webb County; *Site 3* (550 acres)—within the 1,400-acre Killiam industrial area, owned by Killiam Oil Co., at 12800 Old Mines Road; *Site 4* (1,500-acres)—within 7,000-acre International Commerce Center, Laredo Northwest business and residential development.

The applicant is now requesting authority to expand the zone to include a site (proposed *Site 5*—930 acres)—located at a proposed industrial park (currently known as the ''La Barranca Ranch'' site), Interstate Highway 35,

adjacent to the Union Pacific rail line, in northern Webb County, some 15 miles north of Laredo. The site is owned by Librado Pina, Inc.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment on the application is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is May 3, 1996. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to May 20, 1996).

A copy of the application and accompanying exhibits will be available for public inspection at each of the following locations:

Office of the Port Director, U.S. Customs Service, Lincoln Juarez Bridge, Bldg. #2, Laredo, Texas 78044–3130

Office of the Executive Secretary, Foreign-Trade Zones Board, Room 3716, U.S. Department of Commerce, 14th & Pennsylvania Avenue, NW., Washington, DC 20230

Dated: February 23, 1996.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 96–4981 Filed 3–1–96; 8:45 am]

BILLING CODE 3510–DS–P

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Opportunity to Request Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation.

BACKGROUND: Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspension of investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended, may request, in accordance with section 353.22 or 355.22 of the Department of Commerce (the Department) Regulations (19 CFR 353.22/355.22 (1993)), that the Department conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

OPPORTUNITY TO REQUEST A REVIEW: Not later than March 31, 1996, interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in March for the following periods:

	Period
Antidumping Duty Proceedings:	
Australia: Canned Bartlett Pears (A–602–039)	03/01/95–02/29/96
Bangladesh: Shop Towels (A–538–802)	03/01/95–02/29/96
Brazil: Ferrosilicon (A–351–820)	03/01/95–02/29/96
Brazil: Lead and Bismuth Steel (A–351–811)	03/01/95–02/29/96
Canada: Iron Construction Castings (A–122–503)	03/01/95–02/29/96
Chile: Standard Carnations (A–337–603)	03/01/95–02/29/96
Columbia: Certain Fresh Cut Flowers (A–301–602)	03/01/95–02/29/96
Equador: Certain Fresh Cut Flowers (A–331–602)	03/01/95–02/29/96
France: Brass Sheet and Strip (A–427–804)	03/01/95–02/29/96
France: Lead and Bismuth Steel (A–427–804)	03/01/95–02/29/96
Germany: Brass Sheet and Strip (A–428–602)	03/01/95–02/29/96
Germany: Lead and Bismuth Steel (A–428–811)	03/01/95–02/29/96
India: Sulfanilic Acid (A–533–806)	03/01/95–02/29/96
Israel: Oil Country Tubular Goods (A–508–602)	03/01/95–02/29/96
Italy: Certain Valves and Connections of Brass, for Use in Fire Protection Systems (A–475–401)	03/01/95–02/29/96
Italy: Brass Sheet and Strip (A–475–601)	03/01/95–02/29/96
Japan: Defrost Timers (A–588–829)	03/01/95–02/29/96
Japan: Stainless Steel Butt-Weld Pipe Fittings (A–588–702)	03/01/95–02/29/96
Japan: Television Receivers Monochrome and Color (A–588–015)	03/01/95–02/29/96
Mexico: Steel Wire Rope (A–201–806)	03/01/95–02/29/96
Korea: Steel Wire Rope (A–580–811)	03/01/95–02/29/96
Spain: Stainless Steel Bar (A–469–805)	08/04/94–02/29/96
Sweden: Brass Sheet and Strip (A–401–601)	03/01/95–02/29/96
Taiwan: Light-Walled Welded Rectangular Carbon Steel Tubing (A–583–803)	03/01/95–02/29/96
Thailand: Certain Circular Welded Carbon Steel Pipes and Tubes (A–549–502)	03/01/95–02/29/96
People's Republic of China: Chloropicrin (A–570–002)	03/01/95–02/29/96
People's Republic of China: Ferrosilicon (A–570–819)	03/01/95–02/29/96
People's Republic of China: Glycine (A–570–836)	11/16/94–02/29/96
United Kingdom: Lead and Bismuth Steel (A–412–810)	03/01/95–02/29/96
Suspension Agreements:	
Brazil: Frozen Concentrated Orange Juice (C–351–005)	01/01/95–12/31/95
Columbia: Certain Textile Mill Products (C–301–401)	03/01/95–02/29/96
Thailand: Certain Textile Mill Products (C–549–401)	03/01/95–02/29/96
Countervailing Duty Proceedings:	
Brazil: Cotton Yarn (C–351–037)	01/01/95–12/31/95
Brazil: Certain Castor Oil Products (C–351–029)	01/01/95–12/31/95
Brazil: Hot-Rolled Lead and Bismuth CSP (C–351–812)	01/01/95–12/31/95
Chile: Standard Carnations (C–337–601)	01/01/95–12/31/95
France: Brass Sheet and Strip (C–427–603)	01/01/95–12/31/95
France: Hot-Rolled Lead and Bismuth CSP (C–427–805)	01/01/95–12/31/95
Germany: Hot-Rolled Lead and Bismuth CSP (C–428–812)	01/01/95–12/31/95
India: Sulfanilic Acid (C–533–807)	01/01/95–12/31/95
Iran: In-Shell Pistachios (C–507–501)	01/01/95–12/31/95

	Period
Israel: Oil Country Tubular Goods (C–508–601)	01/01/95–12/31/95
Netherlands: Standard Chrysanthemums (C–421–601)	01/01/95–12/31/95
Pakistan: Cotton Shop Towels (C–535–001)	01/01/95–12/31/95
Turkey: Certain Welded Carbon Steel Pipe and Tube (C–489–502)	01/01/95–12/31/95
Turkey: Welded Carbon Steel Line Pipe (C–489–502)	01/01/95–12/31/95
United Kingdom: Hot-Rolled Lead and Bismuth CSP (C–412–811)	01/01/95–12/31/95

In accordance with sections 353.22(a) and 355.22(a) of the regulations, an interested party as defined by section 353.2(k) may request in writing that the Secretary conduct an administrative review. The Department has changed its requirements for requesting reviews for countervailing duty orders. Pursuant to 19 C.F.R. 355.22(a) of the Department's Interim Regulations (60 FR 25137 (May 11, 1995)), an interested party must specify the individual producers or exporters covered by the order for which they are requesting a review. Therefore, for both antidumping and countervailing duty reviews, the interested party must specify for which individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order it is requesting a review, and the requesting party must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends or the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which were produced in more than one country of origin, and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Seven copies of the request should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, Room B–099, U.S. Department of Commerce, Washington, D.C. 20230. The Department also asks parties to serve a copy of their requests to the Office of Antidumping Compliance, Attention: Pamela Woods, in room 3065 of the main Commerce Building. Further, in accordance with section 353.31(g) or 355.31(g) of the regulations, a copy of each request must be served on every party on the Department's service list.

The Department will publish in the Federal Register a notice of ''Initiation of Antidumping (Countervailing) Duty Administrative Review,'' for requests received by March 31, 1996. If the Department does not receive, by March 31, 1996, a request for review of entries covered by an order or finding listed in this notice and for the period identified above, the Department will instruct the Customs Service to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of (or bond for) estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

This notice is not required by statute, but is published as a service to the international trading community.

Dated: February 28, 1996.

Joseph A. Spetrini,

Deputy Assistant Secretary for Compliance.

[FR Doc. 96–4982 Filed 3–1–96; 8:45 am]

BILLING CODE 3510–DS–M

[A–122–047]

Elemental Sulphur From Canada; Final Results of Antidumping Finding Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Final Results of Antidumping Finding Administrative Review.

SUMMARY: On July 24, 1995, the Department of Commerce (the Department) published the preliminary results of its 1991–92 administrative review of the antidumping finding on elemental sulphur from Canada (60 FR 7872). The review covers 15 manufacturers/exporters of the subject merchandise to the United States and the period December 1, 1991 through November 30, 1992 (the POR). We gave interested parties an opportunity to comment on our preliminary results. Based on our analysis of the comments received, we have made changes, including corrections of certain clerical errors, in the margin calculation for Husky Oil Ltd. (Husky). These changes have resulted in a change in the best information available (BIA) rates assigned to Mobil Oil Canada, Ltd. and Petrosul International (Petrosul) for this review. Therefore, the final results differ from the preliminary results. The final weighted-average dumping margins for each of the reviewed firms are listed below in the section entitled ''Final Results of Review.''

EFFECTIVE DATE: March 4, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas O. Barlow or Michael Rill, Office of Antidumping Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, Washington, D.C. 20230; telephone: (202) 482–0410 or –4733, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 24, 1995, the Department published in the Federal Register the preliminary results of review (60 FR 6872) of the period December 1, 1991 through November 30, 1992. Pennzoil, a domestic producer, and two exporters, Husky and Mobil, requested a public hearing which was held on September 27, 1995. The Department has now conducted this review in accordance with section 751 of the Tariff Act of 1930, as amended (the Tariff Act).

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute and to the Department's regulations are references to the provisions as they existed on December 31, 1994.

Scope of the Review

The period of review (POR) is December 1, 1991 through November 30, 1992. Imports covered by this review are shipments of elemental sulphur from Canada. This merchandise is classifiable under Harmonized Tariff Schedule (HTS) subheadings 2503.10.00, 2503.90.00, and 2802.00.00.

The HTS subheading is provided for convenience and for U.S. Customs purposes. The written description of the scope of this order remains dispositive as to product coverage.

Verification

As provided in section 776(b) of the Tariff Act, we conducted sales and cost verifications of Husky and Mobil and verified information provided by these respondents by using standard verification procedures, including on-site inspection of the producer's facilities, the examination of relevant

sales and financial records, and selection of original documentation containing relevant information. Our verification results are outlined in the public versions of the verification reports.

Analysis of Comments Received

We gave interested parties an opportunity to comment on the preliminary results. We received case briefs and rebuttal briefs from Pennzoil, Husky, Mobil, and Petrosul.

Comment 1

Pennzoil agrees with the Department's decision to base Husky's foreign market value (FMV) on constructed value (CV). Pennzoil maintains, however, that the Department understated Husky's CV by failing to include in the calculations the direct operating and general facilities expenses relating to the sulphur block storage area. Additionally, Pennzoil argues that the Department failed to include in the sulphur cost of manufacture (COM) a portion of the property, plant and equipment (PP&E) writedown attributable to the sections of its processing plants after the split-off point for sulphur production.

Husky argues that it was proper to exclude the direct operating and general facilities expenses it incurred for the sulphur block storage lease. Husky maintains that these expenses relate to natural gas processing and, therefore are not a sulphur handling cost.

Department's Position

We agree with Pennzoil that inclusion of the direct operating and general facility costs related to sulphur block storage in CV is appropriate. As explained in the decision memorandum, *Memorandum To Susan G. Esserman From Joseph A. Spetrini: Team Recommendation Related to the Cost Accounting Treatment of Elemental Sulphur from Canada,* June 29, 1995, all costs incurred after the liquid sulphur exits the sulphur recovery unit relate to the production of sulphur. At this point in the production process, Husky has the choice of either selling the liquid sulphur, forming it for overseas sale, or pouring it to block for long-term storage. All of these choices relate to selling sulphur, either currently or in the future. Accordingly, we consider it appropriate to include, as part of the cost of producing sulphur, all costs incurred in the sulphur block storage lease.

We disagree with Pennzoil, however, that a portion of Husky's writedown of PP&E should be included in the COM for sulphur. These writedowns relate to certain properties in which the carrying value on Husky's books exceeds the estimated future cash value of mineral reserves. Since such costs are associated entirely with exploration and development of mineral reserves, we consider this type of writedown to be a cost incurred prior to the sulphur production split-off point. As such, we consider these costs to be part of Husky's natural gas operations. We have, therefore, excluded Husky's PP&E writedown from our calculated sulphur costs (*see* related byproduct/coproduct issue at Comments 2 and 3).

Comment 2

Pennzoil claims that the Department erred in finding that sulphur produced by Husky is not a coproduct. Pennzoil contends that, in accordance with Generally Accepted Cost Accounting Principles (GACAP), a joint product is deemed to be a coproduct if the value of its production during a certain period of time is significant in relation to the other products generated from the same production process during the same time period (relative value analysis). Pennzoil maintains that, in accordance with GACAP and the Treasury Department's position in *Elemental Sulphur from Canada: Antidumping; Tentative Determination to Modify or Revoke Dumping Finding,* 44 FR 8057, 8058 (February 8, 1979), the standard for significant value is whether the value of production for the joint product exceeds ten percent of the total joint product revenues. Pennzoil argues that the value of Husky's sulphur production during the POR exceeds the threshold for classifying it as a coproduct.

Pennzoil also argues that the Department erred in its preliminary results by determining relative value on a company-wide basis rather than on a plant-specific basis. According to Pennzoil, the value of sulphur production at each of Husky's sour gas processing plants is clearly significant in relation to the value of all other products generated from the same process during the POR. Pennzoil claims that it is Departmental practice to follow GACAP, and that GACAP requires that the relative value analysis be applied only to products that are in fact jointly produced in the same manufacturing process. Pennzoil avers that it is illogical to combine revenues from both sour and sweet gas processing facilities in determining relative value since sweet gas operations have different production processes, a different cost structure, and do not produce sulphur. Furthermore, Pennzoil notes that investments in sour gas facilities are made with the expectation of sulphur revenues, whereas such is not the case with sweet facilities. Accordingly, Pennzoil concludes, sweet gas revenues should not play a role in determining the cost of production (COP) for sulphur. However, even if the Department determines that relative value must be determined on a company-wide basis, Pennzoil maintains that the value of sulphur production during the POR still exceeds the threshold for classifying Husky's sulphur as a coproduct.

In addition to relative sales value considerations, Pennzoil notes several qualitative factors which it claims further support its position that sulphur is a coproduct of natural gas production. First, Pennzoil notes that Husky's normal accounting system does not separately identify the costs of producing individual products. Second, Pennzoil notes that very significant additional processing of hydrogen sulfide (H_2S) occurs after the split-off point. Third, Pennzoil contends that Husky intentionally produces sulphur, as illustrated by its investment in a highly sour gas field and its purchase of liquid sulphur for the manufacture of formed sulphur. According to Pennzoil, all of these factors lead to the conclusion that sulphur must be treated as a coproduct of natural gas production, and that a portion of Husky's joint production costs must therefore be allocated to sulphur based on the volume of H_2S in the raw gas stream.

Husky argues that the record is replete with evidence to support the Department's preliminary results to treat sulphur as a byproduct of natural gas production. Husky maintains that it normally accounts for sulphur as a byproduct and, thus, assigns no inventory value to sulphur production in the ordinary course of its business. Husky notes that this practice is in accordance with its home country Generally Accepted Accounting Principles (GAAP). Husky also argues that GACAP is not a recognized set of authoritative accounting principles. Husky states that the production of sulphur is an unavoidable consequence of natural gas production from sour gas wells and, thus, will occur regardless of any action the company takes. Husky maintains that the only reason it produces sulphur is to fulfill its obligation under Canadian environmental laws to remove H_2S from the unrefined natural gas stream and convert it into elemental sulphur.

Moreover, Husky claims that Pennzoil's assertion that Husky invested in certain sour gas fields with the intention of producing sulphur is misplaced. Husky claims that while it

may have hoped to earn supplemental sulphur income from its investment in sour gas fields, sulphur amounts to little more than a liability to Husky.

Husky argues that its revenue from sulphur production during the POR is insignificant compared to that of the other products produced during the same time period. Husky maintains that, in analyzing relative value, the Department has never held to a bright-line test. In fact, Husky notes that there have been numerous recent antidumping decisions involving byproduct/coproduct issues, and in none of these instances did the Department impose a ten-percent bright-line standard as part of its relative value analysis. Husky claims that Pennzoil's reference to the 1979 tentative Treasury Department decision in support of a ten-percent threshold has never been accepted by the Department and is, therefore, unpersuasive. Husky also notes that Pennzoil's proposed adjustments to relative value analysis performed in the preliminary results are without merit.

Additionally, Husky contends that the relative value analysis must be performed on a company-wide basis for two reasons. First, Husky asserts, not all sulphur processed at a certain facility is associated with sour gas from that same facility. However, Husky argues, when sulphur is sold from the processing facility, the revenues are recorded on the books of the processing facility rather than on the books of the refining facility. Second, Husky claims that it makes all decisions regarding its treatment of sulphur on a company-wide basis. Husky notes that, although each facility maintains lease statistics regarding production and sales quantities for all products and for all producers, corporate sales personnel rather than the individual facility operators make sulphur sales decisions.

Department's Position

In calculating the costs of producing subject merchandise, the Department's practice is to adhere to an individual firm's recording of costs in accordance with GAAP of its home country if the Department is satisfied that such principles reasonably reflect the costs of producing the subject merchandise. *See, e.g., Final Determination of Sales at Less Than Fair Value: Canned Pineapple From Thailand,* 60 FR 29553, 29559–62 (June 5, 1995); *Final Determination of Sales at Less Than Fair Value: Furfuryl Alcohol from South Africa,* 60 FR 22556 (May 8, 1995) (''The Department normally relies on the respondent's books and records prepared in accordance with the home country GAAP unless these accounting principles do not reasonably reflect the COP of the merchandise''). The Department's practice has been sustained by the CIT. *See, e.g., Laclede Steel Co. v. United States,* Slip Op. 94–160 at 21–25 (CIT October 12, 1994) (CIT upheld the Department's decision to reject the respondent's reported depreciation expenses in favor of verified information obtained directly from the company's financial statements that was consistent with Korean GAAP).

Normal accounting practices provide an objective standard by which to measure costs, while allowing a respondent a predictable basis on which to compute those costs. However, in those instances where it is determined that a company's normal accounting practices result in an unreasonable allocation of production costs, the Department will make certain adjustments or may use alternative methodologies that more accurately capture the costs incurred. *See, e.g., Final Determination of Sales at Less Than Fair Value: New Minivans from Japan,* 57 FR 21937, 21952 (May 26, 1992) (Department adjusted a company's U.S. further manufacturing costs because the company's normal accounting methodology did not result in an accurate measure of production costs); *Pineapple,* 60 FR at 29560 (Department adjusted a company's allocation of fruit costs because the company's normal accounting methodology resulted in an unreasonable allocation of such costs between canned pineapple fruit and juice products).

In the instant proceeding, therefore, the Department examined whether Husky's accounting treatment of sulphur was reasonable. In examining Husky's books and records at verification we found that Husky had treated sulphur as a byproduct for at least a number of years. Furthermore, we found no evidence that Husky had not relied historically upon its byproduct treatment of sulphur to compute its production costs. In addition, evidence on the record, *i.e.,* audited financial statements, indicates that Husky's byproduct methodology was accepted by its independent auditors. Given the auditors' acceptance of the respondent's financial statements and any lack of evidence to the contrary, we conclude that Husky's normal accounting treatment of sulphur is consistent with Canadian GAAP.

Notwithstanding the Department's conclusion that Husky's treatment of sulphur as a byproduct is in accordance with Canadian GAAP, the Department's byproduct/coproduct analysis includes a number of additional factors. (As discussed in comment 3 below, the Department accepted Husky's assignment of no sulphur processing plant costs to sulphur production. However, the Department did not accept Husky's normal accounting treatment of sulphur handling facility costs because such treatment did not reasonably reflect the costs associated with production of sulphur.)

The Department's practice, in accordance with GAAP, is to recognize a particular joint product as either a coproduct or byproduct based, in part, on the significance of that product relative to the other joint product[s] and to the producing company as a whole. *See e.g.,* Preliminary Determination of Sales at Less Than Fair Value: Sebacic Acid From the People's Republic of China, 59 FR 565, 568–69 (January 5, 1994); *Cost Accounting: A Managerial Emphasis,* Charles Horngren, George Foster, Seventh Edition, Prentice Hall, Englewood Cliffs, N.J., 1991 at 539–44 (*Horngren*). In this case, we have determined that sulphur is a relatively insignificant byproduct of Husky's natural gas operations. As a result of our relative value analysis and our analysis of other relevant factors, discussed below, we have accepted Husky's treatment of sulphur as a byproduct and have assigned to the subject merchandise only those costs that Husky incurred on the product after it left the sulphur recovery unit. (See our response to related Comment 3 below regarding sulphur production costs.)

In past cases involving coproducts and byproducts, the Department has looked to several factors in order to measure the significance of particular joint products (*see, e.g., Final Determination of Sales at Less Than Fair Value: Furfuryl Alcohol from South Africa,* 60 FR 22550 (May 8, 1995) (*Furfuryl Alcohol*) and *Concurrence Memorandum: Final Determination: Antidumping Duty Investigation of Furfuryl Alcohol from South Africa,* May 1, 1995 (*Furfuryl Memo*) (*See Memo To File From Case Analyst,* December 13, 1995 (making *Furfuryl Memo* part of record of this proceeding); *Final Determination of Sales at Less Than Fair Value: Sebacic Acid From the People's Republic of China,* 59 FR 28056 (May 31, 1994) (*Sebacic Acid*)). Among these factors were the following: 1) the relative sales value of the product compared to that of all other joint products produced during the same time period, 2) whether the product is an unavoidable consequence of producing another product, 3) whether management intentionally controls production of the product, 4) whether

the product requires significant further processing after the split-off point, and 5) how the company has historically accounted for the product. No single factor is dispositive in our determination. Rather, we must consider each factor in light of all of the facts and circumstances surrounding the case. In this case, we considered each of the preceding factors in reaching our decision to treat sulphur as a byproduct of the natural gas production process.

For the first factor, relative sales value, we compared the sales value of sulphur produced during the POR to that of all other joint products respondent produced during the same time period. From this analysis, we determined that the value of sulphur Husky produced represented a relatively insignificant portion of the total revenues generated by Husky's joint production process for refining natural gas.

In making this determination, we analyzed joint product revenues on a company-wide basis for the natural gas production process rather than on a plant-by-plant basis as Pennzoil requested. Pennzoil argued that, since natural gas from sour gas fields must undergo additional processing to remove the sulphur content, the cost structure of sour gas production facilities differs from that of the sweet gas facilities and, thus, should be subjected to a separate relative sales value analysis. While it may be possible, and even reasonable in certain circumstances, to perform a joint product analysis on a plant-by-plant basis, it certainly is not mandated by law, by general accounting practices, or by any other authority. In a case involving joint products, the Department considers the significance of individual joint products resulting from a common production process. (*See Sebacic Acid*). In this case, Husky's common production process is the production of natural gas, a process which yields sulphur. This reality is not changed by the fact that certain of Husky's gas fields (*i.e.,* sweet fields) did not yield levels of H_2S necessitating the conversion of H_2S to sulphur; overall, due to the nature of Husky's natural gas operations, sulphur is an inevitable consequence of that natural gas production process. Husky's primary business objective is the exploration, refinement, and sale of natural gas (and oil). Relative to Husky's natural gas production and revenue, sulphur production and revenue resulting from that natural gas production was not significant during the period under review. Given these considerations, we believe that Husky's sulphur production should be evaluated within the context of its overall natural gas operations.

Furthermore, Husky makes decisions regarding the treatment of sulphur, particularly the accounting treatment of sulphur, on a company-wide basis. In addition, sulphur sales decisions are made by corporate sales personnel and not by the individual facility operators. Given the relationship of sulphur to natural gas production by Husky, Husky's corporate-wide decision-making practices, and the fact that such practices are consistent with Canadian and U.S. GAAP, we believe that it is appropriate to perform our relative sales value analysis on a company-wide basis for the natural gas process.

Lastly with regard to relative sales value, we disagree with Pennzoil's contention that the Department has established a ten-percent threshold in determining the significance of revenues generated by joint products. Pennzoil's reference to the Treasury Department's 1979 tentative determination as the standard in this case does not reflect recent Department decisions involving coproduct/byproduct determinations. As explained above, the Department considers the relative revenues generated by joint products in conjunction with other important factors in order to determine the significance of the joint product in question. *See, e.g., Furfuryl Alcohol* and *Furfuryl Memo,* where the Department based its determination of the coproduct/byproduct issue on the same five factors noted above. Because the relative value analysis must be viewed within the context of other factors, as well as within the specific circumstances of the case, it would be inappropriate for the Department to establish Pennzoil's suggested ''bright-line'' threshold under which the entire coproduct/byproduct analysis would rest solely on whether revenues from the joint product exceeded ten percent of total revenues for all joint products. Pennzoil's minor proposed adjustments to our relative value calculations, therefore, would not effect our analysis of the relative sales value factor, nor our overall analysis.

Concerning the second factor, whether sulphur is an unavoidable consequence of producing natural gas, we believe that Husky's natural gas production determines the amount of sulphur that the company produces. In order to produce natural gas, Husky must remove poisonous H_2S from the unrefined gas stream and convert it to elemental sulphur in accordance with strict environmental laws. Because Husky has no control over the amount of H_2S in the gas stream and, therefore, the production of sulphur, Husky further processed and sold only part of the sulphur resulting from the treatment of H_2S during the POR. Without limiting the production of refined natural gas, Husky did not have the option of limiting sulphur production, and, therefore, poured the remaining portion of sulphur production to block as a means of long-term storage. It is clear that when producing natural gas, Husky has no choice but to produce elemental sulphur from H_2S, if for no other reason than it must do so to meet environmental standards. Sulphur, therefore, is an unavoidable consequence of natural gas production.

In the case of the third factor, whether management intentionally controls production of the product, while we cannot overlook the fact that Husky derives a portion of its revenues from sulphur, we do not find this to be evidence that the company's management intends to produce sulphur. Rather, as noted above, sulphur production is a requirement, resulting from Husky's decision to produce natural gas. The fact remains that, at significantly high levels, sulphur becomes an impediment to cost-effective natural gas production. In these instances, the high sulphur content in natural gas may force producers to abandon their plans to produce either product.

We disagree with Pennzoil's comment that Husky's investment in highly sour gas fields and its purchase of liquid sulphur during the POR indicate an intent on the part of the company's management to produce sulphur. Pennzoil's point concerning Husky's gas field investment is purely speculative. As to Husky's purchase of liquid sulphur from another supplier, the reason Husky purchases liquid sulphur is explained at page 9 of its proprietary January 9, 1994 cost submission to the Department, and this explanation does not support Pennzoil's position.

For the fourth factor, whether the product requires significant further processing after the split-off point, we found that the H_2S resulting from natural gas refining did undergo significant additional processing after the split-off point in order to transform it into marketable sulphur. As further explained in our response to Comment 3 below, however, we consider much of the additional processing to be associated with natural gas production in that it relates to the removal and treatment of the poisonous H_2S gas which, due to environmental laws, Husky must break down into its primary elements of sulphur and water. As a result, any further processing generally

is necessitated by factors not within the company's control.

Finally, with regard to the last factor, how the company has historically accounted for the product, the Department verified that Husky did not assign any of its production costs to sulphur during the POR. Instead, as discussed above, under its normal accounting system, Husky charged all sulphur processing and handling costs to its natural gas operations. Husky's accounting treatment of assigning no costs to sulphur was in accordance with Canadian GAAP and sanctioned by its auditors as demonstrated by the fact that the company's 1991 and 1992 financial statements did not report inventory balances for the sulphur that Husky produced in those years. Notably, for accounting purposes, U.S. producers of natural gas also consider sulphur to be a byproduct.

Contrary to Pennzoil's assertions, we are unaware of the existence of GACAP as a unified body of cost accounting principles that mandates our treating sulphur as a coproduct in this case. We believe that the method Husky used to account for its sulphur production was consistent both with the company's home market GAAP and with its view of sulphur as a byproduct of its natural gas operations. Based on our analysis of the above factors as they relate to the facts in this case, we have determined that the sulphur Husky produced during the POR was a byproduct of its natural gas production operations.

Comment 3

Pennzoil argues that, even if the Department decides to treat sulphur as a natural gas byproduct, it violated the antidumping statute in its preliminary results of review by accounting only for the processing costs Husky incurred subsequent to the sulphur recovery unit. Pennzoil states that section 773(e) of the Tariff Act expressly requires that the cost of fabrication or other processing of any kind be included in CV. Pennzoil maintains that sulphur recovery costs are, in fact, processing costs related to sulphur production that must be included in the Department's CV calculation in accordance with the statute. Pennzoil further argues that, by excluding sulphur recovery costs from its CV calculation, the Department also violated congressional intent as manifested in the sales-below-cost provision of the statute. Pennzoil claims that one of the reasons that Congress enacted the sales-below-cost provision was to afford protection to the U.S. sulphur industry.

According to Pennzoil, the Department's accounting treatment of sulphur production costs is in opposition to what it calls ''GACAP''. Pennzoil maintains that GACAP represents a common and accepted body of cost accounting principles that, among other things, provides guidance concerning the appropriate method for assigning costs to byproducts. According to Pennzoil, in accounting for joint products under GACAP, costs incurred after the production split-off point are separately identifiable and must therefore be charged directly to the specific products produced. In keeping with this principle, Pennzoil contends that, having correctly determined the split-off point in the natural gas production process as occurring prior to the sulphur recovery unit, the Department was compelled under GACAP to account for all of Husky's sulphur recovery costs as part of the cost of processing sulphur. Pennzoil argues that, if the Department continues to treat sulphur as a byproduct, it cannot assign to natural gas production all of the costs associated with Husky's sulphur recovery unit.

Pennzoil notes that, in calculating production costs, the Department relies on respondent's normal cost accounting methodologies so long as those methodologies are in accordance with the company's home market GAAP and reasonably reflect the costs associated with producing the subject merchandise. Pennzoil claims, however, that it cannot find from the record where Husky assigns production costs to either natural gas or sulphur under its normal accounting system. Thus, according to Pennzoil, the Department's assignment of all processing costs (including sulphur recovery unit costs) to natural gas production while charging none to sulphur contravenes Husky's normal accounting practices. Moreover, Pennzoil notes that, even if Husky's accounting method assigns zero production costs to sulphur production, this treatment is distortive because it fails to assign to sulphur the actual costs of producing the sulphur. Thus, Pennzoil contends, the Department should not follow Husky's cost accounting method because it would not reasonably reflect the costs of producing the subject merchandise.

Pennzoil also maintains that Department precedent requires that byproducts absorb all separately identifiable costs incurred after the split-off point in production. In support of this argument, Pennzoil cites *Silicomanganese from Venezuela: Notice of Final Determination of Sales at Less Than Fair Value,* 59 FR 55436 (November 7, 1994), where the Department assigned to merchandise it deemed a byproduct all of the separable further processing costs incurred by the respondent. Pennzoil maintains that the facts in this case are similar to those in the *Silicomanganese from Venezuela* and, thus, there is no reason for the Department to exclude sulphur recovery costs from its sulphur cost calculations if it chooses to treat the subject merchandise as a byproduct.

Pennzoil states that the U.S. Department of Interior (DOI) has prescribed rules for assigning costs to sulphur which mandate that sulphur production be assigned all costs incurred after separation from natural gas. Pennzoil notes that the DOI rules relate to the calculation of royalty payments affecting the joint production of natural gas and sulphur on federal land, and argues that it would be erroneous and contrary to law for the Department to depart from these rules by treating sulphur recovery costs as part of natural gas production costs.

Husky maintains that, contrary to Pennzoil's assertion, Section 773(c) of the Tariff Act does not mandate specific cost allocation methodologies and that the Department's preliminary CV calculations were fully in accordance with its statutory mandate. Husky contends that the Department properly defined the split-off point for purposes of the preliminary results of review, but that H_2S is not a separately identifiable product until after it has been converted into elemental sulphur. According to Husky, the process of converting H_2S into sulphur, a function of the sulphur recovery unit, is a gas cost and is identifiable solely with the process of preparing gas for market. Therefore, Husky contends that the Department should continue to treat all costs up to and including the sulphur recovery unit as related to gas production operations.

Department's Position

We disagree with Pennzoil that the costs Husky incurred in its sulphur recovery unit should be allocated to sulphur production. Rather, we have determined that these costs are associated with Husky's gas production operations. Whether or not Congress enacted the sales-below-cost provision to afford protection to the U.S. sulphur industry, as Pennzoil claims, the statute nowhere specifies how specific processing costs should be allocated among products.

Normally, we consider the split-off point in a joint production process to be where the products become physically separable. We normally assign these post-split-off costs to each separately identifiable product because this is the point where a company has a choice of

whether to further process each separable product or to dispose of it. This case is unique, however, in that even though the physical split-off point is prior to the sulphur recovery unit, Husky does not have the option of disposing of all H_2S. As explained below, in order to refine natural gas, Husky must incur costs in the sulphur recovery unit.

As part of the natural gas production process, H_2S is separated from the unrefined gas stream in the gas processing plant. H_2S output from the gas processing plant enters the sulphur recovery unit where it breaks down into its primary components of sulphur and water. H_2S is a poisonous, corrosive compound for which there is no market and, by Canadian law, it cannot be released into the atmosphere. In order to refine natural gas, Husky has no choice under Canadian environmental regulations but to incur H_2S processing costs in its sulphur recovery unit. To operate or use a natural gas plant and process natural gas, Canadian law requires companies to have certain licenses. These licenses dictate, among other things, certain minimum standards for the reclamation of sulphur contained in the gas delivered to a plant, and the types and quantities of effluent permissible from a plant. Furthermore, agreements with natural gas pipe-line operators specify that no more than a maximum amount of contaminants, including H_2S, be contained in gas introduced into a pipe-line. In addition, there is no dispute as to the extremely poisonous nature of H_2S, a compelling reason to stabilize this element into sulphur and water. Finally, it is undisputed that there is a positive direct correlation between the processing of sour natural gas and the production of H_2S. As saleable natural gas is produced from a sour gas stream and moved into the pipeline, so too must the movement of H_2S proceed within permissible means; otherwise the gas plant must cease operations. Therefore, it is of limited concern to Husky to analyze whether sales revenue it receives for sulphur sales is able to offset costs it incurs in the sulphur recovery unit and handling facility because it must by law dispose of the H_2S in a harmless manner. Rather, only where the costs of the sulphur recovery unit and handling facility impair the profits of refined natural gas might an analysis of sulphur sales revenue vis-a-vis the costs incurred in the sulphur recovery unit and handling facility be of greater consideration. In that case, it is likely that overall production for a particular gas field would cease if the costs associated with the removal and sale of sulphur caused the natural gas line of business to operate at a loss.

Contrary to Pennzoil's claim that Husky assigns no production costs to natural gas under its normal accounting system, we noted during verification that Husky assigns all gas and sulphur processing costs to production of natural gas (see the Department's position to Comment 2).

We disagree with Pennzoil's categorization of GACAP as the accounting rules which dictate our accounting treatment for COP and CV cases. Neither the accounting profession nor the Department recognizes GACAP as an authoritative source. This is a creation of Pennzoil, which selectively chose different cost accounting concepts from over 15 different texts dating back to 1920. While we recognize certain cost accounting concepts, we do not advocate one acceptable concept over another for all cases. Rather, we consider the facts surrounding each case. Cost accounting texts are fairly general in nature, with their purpose being to illustrate the various acceptable methods for allocating costs in certain situations. One of the key points cost accounting texts try to emphasize is that in most instances there is no *single*, right answer *see e.g. Horngren*. The way a company ultimately allocates costs to the various product lines depends on numerous factors unique to that company, including the products it manufactures, its corporate structure, and the way in which its management uses its accounting data. Id.

We disagree with Pennzoil that the facts of this case require that we allocate costs of the sulphur recovery unit. In *Silicomanganese from Venezuela*, the slag which resulted from the production of Grade B silicomanganese did not require further processing and it could have been disposed of in its current state, unlike the H_2S which results from the production of natural gas. The respondent company, however, chose to process it into Grade C product rather than to dispose of it. In this case, Husky does not have this option, but must process the dangerous H_2S in order to break it down into a stable and safe form (*i.e.*, sulphur and water) in accordance with Canadian law.

Finally, there is no connection between the DOI's proposed rules and our statute and regulations. Accordingly, we consider it irrelevant how DOI proposes to calculate royalty payments for sulphur produced on federal land.

In conclusion, we have allocated only costs incurred subsequent to the sulphur recovery unit to sulphur production. We believe these costs reasonably reflect the costs associated with the production of sulphur.

Comment 4

Husky maintains that, in accordance with past precedents, the Department should allow the company to offset its sulphur processing costs with revenues it earned from processing other companies' sulphur. Husky claims that, as a matter of law, costs for antidumping purposes can be offset by income so long as that income is directly related to the production of the product under review.

In support of its position, Husky cites two cases in which the Department offset costs for miscellaneous income, and several cases in which the Department allowed an offset to production costs for the sale of byproducts and scrap which resulted from the production of the subject merchandise. Husky cites *Porcelain-on-Steel Cooking Ware from Mexico; Final Results of Antidumping Administrative Review*, 55 FR 21061, 21063 (May 22, 1990) (*Cooking Ware*), and *Frozen Concentrated Orange Juice from Brazil: Final Determination of Sales at Less Than Fair Value*, 52 FR 8324, 8329 (March 17, 1987) (*Orange Juice*) to support its position.

Pennzoil contends that the Department was correct in not allowing Husky to deduct processing fees from its sulphur COM. According to Pennzoil, the processing fees do not result from Husky's normal operations but, rather, relate to the company's acting as a subcontractor on behalf of other sulphur producers. Pennzoil claims that it is unaware of any situation in which the Department has allowed respondents to offset their production costs for fee income generated from another line of business.

Department's Position

We disagree with Husky's contention that the sulphur processing revenues it received represent a reduction in the company's sulphur production costs. During the POR, in addition to processing its own sulphur, Husky processed large quantities of sulphur belonging to other companies. These companies paid Husky processing fees based on the quantity of sulphur that Husky processed for them. In computing its sulphur costs, Husky offset the total cost of all sulphur it produced during the POR by an amount representing the gross earnings from the sulphur which it processed for the other companies. Husky then calculated a per-unit sulphur cost by dividing the remaining balance of production costs, net of gross

processing revenues, by the quantity of sulphur that the company had produced for its own account. The effect of this methodology was to reduce Husky's own sulphur production costs by the amount of profits that the company earned from processing sulphur that belonged to the other companies.

Contrary to Husky's assertions, we find that the revenues it received from processing sulphur for other companies do not relate directly to the production costs it incurred in producing the subject merchandise on its own account. Instead, these fees represent income Husky earned from a separate line of business as a subcontractor offering sulphur processing services. Husky provided these services to its customers for a fee which represented the processing costs Husky incurred, plus a mark-up for profit. However, the net profits that Husky earned from processing sulphur as part of its separate subcontractor operations did not reduce the costs that it incurred to process and sell its own sulphur.

We disagree with Husky that, by disallowing its processing revenue offset, we are deviating from our position in past cases. In neither of the cases cited by Husky, *Cooking Ware* and *Orange Juice*, did we allow respondents to reduce the production costs of subject merchandise by profit earned from another line of business. Rather, consistent with our normal practice, we allowed offsets to the cost of producing the subject merchandise for revenues earned on the sale of byproducts and scrap which resulted from the production of the subject merchandise. This practice is distinguishable from Husky's situation in that the revenues Husky earned on its subcontracting operations do not directly relate to Husky's production of the subject merchandise. Rather, they relate to its subcontracting operations which is a separate line of business. Therefore, we have not offset Husky's sulphur COP and CV by revenues it earned on its subcontracting operations.

Comment 5

Husky argues that the Department should allocate depreciation expense to the sulphur handling facility on a net realizable value (NRV) basis. Husky maintains that an NRV allocation basis is reasonable since, in its normal accounting system, it allocates no expenses to sulphur. Husky further maintains that it is within the Department's discretion to use a value-based allocation methodology. In support of its position, Husky cites *Pineapple* as a recent determination in which the Department relied on a value-based cost allocation methodology. Husky argues that, using a cost-based allocation methodology, as the Department did for purposes of the preliminary results of this review, overstates the depreciation expense allocated to sulphur production. Husky also claims that it is inconsistent for the Department to determine, as it did in the preliminary results of review, that sulphur is a byproduct based on its relative sales value while, at the same time, rejecting an allocation of depreciation expense that similarly relies on relative sales values.

Husky further contends that, regardless of how the Department decides to allocate depreciation expense to sulphur, it must adjust for the fact that an unrelated company pays Husky a capital charge which, in effect, reimburses Husky for a portion of its depreciation expense incurred for the use of its facility. Husky maintains that, in the preliminary results of review, the Department erroneously computed per-unit depreciation expense for sulphur by including this capital charge in total depreciation costs, but failed to include this company's related quantity of sulphur production. According to Husky, the Department should correct this error either by reducing Husky's depreciation expense for the year by the capital charge payment, or by allocating total depreciation expense over the total quantity of sulphur Husky produced, regardless of ownership.

Pennzoil argues that the Department correctly allocated depreciation expense based on the direct operating costs Husky incurred in each functional leasehold area. According to Pennzoil, the Department prefers to allocate indirect costs using a cost-based allocation methodology rather than one based on net sales revenue. Additionally, Pennzoil notes that Husky recognized this fact when it allocated the cost of its general facilities and other expenses to each lease based on the direct costs incurred for each lease. Pennzoil maintains that depreciation expense incurred in connection with each lease is more closely related to the lease's operating expenses than to the NRV of the products produced at the facility. Additionally, Pennzoil contends that Husky's cite to *Pineapple* as support for a sales-based allocation is misplaced. Pennzoil notes that, in that case, the Department determined that it was appropriate to rely on the value-based allocation method because the respondent had used this method for a number of years in its normal accounting system. Pennzoil notes that, in the instant case, Husky created its NRV allocation methodology solely for the purpose of this review.

Pennzoil also contends that, consistent with its finding in the preliminary results, just as the Department should not reduce Husky's per-unit sulphur COP by the profit earned on processing a certain other company's sulphur, neither should the Department adjust Husky's depreciation expense to account for the capital charge received from the other company.

Department's Position

We disagree with Husky that it is appropriate to allocate depreciation expense among its products based on a relative sales values methodology. Although Husky claims that it does not maintain a fixed asset ledger that records depreciation expense for each of its leases, this does not mean that the company's depreciation expense represents an actual joint production cost that, under certain circumstances, may be appropriately allocated on the basis of relative sales value. On the contrary, in this instance, the depreciation expense for fixed assets that Husky used to produce sulphur, natural gas, and other products bears no direct relationship to the sales value generated from those products. Therefore, allocation on the basis of sales value could lead to cost distortions and would not be appropriate.

The Department typically has found that respondents maintain sufficiently detailed fixed asset records that allow them to account for depreciation expense on a product-specific basis. In this case, however, because Husky's records do not permit the company to trace depreciation expense in such a manner, we believe that it is appropriate to treat these costs like other indirect costs, such as manufacturing overhead or general and administrative expenses. The Department generally favors a cost-based allocation methodology for indirect costs. For example, the Department has consistently required that respondents allocate general and administrative expenses on the basis of cost of sales rather than on relative sales revenue or other inappropriate bases. *See, e.g., Tapered Roller Bearings, Finished and Unfinished, and Parts Thereof from Japan, Final Results of Antidumping Administrative Review,* 56 FR 41508, 41516, August 21, 1991). As Pennzoil has pointed out, Husky itself adopted such a cost-based methodology in allocating its indirect general facilities costs on the basis of the direct costs it incurred at each lease. Thus, the cost-based methodology the Department used to re-allocate Husky's depreciation

expense for the preliminary results was both consistent with past Department practice and with Husky's own method of allocating the other indirect costs the company incurred during the POR.

Husky is incorrect in referring to the Department's determination in *Pineapple* as support for its value-based allocation of depreciation expense. As noted above, in the instant case, the need to treat depreciation expense as an indirect cost (and thereby allocate the amount incurred among the various products produced by Husky) arises from limitations in the company's own accounting system. Since Husky's accounting system does not distinguish fixed assets used to produce sulphur after the split off point in production, some method must be used to allocate the otherwise fully separable costs associated with fixed assets to produce sulphur. In *Pineapple,* however, the Department dealt with the issue of allocating genuine joint production costs that were otherwise inseparable up to the production split-off point where the process yielded distinct products.

Pineapple also differs from the instant case in the fact that the pineapple growers had, for many years prior to the antidumping investigation, accounted for joint processing costs on the basis of relative sales value. As noted previously, however, Husky's value-based methodology is not part of its normal accounting system and was devised by the company specifically for the purpose of allocating depreciation costs in this review.

We disagree with Husky's claim that use of the relative sales value in our sulphur byproduct analysis is inconsistent with our rejection of it as the basis for allocating depreciation expense among the company's products. As discussed in our response to Comment 2, relative sales value is but one of several factors that we considered in measuring the significance of sulphur as part of our coproduct/byproduct analysis. It is not a dispositive factor, especially in situations in which the relative sales values of subject and non-subject merchandise are measured only during periods covered by an antidumping investigation or administrative review. Contrary to Husky's assertions, the fact that the Department considers sales value as one of several factors in its coproduct/byproduct analysis for the subject merchandise does not, as a consequence, make the price charged for that merchandise a reliable basis upon which to allocate depreciation expenses or other such normally separable costs. Accordingly, the Department has allocated depreciation expense using a cost-based methodology, consistent with its treatment in the preliminary results.

Lastly, we agree with Husky that it is appropriate to include a certain company's sulphur production quantity in the calculation of per-unit depreciation expense. Therefore, we have accounted for all quantities processed at the facility, regardless of whether the product was owned by Husky, in establishing the per-unit depreciation costs.

Comment 6

Pennzoil asserts that, with regard to selling, general and administrative (SG&A) expenses included in CV, the Department properly included Husky's third-country royalty expenses, but neglected to include PRISM Sulphur Corporation's (PRISM's) SG&A expenses incurred on Husky's behalf. Pennzoil cites the Department's Dumping Manual at p. 53 and *Final Determination of Sales at Less Than Fair Value: Certain Forged Steel Crankshafts From the Federal Republic of Germany,* 52 FR 28170 (July 28, 1987), to support its position.

Husky asserts that the Department properly excluded PRISM's general expenses from CV and that the Department correctly limited general expenses to those Husky incurred, since only Husky's general expenses are included in the third-country sales prices it reported. Husky asserts that the third-country prices the Department used in its analysis were not the prices PRISM charged to its unrelated customers but rather were the ''netback'' revenue Husky received from PRISM, which represents Husky's net return, exclusive of the expenses (including general expenses) PRISM incurred in selling the sulphur to third countries. Husky asserts that exceeding the 20-percent difference-in-merchandise threshold (DIFMER) is the only reason the Department did not use the reported prices (netback revenues) and, since these prices were the verified arm's-length prices from Husky to PRISM, the Department appropriately limited the general expenses included in the CV calculation to the general expenses in that price. Therefore, Husky contends that the Department should dismiss Pennzoil's argument and base the final results on the reported and verified expenses Husky incurred.

Department's Position

We agree with Pennzoil and have attributed a portion of PRISM's selling expenses to Husky for CV purposes. Section 773(e) of the Tariff Act specifies that general expenses be equal to that usually reflected in sales of merchandise of the same general class or kind but not less than 10 percent of COM. Because PRISM, essentially a sales organization, incurred expenses of the kind usually reflected in sales of merchandise of the same general class or kind on Husky's behalf, we have allocated PRISM's operating expenses to Husky, and, therefore, to the calculation of CV in our determination of Husky's dumping margin.

Comment 7

Pennzoil asserts that the Department's margin calculation for Husky contains an error in that the Department calculated Husky's weighted-average margin by dividing total duties due by the gross sales value of U.S. sales instead of dividing the total duties due by the net U.S. sales value.

Department's Position

We agree and have recalculated Husky's weighted-average dumping margin by dividing total duties due by the net U.S. sales value, consistent with our normal practice.

Comment 8

Husky asserts that the Department made two ministerial errors in its calculation of Husky's margin and requests the Department to correct these errors. Husky indicates that the Department double-counted U.S. packing costs for bagged and powdered sulphur and that the royalty expense the Department included as a direct selling expense component of general expenses was not equivalent to the royalty expense the Department subtracted as a circumstance-of-sale adjustment as required by statute and Department practice.

Department's Position

We agree and have corrected the errors in these final results.

Comment 9

Pennzoil asserts that the Department erred in determining that the rate it calculated for Husky should be applied to Mobil as BIA, because Petrosul's margin would be more adverse and must be applied to Mobil as BIA.

Mobil asserts that, if the Department calculates a margin for Petrosul based on Pennzoil's cost allegation or on Husky's CV as Pennzoil proposes, under no circumstances should the Department apply this rate to Mobil. Mobil asserts that the Department's preference is to use verified information as the basis of BIA for a cooperative respondent and cites *In the Matter of Replacement Parts for Self-Propelled Bituminous Paving Equipment from*

Canada, USA–90–1904–01 at 81 (May 15, 1992), concerning the Department's selection of BIA, *Smith Corona* v. *United States*, 796 F. Supp. 1532, 1536–37 (CIT 1992), and other cases for the proposition that the court favors a verified BIA rate over an unverified BIA rate, and favors BIA based on ''reasonably accurate'' information of record if verified data is not available (*Associacion Colombiana de Exportadores de Flores*, 717 F. Supp. 834 (CIT 1989); *Alberta Pork Producers' Marketing Board* v. *United States*, 669 F. Supp. 445 (CIT 1987)). Mobil asserts that, because it cooperated in this review, the Department based its BIA margin on Husky's verified information and that it would be unreasonable to penalize Mobil by using unverified information that results in an artificially high dumping margin.

Mobil asserts that there is no support for Pennzoil's approach because 1) the Department did not verify the price information Petrosul submitted, 2) the CV information in Pennzoil's cost allegation was not only not verified, but was based on a coproduct methodology, and 3) the Department thoroughly and successfully verified Mobil's cost responses and determined Mobil produces sulphur as a byproduct.

Department's Position

In our preliminary results, we determined that, because Mobil substantially cooperated in this segment of the proceeding by responding to our requests for information and participating in verification, application of second-tier BIA for Mobil was appropriate. The second-tier approach results in the application of the higher of (1) the highest rate ever applicable to the firm for the same class or kind of merchandise from either the LTFV investigation or a prior administrative review or, if the firm has never before been investigated or reviewed, the ''all others'' rate from the LTFV investigation; or (2) the highest calculated rate in this review for the class or kind of merchandise for any firm from the same country of origin (*see, e.g., Allied-Signal Aerospace Co.* v. *United States*, 966 F.2d 1185, 1191 (Fed. Cir. 1993); *Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From France, et al.: Final Results of Antidumping Duty Administrative Reviews, Partial Termination of Antidumping Reviews, and Revocation in Part of Antidumping Duty Orders*, 60 FR 10900, 10908 (February 28, 1995)). The highest rate previously applicable to Mobil is 5.56 percent. Therefore, the rate calculated for Husky, the highest calculated rate in this review, shall apply to Mobil as this rate is higher than the rate previously applicable to Mobil. Pennzoil has not presented an argument which persuades the Department to deviate from application of its established BIA policy with regard to Mobil. With regard to the Department's treatment of Petrosul, see Comment 13.

Comment 10

Pennzoil asserts that the Department erred in concluding that 5.66 [sic] percent was the highest rate previously assigned to Mobil, as the Department's first administrative review found a margin for Mobil of 12.9 percent, and, although unpublished, Mobil's entries were liquidated at that rate. Pennzoil cites *Elemental Sulphur from Canada: Preliminary Results of Administrative Review of Antidumping Finding and Tentative Determination to Revoke in Part*, 49 FR 45789, 45790 (September 15, 1981), and provides copies of telexes to Customs and an attachment to a letter to a respondent with proposed assessment rates to support its position. Accordingly, Pennzoil asserts, if the revised BIA rate the Department calculates for Petrosul is the highest calculated rate in this review, the Department should apply that rate to Mobil, but under no circumstances should Mobil receive a rate lower than 12.9 percent.

Mobil asserts that its highest previous rate is 5.56 percent, and disputes Pennzoil's assertion that its highest previous rate is 12.9 percent. Mobil claims that although the Department's September 15, 1981 preliminary results indicate a 12.9-percent rate for the period July 1, 1978 through December 31, 1978 and a 75.19-percent rate for the period January 1, 1979 through November 30, 1980, there was a correction to the November 28, 1986 instructions on which Pennzoil relies in its arguments. Mobil explains that the Department issued instructions stating that entries for the January 1979 through November 1981 should not be liquidated. Mobil points to the Department's 1987 final results for the period January 1, 1979 through November 30, 1981, which established a rate of zero for Mobil (52 FR 41601). Mobil concludes that there are no published final results or Customs instructions that would support Pennzoil's claimed rate of 12.9 percent for the period July 1, 1978 through December 31, 1978. Concerning the October 6, 1986 telex identified by Pennzoil relating to Mobil's entries for 1982–83 at 12.9 percent, Mobil asserts that it was obviously based on the same error underlying the November 28, 1986 instruction.

Department's Position

We agree with Mobil. The Department's practice is to rely on the published final results of a review or investigation to determine the highest rate ever applicable to a firm. We never published final results of review with a rate of 12.9 percent, for any period, for Mobil's sales. The highest published final review rate the Department has been able to ascertain for Mobil is 5.56 percent.

However, because the rate calculated in this review for Husky is higher than 5.56 percent, that rate shall apply to Mobil's transactions as second-tier BIA in this review.

Comment 11

Mobil believes a 1978 U.S. Customs ruling issued to Mobil Chemical (Mochem) (predecessor of Mobil Mining and Minerals (MMM), a U.S. affiliate of Mobil), holding that sulphur purchased by Mochem for internal use was exempt from antidumping duties, is still applicable. Mobil asserts that the reason for the exemption was that, although the sulphur is used in the manufacture of diammonium phosphate fertilizer (DAP), the end-product, DAP, contains no sulphur as it ends up in the form of gypsum, a waste product. Thus, Mobil contends that there is no sale to an unrelated customer of sulphur or of the product containing sulphur from which U.S. price could be derived. Mobil asserts that Mobil, Mochem, and MMM have relied on this ruling and Customs has never assessed antidumping duties on sulphur imported by MoChem and MMM for use in the manufacture of DAP.

Mobil further asserts that it has an arrangement with MMM and a certain unrelated U.S. entity whereby Mobil sells sulphur to its U.S. affiliate, MMM, which then ''swaps'' this sulphur with the unrelated U.S. entity, such that Mobil sulphur is delivered to this unrelated U.S. entity in return for the delivery of sulphur from this unrelated U.S. entity to MMM.

Mobil asserts that MMM does not resell the sulphur, but discards it as a waste product in the form of gypsum. As there is no arm's-length price, Mobil contends that the Customs Service ruling applies. Mobil requests that the Department issue liquidation instructions which direct Customs not to assess duties on any imports of Mobil sulphur by a certain unrelated U.S. entity which that entity purchased pursuant to the swap arrangement.

Pennzoil asserts that the Department may not exempt imports of Mobil sulphur by this unrelated U.S. entity from the assessment of antidumping duties. Pennzoil argues that the 1978 Customs ruling does not apply to the sulphur the unrelated entity acquired in its swap transactions.

Pennzoil asserts that the limited exemption in the 1978 Customs ruling was based on a repealed statute and Treasury Department regulation and that the ruling applies only to sulphur MMM used to produce DAP at a plant which closed in 1987. Pennzoil further asserts that, because Mobil has not disclosed the purpose for which the entity used the sulphur, the Department cannot determine that the ruling applies to Mobil's sulphur, given that Customs granted the exemption under the provision that the sulphur was consumed in the production of DAP. Pennzoil contends that the unrelated U.S. entity may have imported the Mobil sulphur for resale to U.S. customers and there is no evidence on the record of this review that the entity ever produced DAP, let alone consumed the Mobil sulphur in the course of producing that product. Pennzoil notes that, contrary to the statement in the Customs ruling, gypsum is a salable product.

Pennzoil asserts that, given the Department's application of total BIA to Mobil, the Department should not rely on Mobil's factual assertions and reward it by excluding U.S. sales from coverage by the finding.

Finally, Pennzoil asserts that Mobil's request constitutes an improper request for a scope determination and that such an exclusion would create significant administrative burdens for Customs and the Department. Pennzoil contends that any liquidation instructions would need to contain certain restrictions in view of the fact that the 1978 ruling expressly does not cover a percentage of sulphur imported by Mobil's related entity that do not go to the Depue Plant, or that go to Depue but are used in the production of sulfuric acid.

Department's Position

The 1978 Treasury ruling does not apply to these transactions since the ruling is narrowly drafted to apply only to shipments of Mobil sulphur to a Mobil affiliate used for a specific purpose. Moreover, the specific language of the Treasury ruling does not address ''swap'' transactions.

After discussing the basis for the exclusion, the ruling concludes: ''Sulphur imported by Mobil Chemical from its Canadian affiliate, Mobil Oil Canada, and used in the production of diammonium phosphate fertilizer (DAP) will be appraised by U.S. Customs without regard to the Antidumping Act, 1921, as amended. That portion of the Canadian elemental sulphur imported by Mobil Chemical from Mobil Oil Canada and not shipped to the Depue plant or that used in the production of sulfuric acid will be appraised for antidumping duties.'' *Letter to Patrick F.J. Macrory, Esq. from Salvatore E. Caramagno, Director, Classification and Value Division, Department of the Treasury, U.S. Customs Service*, January 10, 1978.

The ruling does not apply to Mobil's Canadian sulphur actually consumed by an unrelated U.S. entity, regardless of the use to which MMM ultimately put the exchanged or ''swapped'' sulphur (ostensibly, this is U.S.-produced sulphur, obtained from the unrelated U.S. entity). It is the U.S.-produced product that is ''discarded as a waste product in the form of gypsum'' (*Mobil Brief*, August 28, 1995 at 5), and not Mobil's Canadian sulphur.

In any event, even if the ruling applied to these transactions, the Department agrees with Pennzoil that any exemption of this sulphur would be improper in the context of the application of total BIA to Mobil, given the serious doubts concerning the reliability and completeness of its submissions. While Mobil segregated the volumes of sulphur that were subject to these swap transactions in its sales listings, as exhibited by *Verification of Sales Questionnaire Response of Mobil Oil Canada Ltd.*, November 22, 1994 (*Verification Report*), and explained in *Memorandum to Joseph A. Spetrini from Holly A. Kuga, re: Use of Best Information Available for Mobil Oil Canada, Ltd., in 1991–92 Administrative Review of Antidumping Finding on Elemental Sulphur from Canada* (May 10, 1995)) (*Memo*), the Department concluded that problems it encountered at Mobil's sales verification rendered ''Mobil's entire sales response seriously defective and an inappropriate basis on which to conduct a dumping analysis.'' *Memo* at 4. The Department further concluded, among other things, that, ''given the magnitude and scope of the other problems encountered at verification of Mobil, the Department has serious doubts concerning the overall reliability and completeness of Mobil's submission. Therefore, we do not believe that Mobil's responses constitute a proper basis on which to base a calculated margin.'' *Memo* at 4–5.

For purposes of these final results, we believe that a problem exists in addition to our inability to conduct a proper dumping analysis. This problem concerns the proper segregation of the swap transactions by Mobil in its sales response, since not all transactions with this unrelated U.S. entity during the POR were the subject of these swaps. Given the overall unreliability of Mobil's sales submissions to the Department, and for the additional reason above, the Department will not exempt from the assessment of antidumping duties any of the Canadian sulphur delivered to this unrelated U.S. entity during the POR.

Comment 12

Mobil states that it recognizes that the Department applied total BIA to its transactions because of difficulties during its sales verification, but offers comments concerning its reported costs that were successfully verified in the event the Department decides to use its costs.

Pennzoil asserts that the Department cannot use the cost data provided by Mobil and urges the Department to reject Mobil's suggestion for a number of reasons. First, Pennzoil comments that Mobil failed the sales verification and the Department's use of total BIA is consistent with the statute, Department precedent and decisions of the CIT. Citing *Empresa Nacional Siderurgica, S.A. and the Government of Spain v. United States*, Ct. No. 93–09–00630–AD, Slip Op. 95–33 at 9 (CIT March 6, 1995), and *Rhone-Poulenc, Inc. v. United States*, 710 F. Supp. 341, 346 (CIT, 1990), Pennzoil asserts that where a company fails verification so that the Department cannot rely on its U.S. selling prices, it has no choice but to resort to total BIA because U.S. prices are an absolutely essential element of the calculation of a dumping margin. Second, Pennzoil argues that the Department cannot rely on Mobil's cost information as the basis for FMV because Mobil failed to report production costs for its sulphur-producing facilities in the manner and detail which the Department's questionnaire requires. Pennzoil asserts that Mobil failed to separately identify the costs associated with sulphur handling and without this information the Department cannot compute the CV of sulphur under either a coproduct or byproduct cost accounting methodology. Third, Pennzoil contends that Mobil's cost data are useless as a basis for determining CV because the Department could not verify the barrel-of-oil equivalent method Mobil used. In addition, Pennzoil asserts that this method is totally inappropriate for identifying sulphur production costs, since the market value of sulphur

derives from its value in fertilizer, not its thermal heat. Further, Pennzoil argues, the relative BOE figures bear no relationship to those products' volume or value and Mobil failed to provide any basis for its BOE-per-MT conversion factor. Pennzoil notes the Department's cost verification report wherein the Department stated the BOE methodology ''might not be an appropriate basis for the allocation of joint costs.'' Finally, citing the Department's BIA memorandum for Mobil wherein the Department states it has ''serious doubts concerning the overall reliability and completeness of Mobil's submissions,'' Pennzoil asserts that the Department determined that it could not rely on any of Mobil's responses to calculate a dumping margin.

Department's Position

We affirm our decision in the preliminary results to assign Mobil total BIA for this review based on problems we encountered at verification of its sales responses. Given those problems, we do not believe that Mobil's responses constitute a proper basis on which to base a calculated margin. *See Memo at 4–5.* Mobil's costs would be of use only if there were reliable, verified sales information, which there is not. The issue of the appropriateness or validity of Mobil's reported costs is, therefore, moot.

Comment 13

Pennzoil asserts that the Department properly resorted to BIA for Petrosul but did not select the correct BIA rate to apply to Petrosul's sales. Pennzoil asserts that, in applying Husky's calculated margin to Petrosul, the Department rewarded Petrosul and its suppliers for their failure to supply requested COP information. Pennzoil argues that the use of Husky's margin assumes that Petrosul's sulphur is produced as a byproduct, and that, in any event, the record demonstrates that Petrosul's U.S. prices varied from Husky's. Instead, Pennzoil contends that the Department should calculate a margin for Petrosul by comparing its reported U.S. prices to a CV calculated from information in Pennzoil's cost allegation, or compare Petrosul's United States prices (USPs) to a public CV calculated for Husky.

Citing the Department's *Final Results of Antidumping Duty Administrative Reviews; Oil Country Tubular Goods from Canada, 56* FR 38408, 38410 (August 13, 1991) (*OCTG*), Pennzoil asserts that it is the Department's practice to use cost information provided by the petitioners as BIA when the suppliers of an otherwise cooperative exporter fail to provide COP information: this information is then compared to the USPs of the exporter to determine margins. Pennzoil states that in relying on a ''company-specific'' finding for Husky and Mobil that sulphur is a byproduct, the Department concluded that because ''only sulphur handling facility costs should be allocated to sulphur production, the necessary [cost] information is not available from Pennzoil's cost allegation'' to use as BIA for Petrosul's suppliers' cost information. Pennzoil asserts that the Department's assumption that a byproduct cost methodology is appropriate for Petrosul is unsupported by evidence on the record and is contrary to the Department's BIA practice of making adverse assumptions when a party fails to provide requested information. Pennzoil asserts that the Department must assume that Petrosul's sulphur was a coproduct and should, as in OCTG, compare Petrosul's USPs to a CV based on the coproduct information in Pennzoil's cost allegation.

Citing *Shop Towels of Cotton from the People's Republic of China; Final Results of Antidumping Duty Administrative Review,* 55 FR 7756 (March 5, 1990), Pennzoil further asserts that the Department acted contrary to its practice when it failed to use ''other information'' on the record that indicated a higher margin existed for Petrosul and insists that the Department should have compared Petrosul's USPs to the CV calculated for Husky plus Petrosul's SG&A expense and profit.

Pennzoil claims that the Department failed to compare Petrosul's USP to Husky's CV on the grounds that Department policy prohibits cross-respondent use of proprietary data, but Pennzoil asserts that *Pineapple* and *Silicon Metal from Brazil,* 59 FR 42806 (August 19, 1994), demonstrate that no such policy exists and that, even if such a policy exists, the Department should not apply it in a manner that thwarts its established BIA practice. Pennzoil concludes that, at a minimum, the Department should calculate a margin for Petrosul by comparing its reported USPs to a CV calculated, in part, using Husky's public data and adding Petrosul's SG&A and profit.

Citing *Allied-Signal Aerospace Co.* v. *United States,* 966 F.2d 1185, 1191 (Fed. Cir. 1993), *Krupp Stahl A.G.* v. *United States,* 822 F. Supp. 789, 792 (CIT 1993), and *Chemical Products Corp.* v. *United States,* 645 F. Supp. 289, 295 (CIT 1986), Petrosul asserts that the Department is accorded substantial discretion and deference in determining BIA and claims that, while it may rely on information submitted by petitioner, it is not required to do so. Petrosul asserts that the Department followed its practice of assigning to Petrosul, a cooperative respondent, the highest calculated rate in this review based on the second-tier of its two-tiered methodology. Citing *Citrosuco Paulista, S.A.* v. *United States,* 704 F. Supp. 1075, 1088 (CIT 1988), Petrosul asserts that the Department must either conform itself to prior decisions or explain the reasons for a departure, and that Pennzoil has provided no new arguments or facts that would justify such a departure.

Petrosul asserts that Pennzoil's reliance on *OCTG* is misplaced because in *OCTG* the Department noted that it could have simply used total BIA, but that it was more reasonable to use BIA to calculate only the COP. In addition, Petrosul asserts that because the review covered only one exporter, the Department was prevented from using other respondents' COP information as surrogate information. Petrosul asserts the only alternative open to the Department would have been to use the highest margin previously assigned to the exporter, but because the exporter was cooperative, the Department declined to do so.

In addition, Petrosul disputes Pennzoil's contentions that, first, application of Husky's rate, calculated using a byproduct methodology, results in a less adverse rate for Petrosul and, second, that the Department should have assigned a higher BIA rate to Petrosul based on Petrosul's U.S. pricing data. Citing *Disposable Pocket Lighters from the People's Republic of China; Final Determination of Sales at Less Than Fair Value,* 60 FR 22359, 22360 (May 5, 1995), Petrosul asserts that the Department normally assigns less adverse margins to respondents that cooperate, and citing *Emerson Power Transmission Corporation* v. *United States,* No. 92–07–00480, Slip Op. at 19 (CIT Sept. 1, 1995), Petrosul asserts that once the Department establishes that BIA is appropriate, it has broad discretion in determining what information to use. Citing the preliminary results in this review, Petrosul asserts that the Department may apply either total BIA or select individual pieces of data to substitute for missing or unreliable data. Citing *Shop Towels of Cotton from the People's Republic of China; Final Results of Antidumping Duty Administrative Review,* 55 FR 7756 (March 5, 1990), Petrosul asserts that, while it may be appropriate to rely on other information as BIA, the Department is not required

to rely on more adverse information, particularly where a respondent has been cooperative, and, thus, the Department is not required to assign Petrosul a higher BIA based on information which differs from the information on which it calculated Husky's dumping margin.

Department's Position

We disagree with Pennzoil that we should calculate a margin for Petrosul by comparing its reported USPs to a CV calculated from information in Pennzoil's cost allegation, or compare Petrosul's USPs to a public CV calculated for Husky. We are satisfied that selection of Husky's calculated rate is the appropriate BIA for Petrosul for this review, is consistent with our practice, and effectuates the purpose of the BIA rule.

The Department has broad discretion in determining what constitutes BIA in a given situation (*Krupp Stahl A.G.* v. *United States,* 822 F. Supp. 789, 792 (CIT 1993); *see also Allied-Signal Aerospace Co.* v. *United States, 966 F.2d 1185, 1191 (Fed. Cir. 1993) ''[B]ecause Congress has 'explicitly left a gap for the agency to fill' in determining what constitutes the best information available, the ITA's construction of the statute must be accorded considerable deference.''). The court has upheld the Department's two-tiered BIA methodology as ''a reasonable and permissible exercise of the ITA's statutory authority to use the best information available when a respondent refuses or is unable to provide requested information.'' Allied Signal* at 1192.

We agree with Pennzoil that we are not prohibited from resorting to a petitioner's cost information for BIA when the suppliers of an otherwise cooperative exporter fail to provide COP information. However, we are not compelled to do so. Furthermore, in this case, Pennzoil's cost allegation does not contain the necessary information, as the allegation does not individually identify the costs we have determined to be related to sulphur production and we are not able to ascertain them.

For the preliminary results, the Department concluded that ''[b]ecause the Department has determined that only sulphur handling facility costs should be allocated to sulphur production, the necessary information is not available from Pennzoil's cost allegation. As a result, we do not have the option of utilizing Pennzoil's cost data.'' *See Memorandum to Joseph A. Spetrini, from Holly A. Kuga, re: 1991–92 Antidumping Administrative Review of the Antidumping Finding on Elemental Sulphur from Canada: Use of Best Information Available for Petrosul International Due to Lack of Any Useable Cost of Production Information* (July 11, 1995) at 6 (*Petrosul Memo*). While the determination that ''only sulphur handling facility costs should be allocated to sulphur production'' is based on company-specific determinations of the status of sulphur as either a coproduct or byproduct, the Department notes that it made these determinations with regard to two of the three respondents that actively participated in this review. In *OCTG,* noting the wide discretion afforded it in determining what constitutes BIA, the Department determined that it would be more reasonable to use BIA to calculate cost of production for the respondent instead of applying total BIA because the cost information was not in the control of the respondent (*OCTG* at 38411). The Department acknowledges that it could assume that Petrosul's sulphur is a coproduct, but where we have found byproduct status for two of three respondents' sulphur, and where Petrosul has been deemed to be a cooperative respondent (*see Petrosul Memo at 7*), it is reasonable to disregard Pennzoil's cost data reported under a coproduct methodology.

Furthermore, the Department's decisions in *Pineapple* and *Silicon Metal from Brazil* do not stand for the proposition that cross-respondent use of proprietary data is permissible absent consent or adequate safeguards to protect the confidentiality of the data. In *Pineapple* and *Silicon Metal from Brazil,* adequate safeguards to protect the confidentiality of the data were present, *i.e.,* in *Pineapple,* we used proprietary data from several respondents such that no one respondent's proprietary data was vulnerable to disclosure. That is not the case in this review. The Department does not believe that use of Husky's public or ranged proprietary data would protect the confidentiality of the data.

In addition, in *TECHNOIMPORTEXPORT and Peer Bearing Company* v. *United States,* 766 F. Supp. 1169, 1177 (CIT 1991), the court stated that ''the use of confidential data without the communicated consent of the company from which the data is compiled is contrary to law and established ITA policy.''

Finally, the fact that Petrosul's U.S. sales data indicate USPs that differ from Husky's does not alter our decision. The Department must assess all of the facts on the record in making its determination, including the degree of cooperation or noncooperation of a respondent. For these final results, we determine that it is appropriate to apply total cooperative BIA to Petrosul since it is consistent both with our practice and the purpose of the BIA rule.

Comment 14

Petrosul asserts that the Department's COP investigation should focus on Petrosul's cost of acquisition (COA) rather than production costs of its suppliers and that as a matter of law the Department is not entitled to disregard Petrosul's COA in a COP investigation. Petrosul asserts that there is no statutory basis for disregarding Petrosul's COA as Petrosul is not related to its suppliers and, citing section 773(e)(4) of the Tariff Act, asserts that the scope of the Department's authority to disregard transaction values is limited expressly to transactions between related parties. Therefore, in determining FMV through CV, Petrosul contends that the Department may not look beyond the cost of acquiring materials to the supplier's COP where the transactions are between parties that are not related as defined by the Tariff Act.

Citing *Consolidated International Automotive, Inc.* v. *United States,* 809 F. Supp. 125 (CIT 1992), and *Washington Red Raspberry Comm. v. United States,* 657 F. Supp. 537 (CIT 1987), Petrosul asserts that the court rejected the argument that a CV analysis should look beyond transfer prices of inputs to the COP of such inputs incurred by unrelated suppliers, and explicitly reversed the Department's refusal to accept transaction prices in COP investigations of resellers where the transactions were unrelated. Petrosul asserts that it is unrelated to its suppliers, and, unlike the exporters in *Red Raspberry,* it is a truly independent reseller. Petrosul contends that the total absence of any relationship precludes the Department from pursuing an investigation based on the COP of Petrosul's suppliers.

Pennzoil asserts that, while section 773(b) of the Tariff Act does not define the ''cost of production'', by its terms it requires actual production costs, not a purchaser's cost of acquiring the finished product, to be compared to home market prices, and that Department regulations expressly state that COP will be based on ''the cost of materials, fabrication, and general expenses, but excluding profit.'' Pennzoil asserts that Petrosul's argument for basing COP on acquisition cost does not address the language of section 773(b) of the Tariff Act, Department precedent, the Department's explanation for its use of BIA in the preliminary results, or the Department memorandum on these matters. Instead,

Pennzoil argues, Petrosul's cites to statutory language and cases dealing with the valuation of inputs used in producing subject merchandise in determining CV which, according to Pennzoil, is irrelevant since Petrosul, a reseller, did not manufacture sulphur from any inputs.

Pennzoil rebuts Petrosul's reference to section 773(e)(4) of the Tariff Act, and argues that it defines ''related parties'' for the purposes of sections 773(e) (2) and (3), and that these sections address valuation of inputs in determining CV. Pennzoil asserts that section 773(e)(1) requires that CV include all inputs in the production of subject merchandise and that, since Petrosul did not purchase liquid sulphur as a material input in the production of that same subject merchandise, Pennzoil contends that these provisions are irrelevant.

Pennzoil further asserts that *Consolidated Automotive* and *Red Raspberry* involve valuation of inputs in calculating CV, the first which upheld the Department's use of the transaction price of lug nut blanks (an input) in determining the CV of chrome-plated lug nuts (subject merchandise), and the latter which found unlawful the Department's failure to use the transaction price of red raspberries (an input) in determining the CV of fresh and frozen red raspberries packed in bulk containers and suitable for further processing (the subject merchandise). Pennzoil asserts that, contrary to Petrosul's assertion, the exporters in *Red Raspberry* were not resellers, but rather manufacturers.

Pennzoil concludes that the CIT has not reviewed the Department's practice of rejecting acquisition cost as a basis for the COP of merchandise sold by a reseller, but that, given the substantial discretion afforded the Department, its interpretation of section 773(b) is proper because using acquisition cost would be contrary to the plain language of the sales-below-cost provision and would defeat its purpose.

Department's Position

The record indicates that Petrosul purchases elemental sulphur after its conversion from H_2S and without further processing. Petrosul admits it is not a producer of elemental sulphur, but rather merely a reseller. Because Petrosul is not involved in the production of elemental sulphur, the issue of the proper valuation of inputs is not relevant. Therefore, the statutory provisions and cases cited by Petrosul are not relevant.

Petrosul does not itself produce the elemental sulphur it sells. Department practice in such situations is to compare the production costs of the producer (Petrosul's supplier/producers), plus the producer's SG&A and the SG&A of the seller (Petrosul), to the seller's home market sales to determine whether home market sales were made below the COP. Upon receiving a satisfactory allegation of sales below cost, the Department is required to investigate those allegations. This investigation is mandated by section 773(b) of the Tariff Act, which provides that:

> Whenever the administering authority has reasonable grounds to believe or suspect that sales in the home market of the country of exportation, or, as appropriate, to countries other than the United States, have been made at prices which represent less than the *cost of producing the merchandise* in question, it shall determine whether, in fact, such sales were made at less than the *cost of producing the merchandise*. . . .

Section 773(b) of the Act (1994) (emphasis added).

As stated above, consistent with the Department's policy on this matter with regard to resellers, the Department has interpreted ''cost of producing the merchandise'' to mean the production costs of the producer, plus the producer's SG&A, plus the SG&A of the reseller. *See Memorandum from David Mueller to Reviewers,* December 18, 1990, attached to *Petrosul Memo; see, also, Fresh and Chilled Atlantic Salmon from Norway,* 56 FR 7661 (February 25, 1991); *Oil Country Tubular Goods (OCTG) from Canada,* 56 FR 38406 (August 13, 1991); and *Fresh Kiwifruit from New Zealand,* 57 FR 13695 (April 17, 1992). *See also Petrosul Memo.* While this interpretation may create a burden upon a respondent such as Petrosul, to hold otherwise would allow a huge loophole and open domestic producers to competition with below cost exports without remedy because the producer could continue to sell his production below cost, and, as long as he does not know the destination, the intermediate prices would be taken as COP for resellers, regardless of the actual costs incurred. Because the Department was unable to obtain the costs of producing the elemental sulphur supplied to Petrosul, the Department was unable to proceed to the next step in a sales-below-cost-investigation: comparison of the sulphur COP to Petrosul's home-market prices. Therefore, the Department relied on BIA.

Comment 15

Petrosul asserts that the use of its COA is particularly appropriate in the case of a waste product like elemental sulphur and claims that the substance actually recovered from natural gas or oil is hydrogen sulphide gas, which is not ''merchandise'' within the COP language of section 773(b) of the Tariff Act (19 U.S.C. § 1677b(b)). Therefore, Petrosul contends that the cost of extracting hydrogen sulphide and converting it into elemental sulphur is not a ''cost of producing the merchandise'' but is a cost mandated by both commerce and law of disposal of hydrogen-sulphide, a byproduct or waste product.

Petrosul asserts that production of recovered elemental sulphur is involuntary, that it is purchased immediately after its conversion from hydrogen sulphide without further processing, and, therefore, the ''cost of producing the merchandise'' is properly limited to acquisition, handling, administrative and sales costs incurred by Petrosul. Petrosul asserts that its COA is the most accurate measure of the product's COP since that is the first time value is attributed to the product.

Department's Position

Petrosul obtains elemental sulphur for resale and not H_2S. Therefore, we need the COP of sulphur for our analysis. In addition, the Department has determined that it must ascribe some costs to the production of sulphur, even if it considers sulphur a byproduct (*see, e.g., Comment 3; see also* Memorandum to Susan G. Esserman from Joseph A. Spetrini; Team Recommendation Related to The Cost Accounting Treatment of Elemental Sulphur From Canada, June 29, 1995). It is clear that Petrosul's suppliers bear some of these costs in handling elemental sulphur after converting it from H_2S as the Department determined that costs incurred in the sulphur handling facility, including loading, transferring of the product and a portion of general facilities costs relate directly to the sale of sulphur (*Id.* at 6). Because the Department does not have these costs, it was unable to proceed with its cost investigation of Petrosul.

Comment 16

Petrosul asserts that the Department acknowledged that Petrosul cooperated fully in this review, and that it provided all information requested except for its suppliers' COPs, which it does not have and cannot force its suppliers to provide. Under such circumstances, Petrosul contends that reliance on BIA is arbitrary, capricious, an abuse of discretion and contrary to law as there is nothing that Petrosul could do.

Petrosul asserts that even in antidumping proceedings, parties are entitled to due process protection, citing *Sugiyama Chain Co., Ltd.* v. *United*

States, 852 F. Supp. 1103, 1115 (CIT 1994) (*Sugiyama*), yet the Department's approach here condemns all independent resellers to BIA margins in COP investigations where the unrelated supplier chooses not to cooperate. Petrosul contends that it is a violation of due process of law for the Department to assign BIA margins to respondents that cannot produce information which is not, and will never be, in their possession.

Petrosul asserts that it never had an opportunity to respond to the Department's request for its suppliers' costs, information which is beyond Petrosul's reach, and that Petrosul is being denied the opportunity to respond. Petrosul cites *Sigma Corp.* v. *United States,* 841 F. Supp. 1255 (CIT 1993), where the court reversed the Department's reliance on BIA for a respondent that never was given an opportunity to respond, to support its position.

Pennzoil asserts that basing Petrosul's margin of dumping on BIA is not fundamentally unfair, an abuse of discretion or a denial of due process. Pennzoil argues that there is no alternative to reliance on BIA for Petrosul in the absence of actual COP data, as use of acquisition cost would subvert the sales-below-cost provision of the Tariff Act.

Department's Position

The Department believes Petrosul has been fully afforded procedural due process. The Department requested cost information from Petrosul's suppliers, all of whom refused to provide such information. Section 776(c) of the Act requires the Department to use BIA ''whenever a party or any other person refuses or is unable to produce information requested in a timely manner or in the form required, or otherwise significantly impedes an investigation.'' Further, Department regulations provide that ''[t]he Secretary will use the best information available whenever the Secretary (1) [d]oes not receive a complete, accurate, and timely response to the Secretary's request for factual information; or (2) [i]s unable to verify, within the time specified, the accuracy and completeness of the factual information submitted.'' 19 CFR 353.37(a). Because the Department could not identify any other source of data that would provide a reasonable surrogate for the missing supplier-producers' cost of producing elemental sulphur, the only alternative open to the Department is to apply total BIA to Petrosul.

With regard to Petrosul's assertion that it never had an opportunity to respond to the Department's request for its suppliers's costs, given the Department's practice, Petrosul was fully aware of the import of its suppliers' refusal to reply to the Department's questionnaire.

Final Results of Review

We determine the following percentage weighted-average margins exist for the period December 1, 1991 through November 30, 1992:

Manufacturer/exporter	Percent margin
Husky Oil Ltd.	7.17
Mobil Oil Canada, Ltd.	[1] 7.17
Petrosul	[1] 7.17
Alberta	([2])
Allied	([2])
Norcen	([2])
Brimstone	[3] 28.9
Burza	[3] 28.9
Canamex	[3] 28.9
Delta	[3] 28.9
Drummond	[3] 28.9
Fanchem	[3] 28.9
Real	[3] 28.9
Saratoga	[3] 28.9
Sulbow	[3] 28.9

[1] Cooperative BIA rate.
[2] No shipments or sales subject to this review. The firm has no individual rate from any segment of this proceeding. As a result, the firm will be subject to the ''all others'' rate.
[3] Non-cooperative BIA rate.

The Department shall determine, and the Customs Service shall assess, antidumping duties on all appropriate entries. Individual differences between USP and FMV may vary from the percentages stated above. The Department will issue appraisement instructions on each exporter directly to the Customs Service.

Furthermore, the following deposit requirements will be effective for all shipments of elemental sulphur, entered or withdrawn from warehouse, for consumption on or after the publication date of these final results, as provided by section 751)a)(1) of the Tariff Act: (1) the cash deposit rate for the reviewed companies will be the rates listed above; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original LTFV investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this or any previous review, or the less-than-fair-value (LTFV) investigation, the cash deposit rate will be the ''new shipper'' rate established in the first review conducted by the Department in which a ''new shipper'' rate was established, as discussed below.

On May 25, 1993, the Court of International Trade (CIT), in *Floral Trade Council v. United States,* 822 F. Supp. 766 (CIT 1993), and *Federal-Mogul Corporation and The Torrington Company v. United States,* 822 F. Supp. 782 (CIT 1993), decided that once an ''All Others'' rate is established for a company it can only be changed through an administrative review. The Department has determined that in order to implement these decisions, it is appropriate to reinstate the ''All Others'' rate from the LTFV investigation (or that rate as amended for correction or clerical errors as a result of litigation) in proceedings governed by antidumping duty orders. In proceedings governed by antidumping findings, unless we are able to ascertain the ''All Others'' rate from the Treasury LTFV investigation, we have determined that it is appropriate to adopt the ''new shipper'' rate established in the first final results of administrative review we published (or that rate as amended for correction or clerical errors as a result of litigation) as the ''All Others'' rate for the purposes of establishing cash deposits in all current and future administrative reviews.

Because this proceeding is governed by an antidumping finding, and we are unable to ascertain the ''All Others'' rate from the Treasury LTFV investigation, the ''All Others'' rate for the purposes of this review would normally be the ''new shipper'' rate established in the first notice of final results of administrative review we published. However, a ''new shipper'' rate was not established or ascertainable in that notice. Therefore, for the purposes of this review, we have drawn the ''All Others'' rate of 5.56 percent from the final results of administrative review of this finding we conducted generally for the period December 1, 1980 through November 30, 1982. *See Elemental Sulphur from Canada; Final Results of Administrative Review of Antidumping Finding,* 48 FR 53592 (November 28, 1983).

These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement

could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective orders (APOs) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 353.34(d)(1). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

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 19 CFR 353.22.

Dated: February 22, 1996.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 96–4979 Filed 3–1–96; 8:45 am]

BILLING CODE 3510–DS–P

[A–580–601]

Certain Stainless Steel Cooking Ware From the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of preliminary results of Antidumping Duty Administrative Review.

SUMMARY: In response to a request from Farberware, Inc. (petitioner), the Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on certain stainless steel cooking ware from the Republic of Korea. This notice of preliminary results covers the period January 1, 1994 through December 31, 1994. This review covers one manufacturer/exporter, Daelim Trading Company, Ltd. (Daelim). The review indicates the existence of dumping margins during this period.

We have preliminarily determined that sales have been made below the normal value (NV). If these preliminary results are adopted in our final results of administrative review, we will instruct the U.S. Customs Service (Customs) to assess antidumping duties equal to the difference between the United States price (USP) and the NV. Interested parties are invited to comment on these preliminary results. Parties who submit argument in this proceeding are requested to submit with the argument: (1) a statement of the issue; and (2) a brief summary of the argument.

EFFECTIVE DATE: March 4, 1996.

FOR FURTHER INFORMATION CONTACT: Amy S. Wei or Zev Primor, Office of Antidumping Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone (202)482–5253.

SUPPLEMENTARY INFORMATION:

The Applicable Statute

Unless otherwise indicated, all citations of the Tariff Act of 1930, as amended, (the Act) are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Rounds Agreements Act (URAA).

Background

The Department published an antidumping duty order on certain stainless steel cooking ware from the Republic of Korea on January 20, 1987 (52 FR 2139). The Department published a notice of ''Opportunity To Request an Administrative Review'' of the antidumping duty order for the 1994 review period on January 12, 1995 (60 FR 2941). On January 30, 1995, petitioner requested that the Department conduct an administrative review of the antidumping duty order on certain stainless steel cooking ware from the Republic of Korea for one manufacturer/exporter, covering the period January 1, 1994 through December 31, 1994. We initiated the review on February 15, 1995 (60 FR 8629).

The Department extended the time limits for the deadlines for the preliminary and final results of review because of the additional time required for the development of a new questionnaire that accorded with the URAA. See *Antidumping Duty Administrative Reviews; Time Limits*, 60 FR 56141 (November 7, 1995). As a result of the federal government 28-day total shutdown, these deadlines were further extended.

The Department is now conducting this administrative review in accordance with section 751 of the Act.

In addition, on September 11, 1995, petitioner requested that the Department conduct an investigation to determine if Daelim made sales at prices below its cost of production (COP) during the review period. On October 19, 1995, based on petitioner's allegation and the totality of evidence on record, the Department determined that there were reasonable grounds to believe or suspect that Daelim made sales at prices below its COP, in accordance with section 773 (b)(2)(A)(i) of the Act, and initiated a COP investigation for Daelim, pursuant to section 773(b)(1) of the Act. See *Certain Stainless Steel Cooking Ware from Korea—Home Market Sales Below Cost Allegation for Daelim Trading Company, Ltd.*, October 19, 1995.

Scope of the Review

The products covered by this administrative review are certain stainless steel cooking ware from the Republic of Korea. During the review period, such merchandise was classifiable under Harmonized Tariff Schedule (HTS) item number 7323.93.00. The products covered by this order are skillets, frying pans, omelette pans, saucepans, double boilers, stock pots, dutch ovens, casseroles, steamers, and other stainless steel vessels, all for cooking on stove top burners, except tea kettles and fish poachers. Excluded from the scope is stainless steel kitchen ware. The HTS item number is provided for convenience and Customs' purposes. The written description remains dispositive as to the scope of product coverage.

The period of review (POR) is January 1, 1994 through December 31, 1994, covering one manufacturer/exporter, Daelim.

Use of Facts Available

A large portion of Daelim's home market sales were to an affiliated reseller. Because an extremely small percentage of Daelim's total home market sales were to unaffiliated customers, there is not a sufficient factual basis to determine whether sales to the affiliated reseller were made at arm's-length prices. See *Television Receivers, Monochrome and Color, from Japan; Final Results of Antidumping Duty Administrative Review*, 52 FR 8940, 8943 (March 20, 1987). Therefore, the Department will request that Daelim provide the information on sales by its affiliated reseller to the first unaffiliated customer for certain home market models.

For purposes of the preliminary results, the Department has applied a neutral facts available (FA) rate for the missing downstream sales information, in accordance with section 776(a)(1) of the Act. For a neutral FA rate, we applied the weighted-average margin calculated for sales to the United States (U.S.) for which there were appropriate home market sales for matching

purposes. If Daelim timely responds to our request for additional information, we will examine Daelim's response and incorporate the information provided in our analysis in the final results of administrative review. If Daelim fails to provide the requested data, we may evaluate the application of FA accordingly.

United States Price

In calculating USP for Daelim, we used export price, as defined in section 772(a) of the Act, because the merchandise was sold to unaffiliated U.S. purchasers prior to the date of importation. Daelim reported that export price was based on the packed, FOB price to unaffiliated purchasers in the United States. We made deductions for brokerage and handling charges, inland freight from the plant, credit expense, wharfage, container freight station (CFS) charges, and export license recommendation fees, in accordance with section 772(c)(2)(A) of the Act, because these expenses were incident to bringing the subject merchandise from the original place of shipment in the exporting country to the place of delivery in the United States. We increased USP for duty drawback, in accordance with section 772(c)(1)(B) of the Act. In addition, because there is a concurrent countervailing duty order on the subject merchandise, we increased USP by the amount of the countervailing duty imposed on the subject merchandise to offset the export subsidy, in accordance with section 772(c)(1)(C) of the Act.

No other adjustments to USP were claimed or allowed.

Normal Value

A. Viability

In order to determine whether there was a sufficient volume of sales in the home market to serve as a viable basis for calculating NV, we compared Daelim's volume of home market sales of the foreign like product to the volume of U.S. sales of the subject merchandise, in accordance with section 773(a)(1)(B) of the Act. Because Daelim's aggregate volume of home market sales of the foreign like product was greater than five percent of its aggregate volume of U.S. sales for the subject merchandise, we determined that the home market provides a viable basis for calculating NV for Daelim, pursuant to section 773(a)(1)(C) of the Act.

B. COP Test

As stated above in the *Background* section, the Department initiated a cost investigation to determine whether Daelim made home market sales during the POR at prices below its COP, as defined in section 773(b) of the Act. We calculated COP based on the sum of the costs of materials and fabrication employed in producing the foreign like product, plus selling, general, and administrative expenses (SG&A), and the cost of all expenses incidental to placing the foreign like product in condition packed ready for shipment, in accordance with section 773(b)(3) of the Act. We relied on the home market sales and COP information provided by Daelim in its questionnaire responses.

In accordance with section 773(b)(1) of the Act, in order to determine whether to disregard home market sales made at prices below the COP, we examined whether such sales were made in substantial quantities within an extended period of time, and whether such sales were made at prices which permit the recovery of all costs within a reasonable period of time.

Pursuant to section 773(b)(2)(C)(i) of the Act, where less than 20 percent of home market sales of a given model are at prices less than the COP, we do not disregard any below-cost sales of that model because the below-cost sales were not made within an extended period of time in ''substantial quantities.'' Where 20 percent or more of home market sales of a given model are at prices less than the COP, we find that sales of that model were made within an extended period of time in ''substantial quantities,'' in accordance with section 773(b)(2)(B) of the Act. Moreover, we determine whether the below-cost sales of a given product are at prices which would not permit recovery of all costs within a reasonable period of time, in accordance with section 773(b)(2)(D) of the Act. If we find that sales have been made within an extended period of time in ''substantial quantities'' and were not at prices which would permit recovery within a reasonable period of time, we disregard the below-cost sales, in accordance with section 773(b)(1) of the Act.

The results of our cost test indicated that within an extended period of time, for certain home market models, more than 20 percent of the home market sales were sold at below the COP prices, which would not permit the recovery of all costs within a reasonable period of time. Thus, we excluded these below-cost sales and used the remaining above-cost sales as the basis of determining NV, in accordance with section 773(b)(1). For those home market models for which there were no above-cost sales, we compared export prices to constructed value (CV), in accordance with section 773(b)(1).

C. Model Match

The Department determined that the model match methodology provided by Daelim in its questionnaire response was too restrictive. Daelim's methodology limited the selection of matches to essentially identical merchandise. When there were no contemporaneous sales of this identical merchandise, Daelim's methodology did not select acceptable similar merchandise, but, instead, resorted to CV as the basis for NV. Therefore, we revised Daelim's model match for the preliminary results of review in order to search for the HM model which is most like or most similar in characteristics and uses with each US model, pursuant to section 771 (10) of the Act. First, from Daelim's one product category, we established three foreign like product categories: (1) Sauce pans and pots; (2) frying pans; and (3) other cooking ware, such as steamers, covers, or boiler inserts. Second, we broadened Daelim's model match criteria of capacity, gauge, and body style, and did not use the parameters Daelim suggested. To perform the model match, we first searched for the most similar home market model with regard to capacity. If there were several home market models with identical capacities, we then searched for the most similar home market model with regard to gauge. We continued this process with regard to body shape. If, as a result of this analysis, several home market models were deemed equally similar, we chose the home market model which, when compared to the U.S. model, had the lowest difference in variable costs of manufacturing (difmer), provided the difmer did not exceed 20 percent of the total cost of manufacturing of the U.S. model.

Our model match resulted in several price-to-price comparisons involving sales to the affiliated reseller, requiring downstream sales information. For those U.S. models where no foreign like product was found with a difmer of less than 20 percent or where the U.S. model matched to a home market model which was found to be sold at below cost, we resorted to CV as the basis of NV, in accordance with section 773(a)(4) of the Act.

D. Constructed Value

In accordance with section 773(e) of the Act, we calculated CV based on Daelim's cost of materials and fabrication employed in producing the subject merchandise, SG&A and profit incurred and realized in connection

with the production and sale of the foreign like product, and U.S. packing costs. We used the costs of materials, fabrication, and G&A as reported in the CV portion of Daelim's questionnaire response. We used the U.S. packing costs as reported in the U.S. sales portion of Daelim's questionnaire response. We based selling expenses and profit on the information reported in the home market sales portion of Daelim's questionnaire response. See *Certain Pasta from Italy; Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination*, 61 FR 1344, 1349 (January 19, 1996). For selling expenses, we used the average of above-cost per-unit HM selling expenses weighted by the total quantity sold. For actual profit, we first calculated the difference between the home market sales value and home market COP, and divided the difference by the home market COP. We then multiplied this percentage by the COP for each U.S. model to derive an actual profit.

E. Price-to-Price Comparisons

For those price-to-price comparisons where we did not resort to CV or the facts available, we based NV on the price which the foreign like product is first sold for consumption in the exporting country, in the usual commercial quantities and in the ordinary course of trade, and to the extent practicable, at the same level of trade as the export price, as defined by section 773(a)(1)(B)(i) of the Act. We reduced NV for home market credit and advertising expenses, in accordance with section 773(a)(6)(C)(iii), due to differences in circumstances of sale. We also reduced NV by packing costs incurred in the home market, in accordance with section 773(a)(6)(B)(i). In addition, we increased NV for U.S. packing costs, in accordance with section 773(a)(6)(A). We made further adjustments to account for differences in physical characteristics of the merchandise, in accordance with 19 CFR 353.57 of the Department's regulations.

When NV was based on CV or home market sales, we adjusted for commissions paid on U.S. sales. In accordance with 19 CFR 353.56(b)(1), we offset these commissions with the weighted average of home market indirect selling expenses, because no sales commissions were incurred in the home market, up to the amount of the commissions paid on U.S. sales. In addition, we increased NV by U.S. credit expenses, in accordance with section 773(a)(6)(C)(iii) of the Act, because of differences in the circumstances of sale. No other adjustments were claimed or allowed.

Preliminary Results

As a result of this review, we preliminarily determine that the following weighted-average dumping margin exists:

Manufacturer/ exporter	Period	Margin (percent)
Daelim Trading Co., Ltd	1/1/94–12/31/94	6.31

Parties to this proceeding may request disclosure within five days of publication of this notice and any interested party may request a hearing within 10 days of publication. Any hearing, if requested, will be held 44 days after the date of publication, or the first working day thereafter. Interested parties may submit case briefs and/or written comments no later than 30 days after the date of publication. Rebuttal briefs and rebuttals to written comments, limited to issues raised in such briefs or comments, may be filed no later than 37 days after the date of publication. The Department will publish a notice of the final results of the administrative review, which will include the results of its analysis of issues raised in any such written comments or at the hearing, within 180 days from the issuance of these preliminary results.

The Department shall determine, and Customs shall assess, antidumping duties on all appropriate entries. Individual differences between USP and NV may vary from the percentages stated above. The Department will issue appraisement instructions directly to Customs. The final results of this review shall be the basis for the assessment of antidumping dumping duties on entries of merchandise covered by the determination and for future deposits of estimated duties.

Furthermore, the following deposit requirements will be effective upon completion of the final results of these administrative reviews for all shipments of certain stainless steel cooking ware from the Republic of Korea entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of these administrative reviews, as provided by section 751(a)(1) of the Act: (1) The cash deposit rate for Daelim will be the rate established in the final results of administrative review; (2) for merchandise exported by manufacturers or exporters not covered in these reviews but covered in the original LTFV investigation or a previous review, the cash deposit will continue to be the most recent rate published in the final determination or final results for which the manufacturer or exporter received a company-specific rate; (3) if the exporter is not a firm covered in these reviews, or the original investigation, but the manufacturer is, the cash deposit rate will be that established for the manufacturer of the merchandise in the final results of these reviews, or the LTFV investigation; and (4) if neither the exporter nor the manufacturer is a firm covered in these or any previous reviews, the cash deposit rate will be 8.10 percent, the ''all others'' rate established in the LTFV investigation (52 FR 2139, January 20, 1987).

This notice serves as a preliminary reminder to parties subject to administrative protective orders (APOs) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 353.34(d). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 353.26(b) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during these review periods. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

These administrative reviews and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)).

Dated: February 28, 1996.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 96–4983 Filed 3–1–96; 8:45 am]

BILLING CODE 3510–DS–P

[C–508–605]

Industrial Phosphoric Acid From Israel; Preliminary Results of Countervailing Duty Administrative Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce

ACTION: Notice of preliminary results of Countervailing Duty Administrative Reviews.

SUMMARY: The Department of Commerce (the Department) is conducting two administrative reviews of the countervailing duty order on industrial phosphoric acid from Israel. We preliminarily determine the net subsidy to be 3.84 percent *ad valorem* for all companies for the period January 1, 1992 through December 31, 1992, and 5.50 percent *ad valorem* for all companies for the period January 1, 1993 through December 31, 1993. If the final results of these reviews remain the same as these preliminary results, the Department intends to instruct the U.S. Customs Service to assess countervailing duties as indicated above. Interested parties are invited to comment on these preliminary results.

EFFECTIVE DATE: March 4, 1996.

FOR FURTHER INFORMATION CONTACT: Brian Albright or Cameron Cardozo, Office of Countervailing Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–2786.

SUPPLEMENTARY INFORMATION:

Background

On August 19, 1987, the Department published in the Federal Register (52 FR 31057) the countervailing duty order on industrial phosphoric acid from Israel. On August 3, 1993, and August 3, 1994, the Department published notices of ''Opportunity to Request Administrative Review'' of this countervailing duty order for the periods January 1, 1992 through December 31, 1992 and January 1, 1993 through December 31, 1993, respectively (58 FR 41240 and 59 FR 39543). We received a timely request for review for the 1992 review period from the petitioners, FMC Corporation and the Monsanto Company. We received timely requests for review for the 1993 review period from both the petitioners and the respondent, Rotem Fertilizers Ltd.

We initiated the review covering the period January 1, 1992 through December 31, 1992, on September 30, 1993 (58 FR 51054). We initiated the review covering the period January 1, 1993 through December 31, 1993, on September 16, 1994 (59 FR 47609). Each review covers one manufacturer/exporter of the subject merchandise, which accounts for virtually all of the exports of subject merchandise from Israel to the United States during the review period, and ten programs.

Applicable Statute and Regulations

The Department is conducting these administrative reviews in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). Unless otherwise indicated, all citations to the statute and to the Department's regulations are in reference to the provisions as they existed on December 31, 1994. However, references to the Department's *Countervailing Duties; Notice of Proposed Rulemaking and Request for Public Comments,* 54 FR 23366 (May 31, 1989) (*Proposed Regulations*), are provided solely for further explanation of the Department's countervailing duty practice. Although the Department has withdrawn the particular rulemaking proceeding pursuant to which the *Proposed Regulations* were issued, the subject matter of these regulations is being considered in connection with an ongoing rulemaking proceeding which, among other things, is intended to conform the Department's regulations to the Uruguay Round Agreements Act. *See* 60 FR 80 (Jan. 3, 1995).

Scope of Review

Imports covered by this review are shipments of industrial phosphoric acid (IPA) from Israel. Such merchandise is classifiable under item number 2809.20.00 of the *Harmonized Tariff Schedule* (HTS). The HTS item number is provided for convenience and Customs purposes. The written description remains dispositive.

Calculation Methodology for Assessment and Cash Deposit Purposes

Because Rotem is the only manufacturer/exporter of the subject merchandise to the United States, Rotem's net subsidy rate is also the country-wide rate.

Privatization

Israeli Chemicals Ltd. (ICL), the parent company which holds one hundred percent of Rotem's shares, was partially privatized in 1992 and again in 1993. Accordingly, we have determined that the partial privatization of ICL represents a partial privatization of each of the companies in which ICL holds an ownership interest.

In these reviews and prior reviews of the subject merchandise, the Department has found that Rotem and/or its predecessor, Negev Phosphates Ltd., received non-recurring countervailable subsidies prior to these partial privatizations. Further, the Department has found that a private party purchasing all or part of a government-owned company can repay prior non-recurring subsidies on behalf of the company as part or all of the sales price (*see* the General Issues Appendix appended to the *Final Countervailing Duty Determination; Certain Steel Products from Austria,* 58 FR 37262 (July 9, 1993) (*General Issues Appendix*)). Therefore, to the extent that a portion of the sales price paid for a privatized company can be reasonably attributed to prior subsidies, that portion of those subsidies are repaid.

To calculate the non-recurring subsidies remaining with Rotem after each partial privatization, we performed the following calculations. We first calculated the amount of the purchase price paid for the ICL shares which could be attributed to Rotem using the ratio of Rotem's net assets to ICL's net assets in the year of sale. (For a further explanation of the Department's analysis of the purchase price attributable to Rotem, *see* October 25, 1995 memorandum to Barbara E. Tillman regarding partial privatization of ICL, which is on file in the public file of the Central Records Unit, Room B–099 of the Department of Commerce.) We then calculated the net present value (NPV) of the future benefit stream of the non-recurring subsidies received by Rotem at the time of the sale of the shares. Next, we calculated the portion of the purchase price which represents repayment of prior subsidies in accordance with the methodology described in the ''Privatization'' section of the *General Issues Appendix* (58 FR 37259). This amount was then subtracted from the NPV of the subsidies, and the result was divided by the NPV of the subsidies to calculate the ratio representing the amount of subsidies remaining with Rotem after each partial privatization.

To calculate the benefit provided to Rotem for 1992 and 1993, we multiplied the benefit calculated for Encouragement of Capital Investment Law grants (the only subsidies relevant to the privatization calculation) for each period by the ratio representing the amount of subsidies remaining with Rotem after the partial privatization. We then divided the results by the company's total sales of subject merchandise in each respective period.

Analysis of Programs

I. Programs Preliminarily Determined to Confer Subsidies

(A) Encouragement of Capital Investments Law (ECIL) Grants

The ECIL grants program was established to attract capital to Israel. In

order to be eligible to receive various benefits under the ECIL, including investment grants, capital grants, accelerated depreciation, reduced tax rates, and certain loans, the applicant must obtain approved enterprise status. Approved enterprise status is obtained after a review of information submitted to the Investment Center of the Israeli Ministry of Industry and Trade. Investment grants are given as a percentage of the cost of the approved investment. The amount of the grant benefits received by approved enterprises depends on the geographic location of the eligible enterprise. For purposes of the ECIL program, Israel is divided into three zones—Development Zone A, Development Zone B, and the Central Zone—each with a different funding level.

Since 1978, only investment projects outside the Central Zone have been eligible to receive grants. The Central Zone comprises the geographic center of Israel, including its largest and most developed population centers. In *Final Affirmative Countervailing Duty Determination: Industrial Phosphoric Acid from Israel*, 52 FR 25447 (July 7, 1987) (*IPA Investigation*), the Department found the ECIL grants program to be *de jure* specific and thus countervailable because the grants are limited to enterprises located in specific regions. In these reviews, the Government of Israel (GOI) has provided no new information or evidence of changed circumstances to warrant reconsideration of this determination.

Rotem Fertilizers Ltd. (Rotem) is located in Development Zone A, and received ECIL investment, drawback, and capital grants in disbursements over a period of years for several projects. We followed the methodology developed in *IPA Investigation* to determine the benefits from the ECIL grants. However, consistent with the *Final Affirmative Countervailing Duty Determination: Certain Carbon Steel Butt-Weld Pipe Fittings From Israel,* 60 FR 10569 (February 27, 1995) (*Butt-Weld Pipe Investigation*), in these reviews we have amended the calculation methodology to conform with the use of variable rather than fixed interest rates in the years these grants were disbursed. Section 355.49(b)(3) of the Department's *Proposed Regulations* relies on a discount rate, based on the cost of fixed-rate long-term debt for the firm under review or generally in the country under review. However, Rotem had no fixed-rate long-term debt during the years in which it received ECIL grants. Moreover, in *Butt-Weld Pipe Investigation,* the Department determined that no long-term loans with fixed interest rates (or other long-term debt) were available in Israel during that period; the only long-term loans (or other long-term debt) available to companies in Israel were provided at variable interest rates.

This methodology reflects the actual long-term options open to Israeli firms, and also ensures that the net present value of the amount countervailed in the year of receipt does not exceed the face value of the grant. In accordance with *General Issues Appendix,* we allocated these grants over ten years (the average useful life of renewable physical assets in the chemical manufacturing industry, as determined under the U.S. Internal Revenue Service Asset Depreciation Range System). As the discount rate, we have used the rate of return on CPI-indexed commercial bonds (the real rate of return, as published in the Bank of Israel Annual Reports, plus the CPI).

We summed the benefits from these projects for each year (1992 and 1993), and then reduced the annual benefits according to the methodology outlined in the ''Privatization'' section above. We then divided the results by the value of IPA sold by Rotem during the relevant review period. On this basis, we preliminarily determine the net subsidy from this program to be 3.82 percent *ad valorem* for 1992 and 5.47 percent *ad valorem* for 1993.

(B) Long-term Industrial Development Loans

Prior to July 1985, approved enterprises were eligible to receive long-term industrial development loans funded by the Government of Israel (GOI). During the original investigation, we verified that these loans, like the ECIL grants, were project-specific. They were disbursed through the Industrial Development Bank of Israel (IDBI) and other industrial development banks which no longer exist.

The long-term industrial development loans were provided to a diverse number of industries, including agricultural, chemical, mining, machine, and others. However, the interest rates on loans vary depending on the Development Zone in which the borrower is located. The interest rates on loans to borrowers in Development Zone A are lowest, while those on loans to borrowers in the Central Zone are highest. Therefore, loans to companies in Zone A are provided on preferential terms relative to loans received by companies in the heavily populated and developed Central Zone. In *IPA Investigation,* the Department found long-term industrial development loans to be regional subsidies and countervailable to the extent that they are provided at interest rates which are lower than those applied on loans provided to companies located in the Central Zone. In these reviews, the Government of Israel (GOI) has provided no new information or evidence of changed circumstances to warrant reconsideration of this determination. Rotem had loans outstanding under this program during both review periods. The loans carry the Zone A interest rates because of Rotem's location. Therefore, we determine that Rotem received countervailable benefits under this program because the interest rates paid by Rotem are less than those which would apply in the Central Zone.

As was determined in the *Butt-Weld Pipe Investigation,* under the terms of this program, the interest rates on these loans have two components—a fixed real interest rate and a variable interest rate, the latter of which is based on either the CPI or the dollar/shekel exchange rate. All of Rotem's loans were linked to the dollar/shekel exchange rate. Because the dollar-shekel exchange rate varies from year-to-year, we were unable to apply the Department's methodology described in the *Proposed Regulations* because we cannot calculate *a priori* the payments due over the life of these loans, and hence cannot calculate the ''grant equivalent'' of the loans. Accordingly, in accordance with section 355.49(d)(1) of the *Proposed Regulations,* we have compared the interest that would have been paid by a company in the Central Zone, as a benchmark, to the amount actually paid by Rotem during the review periods.

For each project, we calculated the interest savings accrued during the period of review (POR). We then summed the benefits and divided the total by the value of all IPA sold by Rotem during the POR. On this basis, we preliminarily determine the net subsidy from this program to be 0.01 percent *ad valorem* for 1992, and less than 0.005 percent *ad valorem* for 1993.

(C) Exchange Rate Risk Insurance Scheme

Prior to September 1993, the Exchange Rate Risk Insurance Scheme (EIS), operated by the Israel Foreign Trade Risk Insurance Corporation Ltd. (IFTRIC), was designed to insure exporters against losses which resulted when the rate of inflation exceeded the rate of devaluation and the new Israeli Shekel (NIS) value of an exporter's foreign currency receivables did not rise enough to cover increases in local costs.

The EIS was optional and open to any exporter willing to pay a premium to IFTRIC. Compensation was based on a

comparison of the rate of devaluation of the NIS against a basket of foreign currencies with the change in the consumer price index. If the rate of inflation exceeded the rate of devaluation, the exporter was compensated by an amount equal to the difference between these two rates multiplied by the value-added of the exports. If the rate of devaluation was higher than the rate of inflation, however, the exporter was required to compensate IFTRIC. The premium was calculated for all participants as a percentage of the value-added sales value of exports. IFTRIC changed this percentage rate periodically, but at any given time it was the same for all exporters.

In determining whether an export insurance program provides a countervailable benefit, we examine whether the premiums and other charges are adequate to cover the program's long-term operating costs and losses. Despite periodic increases in the premium rate, we determined in *IPA Investigation* that this program did not cover its long term costs and losses and, therefore, conferred an export subsidy on exports of IPA from Israel. In addition, in the *Final Results of Countervailing Duty Administrative Review; Industrial Phosphoric Acid from Israel* (59 FR 5176; February 3, 1994), covering the 1991 review period, we found that this program conferred a countervailable benefit on exporters in Israel of the subject merchandise. Normally, five years is a sufficiently long enough period of time to establish that the premiums and other charges are manifestly inadequate to cover the long-term operating costs and losses of the program. (See section 355.44(d)(1) of the *Proposed Regulations*). We reviewed EIS financial statements in these reviews which showed that EIS has continuously operated at a loss from 1981 through 1992. Since EIS has operated at a loss for 12 years, the determination that this program is countervailable remains unchanged.

We verified that Rotem did not receive benefits from IFTRIC for its IPA exports to the United States during 1992. However, Rotem did receive benefits from IFTRIC for its IPA exports to United States during 1993. Therefore, for the 1993 review period, we have calculated the benefit rate by dividing the net amount of compensation Rotem received during the review period from IFTRIC for IPA exported to the United States, by the value of the company's exports of IPA to the United States during the same period. On this basis, we preliminarily determine the benefit from this program to be zero for the 1992 review period and 0.02 percent *ad valorem* for the 1993 review period.

(D) Encouragement of Industrial Research and Development Grants (EIRD)

Rotem received several grants under this program in both the 1992 and 1993 review periods. In *IPA Investigation,* we determined that the results of research funded by EIRD grants are not made publicly available, and that such grants are countervailable. (See also section 355.44(l) of the *Proposed Regulations*). We followed the methodology developed in *IPA Investigation* in determining the benefits from the EIRD funding.

The EIRD grant issued to Rotem on January 13, 1992 benefited a research project concerning green acid, which is used as an input in the production of IPA. We view this as a ''non-recurring'' grant based on the analysis set forth in the Allocation section of the *General Issues Appendix.* Since the grant value was less than 0.50 percent of all Rotem's sales, we allocated the full amount of the grant to 1992 and divided by Rotem's total sales of all products. On this basis, we preliminarily determine the benefit from this program to be less than 0.005 percent *ad valorem.*

II. New Program Preliminarily Determined Not to Confer Subsidies

Law for the Encouragement of the Business Sector (Absorption of Workers)

The questionnaire responses submitted by the GOI and Rotem for the 1992 and 1993 review periods stated that Rotem participated in a temporary program aimed at encouraging employment in order to cope with the problems caused by immigration. This program, enacted under the temporary Law for the Encouragement of the Business Sector (Absorption of Workers), has not been examined in any prior reviews or in the investigation of the subject merchandise. Therefore, we requested additional information on this program, and on the benefits received by Rotem, in a supplemental questionnaire, and we verified the information in both responses in order to determine whether the program was limited, either *de jure* or *de facto,* to a specific enterprise or industry, or a group of enterprises or industries, and thus countervailable.

The temporary Law for the Encouragement of the Business Sector (Absorption of Workers) was instituted in 1991 in an effort to expand employment opportunities in the Israeli economy, following rising levels of unemployment between 1988–1991 caused by large Russian immigration. Under the Absorption of Workers program, funded by the Treasury and administered by the National Insurance Institute (NII), any employer in the business sector employing a monthly average of over five employees is eligible to receive a monthly grant from the Treasury for each additional employee hired. The period of payment of the grant for each employee is limited to two years. During the first year, the grant consists of one-third of the monthly wages paid to the employee but cannot exceed NIS 1000 per month. During the second year, the grant consists of one-fourth of the monthly wages paid to the employee but cannot exceed NIS 750 per month. Payments under the program began in July 1991 and are scheduled to terminate in December 1995.

Companies that wish to participate in this program submit an application, certified by a CPA, through their bank to the NII within nine months of the end of the quarter for which they are requesting assistance. The NII reviews the application form and compares it to the company's insurance records and Department of the Interior records to calculate the average number of workers employed prior to the period of application. Any workers hired over this baseline number make the company eligible for participation in the program. For eligible companies, payment is transferred directly into the employer's bank account within 45 days of the application. The NII conducts random audits of approximately 20 percent of the recipients.

We verified that all companies in the business sector employing a minimum of five workers are eligible to participate in the program and, upon submission of a complete and accurate application within the specified time frame, will receive a grant for each additional worker hired. Moreover, we found no evidence that the program is regional or that approval is contingent upon the export performance of the company. Finally, we found no evidence that the program is limited to a specific enterprise or industry, or a group of enterprises or industries. There are a large number and wide variety of users of the program. The range of industrial branches that received grants includes agriculture, general industry, electricity and water, construction, food and hospitality, transportation, financial, public services, and private services. Chemical producers are neither a dominant nor disproportionate recipient of the grants, and there is no evidence that the GOI exercises discretion, in general or across industries, in

conferring the grants. Thus, we preliminarily determine that this program is not countervailable within the meaning of section 701(a) of the Act. (For a more detailed explanation of the Department's decision, *see* the May 26, 1995 Memorandum for the 1992 Administrative Reviews of IPA from Israel, on file in the public file of the Central Records Unit, Room B–099 of the Department of Commerce).

III. Programs Preliminarily Determined Not to Be Used

We also examined the following programs and preliminarily determine that the producer/exporter of the subject merchandise did not apply for or receive benefits under these programs during the 1992 or 1993 review periods:

A. Reduced tax rates under ECIL;
B. ECIL section 24 loans;
C. Preferential accelerated depreciation under ECIL;
D. Labor training grants; and
E. Dividends and Interest Tax Benefits under Section 46 of the ECIL.

Preliminary Results of Reviews

For the period January 1, 1992, through December 31, 1992, we preliminarily determine the net subsidy to be 3.84 percent *ad valorem* for all firms. For the period January 1, 1993 through December 31, 1993, we preliminarily determine the net subsidy to be 5.50 percent *ad valorem* for all firms.

If the final results of this review remain the same as these preliminary results, the Department intends to instruct the U.S. Customs Service to assess the following countervailing duties:

Manufacturer/ exporter	Period	Rate (per-cent)
All companies ...	1992	3.84
All companies ...	1993	5.50

The Department also intends to instruct the U.S. Customs Service to collect a cash deposit of estimated countervailing duties, as provided by section 751(a)(1) of the Act, of 5.50 percent of the f.o.b. invoice price on all shipments of the subject merchandise from Israel entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of these administrative reviews.

Parties to the proceedings may request disclosure of the calculation methodology used in either review and interested parties may request a hearing not later than 10 days after the date of publication of this notice. Interested parties may submit written arguments in case briefs on these preliminary results within 30 days of the date of publication. Rebuttal briefs, limited to arguments raised in the case briefs, may be submitted seven days after the time limit for filing the case brief. Parties who submit written arguments in these proceedings are requested to submit with the argument (1) a statement of the issue and (2) a brief summary of the argument. Written arguments that are intended to comment on the preliminary results for both the 1992 and 1993 reviews must be submitted to the file for each proceeding. Any hearing, if requested, will be held seven days after the scheduled date for submission of rebuttal briefs. Copies of case briefs and rebuttal briefs must be served on interested parties in accordance with 19 CFR 355.38(e).

Representatives of parties to these proceedings may request disclosure of proprietary information under administrative protective order no later than 10 days after the representative's client or employer becomes a party to the proceeding, but in no event later than the date the case briefs, under section 355.38(c), are due. The Department will publish the final results of these administrative reviews including the results of its analysis of issues raised in any case or rebuttal brief or at a hearing.

These administrative reviews and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and 19 CFR 355.22.

Dated: February 22, 1996.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 96–4984 Filed 3–1–96; 8:45 am]

BILLING CODE 3510–DS–P

National Oceanic and Atmospheric Administration

National Weather Service To Discontinue the Issuance of All Routine Agricultural Forecasts and Fruit Frost Forecasts

AGENCY: National Weather Service, National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice.

SUMMARY: This notice updates the National Weather Services (NWS) plans to transfer Agricultural Weather Services to the private sector, notice of which was published on July 5, 1995; *see* National Weather Service Transfer of Specific Products and Services to the Private Sector, 60 Fed. Reg. 34969.

EFFECTIVE DATE: This action becomes effective April 1, 1996, for routine agricultural forecasts and April 20, 1996, for fruit frost forecasts.

ADDRESSES: National Weather Service, Industrial Meteorology Staff, 1325 East-West Highway, #18462, Silver Spring, Maryland 20910.

FOR FURTHER INFORMATION CONTACT: Edward Gross, 301–713–0258.

SUPPLEMENTARY INFORMATION: On July 5, 1995, the National Weather Service (NWS) announced that it planned to transfer specific products and services to the private sector effective October 1, 1995. Subsequently, concerns were raised about the disruption of critical forecasts to regions of the United States dependent on receiving NWS agricultural weather services and the Conference Report for the Department of Commerce Fiscal Year 1996.

Appropriations Bill to accompany H.R. 2076 noted that, ''it may be necessary within funds available to provide Agricultural Weather Services for a limited time.''

Accordingly, NWS has continued and will continue routine agricultural forecasts until April 1, 1996, and will continue those Fruit Frost Forecasts that it has already commenced providing until April 20, 1996. At that time, funds available for Agricultural Weather Services will be exhausted. However, if a freeze or very cold weather is in progress on April 20, 1996, fruit frost products will continue until the episode ends.

The NWS has been notifying customers of changes to its Agricultural Weather Services program since July 1995. The provision of these services has been extended from October 1, 1995 until April 20, 1996 for the purpose of minimizing the disruption of critical forecasts to certain regions and to allow customers an opportunity to find alternative sources of agricultural weather information from the private sector. This action complies with the conference language of maintaining a goal of smoothly transferring services to those private sector vendors capable and willing to assume them.

The following NWS agricultural products will no longer be available:

Agricultural Weather Forecast
Fruit Frost Forecast
Special Agricultural Weather Advisory
Weather Advisory for Ag Operations
30-day Agricultural Weather Outlook
National Agricultural Weather Highlights
Cranberry Bog Forecasts

The U.S. Department of Agriculture's Joint Agricultural Weather Facility will continue producing the International Weather and Crop Bulletin.

Dated: February 27, 1996.

Susan F. Zevin,

Deputy Administrator for Operations.

[FR Doc. 96–4902 Filed 3–1–96; 8:45 am]

BILLING CODE 3510–08–M

Patent and Trademark Office

Address-Affecting Provisions

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before May 3, 1996.

ADDRESSES: Direct all written comments to Linda Engelmeier, Acting Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Request for additional information or copies of the information collection instrument(s) and instructions should be directed to Robert J. Spar, Patent and Trademark Office, Washington, DC 20231, (703)305–9285.

SUPPLEMENTARY INFORMATION:

I. Abstract

Under existing law, a patent applicant or assignee may appoint, revoke or change a representative to act in a representative capacity. Also, an appointed representative may withdraw from acting in a representative capacity. This collection includes the information needed to ensure that PTO correspondence reaches the appropriate individual.

II. Method of Collection

By mail, facsimile or hand-carry when the applicant or agent is to notify the Patent and Trademark Office (PTO) of changes, revocations or additions in powers of attorney or agents and changes in addresses, or when an appointed representative withdraws.

III. Data

OMB Number: 0651–0035.

Form Number: PTO/SB/82/83.

Type of Review: Revision.

Affected Public: Individuals or households, business or other non-profit institutions, not-for-profit institutions and Federal Government.

Estimated Number of Respondents: 45,350.

Estimated Time Per Response: .2 hours.

Estimated Total Annual Burden Hours: 9070 hours/year.

Estimated Total Annual Cost: $87,979/year.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: February 27, 1996.

Linda Engelmeier,

Acting Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 96–4903 Filed 3–1–96; 8:45 am]

BILLING CODE 3510–16–P

Disclosure Document Program

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before May 3, 1996.

ADDRESSES: Direct all written comments to Linda Engelmeier, Acting Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Request for additional information or copies of the information collection instrument(s) and instructions should be directed to Robert J. Spar, Patent and Trademark Office, Washington, DC 20231, (703) 305–9285.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Disclosure Document Program allows inventors to submit papers that provide evidence of the date of conception of an invention. The disclosure document papers will be retained by the PTO for two years, during which time the inventors should file a patent application if patent protection is desired.

II. Method of Collection

By mail, facsimile and hand-carry when the inventor desires to participate in the information collection.

III. Data

OMB Number: 0651–0030.

Form Number: PTO/SB/95.

Type of Review: Revision.

Affected Public: Individuals or households, business or other non-profit institutions, not-for-profit institutions, and Federal Government.

Estimated Number of Respondents: 27,000.

Estimated Time Per Response: .2 hours.

Estimated Total Annual Burden Hours: 5,400 hours.

Estimated Total Annual Cost: $12,757.5/year.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: February 27, 1996.

Linda Engelmeier,

Acting Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc 96–4904 Filed 3–1–96; 8:45 am]

BILLING CODE 3510–16–P

Post Allowance and Refiling

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before May 3, 1996.

ADDRESSES: Direct all written comments to Linda Engelmeier, Acting Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Request for additional information or copies of the information collection instrument(s) and instructions should be directed to Robert J. Spar, Patent and Trademark Office, Washington, DC 20231, (703) 305–9285.

SUPPLEMENTARY INFORMATION:

I. Abstract

This collection of information is required to administer the patent laws pursuant to Title 35 of the U.S. Code concerning the issuance of patents and related actions. The affected public includes any individual or institution whose application for a patent has been allowed or who takes action as covered by the applicable rules.

II. Method of Collection

By mail, facsimile and hand-carry when the inventor desires or is required to participate in the information collection.

III. Data

OMB Number: 0651–0033.

Title of form	Form No.	Estimated time for response	Estimated annual burden hours	Estimated annual responses
Request for filing patent application under 37 CFR 1.60/.62	PTO/SB/3/14	.50	22,500	45,000
Issue Fee transmittal	PTOL–85b	.20	20,400	102,000
Certificate of correction	PTO/SB/44	1	3,000	3,000
Request for reexamination	PTO/SB/57	2	700	350
Reissue	PTO/SB/51–56	5	2,500	500

Type of Review: Regular.

Affected Public: Individuals or households, business or other non-profit, institutions, not-for-profit institutions, and Federal Government.

Estimated Number of Respondents: 150,850.

Estimated Total Annual Burden Hours: 49,100 hours.

Estimated Total Annual Cost: $7,217,700/year.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: February 27, 1996.

Linda Engelmeier,

Acting Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 96–4905 Filed 3–1–95; 8:45 am]

BILLING CODE 3510–16–P

Patent Processing (Updating)

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before May 4, 1996.

ADDRESSES: Direct all written comments to Linda Engelmeier, Acting Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT:

Request for additional information or copies of the information collection instrument(s) and instructions should be directed to Robert J. Spar, Patent and Trademark Office, Washington, DC 20231, (703)305–9285.

SUPPLEMENTARY INFORMATION:

I. Abstract

During the processing for an application for a patent, the applicant/agent may be required or desire to submit additional information to the Patent and Trademark Office(PTO) concerning the examination of a specific application. The specific information required or which may be submitted: Information Disclosure Citations; Terminal Disclaimers; Petitions to Revive; Express Abandonment; Appeal Notice; Small Entity; Petition for Access; Power to Inspect; Certificate of Mailing; Amendment Transmittal Letter; Deposit Account Order Form.

II. Method of Collection

By mail, facsimile and hand-carry when the inventor(s) desires or is required to participate in the information collection.

III. Data

OMB Number: 0651–0031.

Title of form	Form No.	Estimated time for response (hours)	Est. annual burden hours	Est. annual responses
Information Disclosure (in Appl'n)	PTO/SB/08	2.0	280,000	140,000
Information Disclosure (in patent)	PTO/SB/42	2.0	2,000	1,000
Statutory 7,500 Disclaimers	PTO/SB/43	.20	1,500	
Terminal Disclaimers	PTO/SB	.20	1,500	7,500
	25–26			
	62–63			
Extensions of Time	PTO/SB	.10	11,000	110,000
	22–23,32			
Petitions to Revive	PTO/SB	1.0	4,000	4,000
	61,			
	61/PCT,			
	64,			
	64/PCT			
Express Abandonment	PTO/SB/24	.20	800	4,000
Small Entity	PTO/SB	.30	18,000	60,000
	09–12			
Petition for Access	PTO/SB/68	.20	4	20
Power to Inspect/Copy	PTO/SB/67	.20	4,000	10,000
Certificate of Mailing	PTO/SB	.10	300,000	30,000
	92–93			
Amendment Transmittal Letter	PTO/SB/21	.20	200,000	40,000
Deposit 100,000	PTO/SB/91	.20	20,000	

Type of Review: Regular.

Affected Public: Individuals or households, business or other non-profit, not-for-profit institutions, and Federal Government.

Estimated Number of Respondents: 659,020.

Estimated Total Annual Burden Hours: 385,804 hours.

Estimated Total Annual Cost: $116,766,376/year.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: February 27, 1996.

Linda Engelmeier,

Acting Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc 96–4906 Filed 3–1–96; 8:45 a.m.]

BILLING CODE 3510–16–P

Rules for Patent Maintenance Fees

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before May 3, 1996.

ADDRESSES: Direct all written comments to Linda Engelmeier, Acting Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Request for additional information or copies of the information collection instrument(s) and instructions should be directed to Robert J. Spar, Patent and Trademark Office, Washington, DC 20231, (703) 305–9285.

SUPPLEMENTARY INFORMATION:

I. Abstract

Maintenance fees are required to maintain a patent in force under Title 35 of the U.S. Code. Payment of maintenance fees are required at 3½, 7½ and 11½ years after the grant of the patent. A patent number and serial number of the patent on which maintenance fees are paid are required in order to insure proper crediting of such payments.

II. Method of collection

By mail, facsimile or hand-carry when the applicant or agent is to pay the maintenance fee required to maintain the benefit patent protection.

III. Data

OMB Number: 0651–0016.

Form Number: PTO/SB/45.

Type of Review: Regular.

Affected Public: Individuals or households, business or other non-profit institutions, not-for-profit institutions, and Federal Government.

Estimated Number of Respondents: 104,569.

Estimated Time Per Response: .08 hours.

Estimated Total Annual Burden Hours: 8,714 hours/year.

Estimated Total Annual Cost: $43,570/year.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;(b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: February 27, 1996.

Linda Engelmeier,

Acting Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc 96–4907 Filed 3–1–96; 8:45 a.m.]

BILLING CODE 3510–16–P

Grant of Certificate of Interim Extension of the term of U.S. Patent No. 4,062,848; REMERON

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Notice of Term Extension.

SUMMARY: The Patent and Trademark Office has issued a certificate under 35 U.S.C. § 156(d)(5) for a one-year interim extension of the term of U.S. Patent No. 4,062,848 that claims the active ingredient of the human drug product ''REMERON.''

FOR FURTHER INFORMATION CONTACT: Hiram A. Bernstein by telephone at (703) 305–9285; by mail marked to his attention and addressed to the Assistant Commissioner for Patents, Box DAC, Washington, DC 20231; or by fax marked to his attention at (703) 308–6916.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to 5 years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review. Under § 156, a patent is eligible for term extension only if regulatory review of the claimed product was completed before the original patent term expired.

On December 3, 1993, § 156 was amended by Pub. L. No. 103–179 to provide that if the owner of record of the patent or its agent reasonably expects the applicable regulatory review period to extend beyond the expiration of the patent, the owner or its agent may submit an application to the Commissioner of Patents and Trademarks for an interim extension of the patent term. If the Commissioner determines that, except for permission to market or use the product commercially, the patent would be eligible for a statutory extension of the patent term, the Commissioner shall issue to the applicant a certificate of interim extension for a period of not more than one year.

On November 13, 1995, Akzona Incorporated, owner of record in the Patent and Trademark Office of U.S. Patent No. 4,062,848, filed an application for interim extension of the term of this patent under 35 U.S.C. § 156(d)(5). The application states that the patent claims a compound comprising the active ingredient of the drug product ''REMERON.'' The application states that the product is currently undergoing a regulatory review before the Food and Drug Administration for permission to market or use the product commercially. The original term of the patent expired on December 13, 1994. On December 5, 1994, the patent was granted a first interim extension under 35 U.S.C. § 156(d)(5) for a period of one year. Applicant now requests another interim extension of the term of the patent for a period of one year.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that the regulatory review period may extend beyond the date of expiration of the patent, as extended by the first interim extension, a second and final interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate. Accordingly, an interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,062,848 has been granted for a period of one year from the extended expiration date of the patent term in effect.

Dated: February 21, 1996.

Bruce A. Lehman,

Assistant Secretary of Commerce and Commissioner of Patents and Trademarks.

[FR Doc. 96–4974 Filed 3–1–96; 8:45 am]

BILLING CODE 3510–16–M

DEPARTMENT OF DEFENSE

Department of the Army

Rules, Security and Accessorial Services Governing the Movement of Department of Defense Freight Traffic by Air Carrier, Air Forwarder, Air Taxi

AGENCY: Military Traffic Management Command (MTMC), DOD.

ACTION: Notice.

SUMMARY: The Military Traffic Management Command proposes to set forth rules, procedures, and accessorial service charge provisions to standardize all Department of Defense procedures for the movement of freight via air carrier, air forwarder, and air taxi. The publication, MTMC Freight Traffic Rules Publication No. 5 (MFTRP No. 5), will govern air shipments between locations in the Continental United States and to and from locations in Alaska, Hawaii, Puerto Rico, and Canada. Every air Standard Tender of Freight Services, MT Form 364R, issued on or after the effective date of MFTRP No. 5 must cite MFTRP No. 5 as the governing publication, in Section B, Paragraph g. of the tender. The draft publication may be obtained from the MTMC Homepage on the Internet at the following address: http://baileys-mtmcwww.army.mil. When the MTMC Homepage screen has loaded, access the ''Functional Support'' button on the screen. After that screen appears, access the ''Global Traffic Management'' button. Then access ''Freight Regulations''. Then access ''MFTRP No. 5'', and the draft regulation will load for you to highlight and copy to any word processor for reading and/or printing.

Written comments may be sent to Headquarters, MTMC; ATTN: MTOP–T–SR; Room 629; 5611 Columbia Pike; Falls Church, VA 22041–5050, to be received no later than April 1, 1996.

FOR FURTHER INFORMATION CONTACT: Mr. Wade Rice, e-mail ricew@baileys–emh5.army.mil or Mr. Frank Lamm, lammf@baileys–emh5.army.mil, Headquarters, Military Traffic Management Command, ATTN: MTOP–T–ND, 5611 Columbia Pike, Falls Church, VA 22041–5050, telephone (703) 681–6103.

Gregory D. Showalter,

Army Federal Register Liaison Officer.

[FR Doc. 96–4865 Filed 3–1–96; 8:45 am]

BILLING CODE 3710–08–M

Availability of Non-Exclusive, Exclusive or Partially Exclusive Licensing of Object Recognition Technology

AGENCY: Picatinny Arsenal, New Jersey.

ACTION: Notice.

SUMMARY: The Department of the Army announces the general availability of exclusive, partially exclusive or non-exclusive licenses under patent application Serial Number 08/591,839 filed January 25, 1996, Docket No. DAR–28–95, by Paul D. Wilson entitled ''Apparatus and Method of Automatic Recognition of Concealed Objects Using Multiple Energy Computer Tomography''. Licenses shall comply with 35 U.S.C. 209 and 37 CFR 404.

FOR FURTHER INFORMATION CONTACT: Mr. Edward Goldberg, Chief, Intellectual Property Law Division, AMSTA–AR–GCL, U.S. Army ARDEC, Picatinny

Arsenal, NJ 07806–5000, telephone number (201) 724–6950.

SUPPLEMENTARY INFORMATION: Written objections must be filed within 3 months from the date of publication of this notice in the Federal Register.

Gregory D. Showalter,

Army Federal Register Liaison Officer.

[FR Doc. 96–4867 Filed 3–1–96; 8:45 am]

BILLING CODE 3710–08–M

Availability of U.S. Patents for Non-Exclusive, Exclusive or Partially Exclusive Licensing

AGENCY: U.S. Army Research Laboratory, Physical Sciences Directorate, and U.S. Army Communications-Electronics Command.

ACTION: Notice of availability.

SUMMARY: In accordance with 37 CFR 404.6 announcement is made of the availability of the following U.S. patents for non-exclusive, exclusive or partially exclusive licensing. All of the listed patents have been assigned to the United States of America as represented by the Secretary of the Army, Washington, DC.

These patents cover a wide variety of technical arts including permanent magnet designs for various applications, power sources, phased array antennas, microstrip devices and applications, varying types resonators and oscillators for different applications, as well as many other different technical arts.

Under the authority of Section 11(a)(2) of the Federal Technology Transfer Act of 1986 (Public Law 99–502) and Section 207 of Title 35, United States Code, the Department of the Army as represented by the Army Research Laboratory, Physical Sciences Directorate, and the Communications-Electronics Command wish to license the U.S. patents listed below in a non-exclusive, exclusive or partially exclusive manner to any party interested in manufacturing, using, and/or selling devices or processes covered by these patents.

Title: Tunable heavy and light hole coupled bands in variable-strain quantum well semi-conductor heterostructure for novel opto-electronic devices.

Inventor(s): Mitra Dutta, Weimin Zhou, Hongen Shen, Jagadeesh Pamulapati.

Patent No.: 5,412,225—Issued 05/02/95.

Title: Millimeter wave ferrite switch utilizing a superconducting switching coil.

Inventor(s): Richard A. Stern, Richard W. Babbitt, Thomas E. Koscica.

Patent No.: 5,413,983—Issued 05/09/95.

Title: Line-width measurement of metallization coated with insulator on microelectronic circuits using energy dispersive X-ray analysis.

Inventor(s): Richard G. Sartore.

Patent No.: 5,414,265—Issued 05/09/95.

Title: Crystal resonator with multiple segmented lateral-field excitation electrodes.

Inventor(s): John A. Kosinski, Arthur Ballato, Yicheng Lu.

Patent No.: 5,414,322—Issued 05/09/95.

Title: Electric charge metering device and method.

Inventor(s): Bruce D. Jette.

Patent No.: 5,416,406—Issued 05/16/95.

Title: C-axis oriented high temperature superconductors deposited onto single crystals of gadolinium gallium garnet and method of making the same.

Inventor(s): Arthur Tauber, Steven C. Tidrow.

Patent No.: 5,418,215—Issued 05/23/95.

Title: Single electron device including clusters of pure carbon atoms.

Inventor(s): Doran C. Smith.

Patent No.: 5,420,746—Issued 05/30/95.

Title: Piezoelectric resonator.

Inventor(s): John A. Kosinski, Yicheng Lu.

Patent No.: 5,422,533—Issued 06/06/95.

Title: Toroidal permanent magnet solenoid.

Inventor(s): Herbert A. Leupold.

Patent No.: 5,422,618—Issued 06/06/95.

Title: Wide dynamic range detection circuit.

Inventor(s): William J. Skudera, Jr., Elic A. Mariani, Stuart D. Albert.

Patent No.: 5,424,674—Issued 06/13/95.

Title: High-power electrical machine with toroidal permanent magnets.

Inventor(s): Herbert A. Leupold.

Patent No.: 5,426,338—Issued 06/20/95.

Title: Preselector filter with tunable narrowband excision.

Inventor(s): Elio A. Mariani.

Patent No.: 5,426,402—Issued 06/20/95.

Title: Method of forming porous silicon.

Inventor(s): Jagadeesh Pamulapati, Hongen Shen, Mitra Dutta.

Patent No.: 5,427,648—Issued 06/27/95.

Title: Coupled quantum well optical intensity modulator for INP based optoelectronic integrated circuits and methods therefor.

Inventor(s): Milson Silva, Peter R. Herczfeld, Steven A. Malone, Arthur C. Paolella.

Patent No.: 5,428,225—Issued 06/27/95.

Title: Method of making radiation hardened quartz crystal oscillators.

Inventor(s): John R. Vig, Arthur Ballato.

Patent No.: 5,428,315—Issued 06/27/95.

Title: Fast turn-on, temperature stable dielectric resonator oscillator.

Inventor(s): Mohammad A. Mizan, Thomas P. Higgins, Dana J. Sturzebecher.

Patent No.: 5,428,326—Issued 06/27/95.

Title: Field augmented permanent magnet structures.

Inventor(s): Herbert A. Leupold, Anup Tilak.

Patent No.: 5,428,334—Issued 06/27/95.

Title: Field augmented permanent magnet structures.

Inventor(s): Herbert A. Leupold, Anup Tilak.

Patent No.: 5,428,335—Issued 06/27/95.

Title: Method for reducing synchronizing overhead of frequency hopping communications systems.

Inventor(s): George R. Oliva, Jr., Gregory Lorenzo, Kenneth J. Loffer.

Patent No.: 5,428,637—Issued 06/27/95.

Title: Target configurations for increasing the size of films prepared by laser ablation.

Inventor(s): Steven C. Tidrow, William D. Wilber, Arthur Tauber.

Patent No.: 5,432,313—Issued 07/11/95.

Title: High power electrical machinery.

Inventor(s): Herbert A. Leupold, John T. Rehberg.

Patent No.: 5,434,462—Issued 07/18/95.

Title: Yokeless permanent magnet solenoids.

Inventor(s): Herbert A. Leupold, Ernest Potenziani, II.

Patent No.: 5,438,308—Issued 08/01/95.

Title: Method and apparatus for depositing a refractory thin film by chemical vapor deposition.

Inventor(s): Thomas R. AuCoin, Richard H. Wittstruck, Jing Zhao, Peter A. Zawadzki, William R. Baarck, Peter E. Norris.

Patent No.: 5,443,647—Issued 08/22/95.

Title: Method for measuring thin film thickness.

Inventor(s): Donald W. Eckart, Luis M. Casas, Richard T. Lareau.

Patent No.: 5,443,684—Issued 08/22/95.

Title: Microelectronic 3D bipolar magnetotransistor magnetometer.

Inventor(s): Robert A. Lux, James F. Harvey, Charles D. Mulford, Jr., Louis C. Poli.

Patent No.: 5,446,307—Issued 08/29/95.

Title: Planar magnetically-tunable band-rejection filter.

Inventor(s): Elio A. Mariani.

Patent No.: 5,448,211—Issued 09/05/95.

Title: Optically injection-locked self-oscillating dual-gate mesfet mixer.

Inventor(s): Thomas P. Higgins, Dana J. Sturzebecher, Roland Cadotte, Jr., Arthur Paolella.

Patent No.: 5,450,227—Issued 09/12/95.

Title: Solid state electrochemical cell oxygen sensor.

Inventor(s): Wishvender K. Behl, Edward J. Plichta.

Patent No.: 5,451,310—Issued 09/19/95.

Title: Process for setting the frequency of a silicon microresonator.

Inventor(s): John R. Vig.

Patent No.: 5,451,425—Issued 09/19/95.

Title: Quick-mount measuring device for evaluating the electrical characteristics of ferroelectric materials.

Inventor(s): William C. Drach, Thomas E. Koscica, Richard W. Babbit.

Patent No.: 5,451,866—Issued 09/19/95.

Title: Variable gain optical detector.

Inventor(s): Arthur Paolella, Peter R. Herczfeld.

Patent No.: 5,453,630—Issued 09/19/95.

Title: Thin film of $MGIN_2O_4$ for use as an electrode in a ferroelectric device.

Inventor(s): William Wilber, Milind Bedekar.

Patent No.: 5,458,986—Issued 10/17/95.

Title: Solid State electrochemical cell including lithium iodide as an electrolyte additive.

Inventor(s): Wishvender K. Behl, Edward J. Plichta.

Patent No.: 5,458,995—Issued 10/17/95.

Title: Negative absolute conductance device and method.

Inventor(s): Mitra Dutta, Michael A. Stroscio, Vladimir V. Mitin, Rimvydas Mickevicius.

Patent No.: 5,459,334—Issued 10/17/95.

Title: High temperature sodium-graphite electrochemical cell.

Inventor(s): Edward J. Plichta, Wishvender K. Behl.

Patent No.: 5,462,818—Issued 10/31/95.

Title: Passive saw-id tags using a chirp transducer.

Inventor(s): Elio A. Mariani.

Patent No.: 5,469,170—Issued 11/21/95.

Title: Monitoring phase characteristics of BPSK and CW signals.

Inventor(s): William J. Skudera, Jr.

Patent No.: 5,469,173—Issued 11/21/95.

Title: Dual-frequency microstrip antenna with inserted strips.

Inventor(s): Vahakn Nalbandian, Choon S. Lee.

Patent No.: 5,471,221—Issued 11/28/95.

Title: Radiation sensor dosimetry circuit.

Inventor(s): Stanley Kronenberg, Arnold Bard.

Patent No.: 5,477,050—Issued 12/19/95.

Title: Infrared hot electron transistor with a superlattice base.

Inventor(s): Kwong-Kit Choi.

Patent No.: 5,477,060—Issued 12/19/95.

Title: Molten salt electrochemical cell including a alkali metal intercalated petroleum coke as the anode.

Inventor(s): Edward J. Plichta, Wishvender K. Behl.

Patent No.: 5,478,666—Issued 12/26/95.

Title: System and method for calibrating a ferroelectric phase shifter.

Inventor(s): Thomas E. Koscica, Richard W. Babbitt, William C. Drach.

Patent No.: 5,479,139—Issued 12/26/96.

Title: Real time imaging of acoustic wave devices.

Inventor(s): John G. Gualtieri.

Patent No.: 5,479,375—Issued 12/26/95.

Title: High power ultra broadband antenna.

Inventor(s): Erik H. Lenzing, Harry F. Lenzing, Charles D. Hechtman.

Patent No.: 5,479,180—Issued 12/26/96.

Title: Quantum grid infrared photodetector.

Inventor(s): Kwong-Kit Choi.

Patent No.: 5,485,015—Issued 01/16/96.

Title: Spherical magnet structure for use in synchrotron radiation source.

Inventor(s): Herbert A. Leupold.

Patent No.: 5,486,801—Issued 01/23/96.

Title: Spherical magnet structure and use thereof in synchrotron radiation source.

Inventor(s): Herbert A. Leupold.

Patent No.: 5,486,802—Issued 01/23/96.

Title: High voltage direct current power supply with feedback control and circuit protection.

Inventor(s): Thomas E. Koscica, William C. Drach.

Patent No.: 5,486,992—Issuance 01/23/96.

Title: Low cost automated system for evaluating the electrical characteristics of ferroelectric materials.

Inventor(s): William C. Drach, Richard W. Babbitt, Thomas E. Koscica.

Patent No.: 5,487,014—01/23/96.

Title: Wireless thermally insulated crystal oscillator having power and signals coupled through transceivers.

Inventor(s): John R. Vig.

Patent No.: 5,488,333—01/30/96.

Title: Infrared imaging array based on temperature driven anisotropic optical absorption.

Inventor(s): Gerald J. Iafrate, Mitra Dutta, Paul H. Shen, Michael A. Stroscio.

Patent No.: 5,488,266—Issued 1/30/96.

Title: Magic sphere providing distortion-free access to a large internal working space containing a uniform high-intensity magnetic field.

Inventor(s): Herbert A. Leupold.

Patent No.: 5,491,459—Issued 02/13/96.

Title: Photon-triggered RF radiator having discrete energy storage and energy radiation sections.

Inventor(s): Anderson H. Kim, Robert J. Youmans, Stephen E. Saddow, Louis J. Jasper, Jr., Maurice Weiner.

Patent No.: 5,491,490—Issued 02/13/96.

Title: Solid state electrochemical cell for performing electrochemical measurements on a solid electrolyte at high temperatures.

Inventor(s): Wishvender K. Behl, Edward J. Plichta.

Patent No.: 5,492,610—Issued 02/20/96.

Title: Electrochemical cell.

Inventor(s): Wishvender K. Behl, Edward J. Plichta.

Patent No.: 5,494,763—Issued 02/27/96.

Title: Solution rejection filter.

Inventor(s): Stuart D. Albert, William J. Skudera, Jr.

Patent No.: 5,495,253—Issued 02/27/96.

FOR FURTHER INFORMATION OR COPIES OF THE PATENTS LISTED CONTACT: Mr. William H. Anderson, United States Army Communications-Electronics Command, ATTN: AMSEL–LG–L, Fort Monmouth, New Jersey 07703–5010 (908) 532–4112.

Gregory D. Showalter,

Army Federal Register Liaison Officer.

[FR Doc. 96–4673 Filed 3–1–96; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Proposed collection; comment request.

SUMMARY: The Director, Information Resources Group, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before May 3, 1996.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Wendy Taylor, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10235, New Executive Office Building, Washington, DC 20503. Requests for copies of the proposed information collection requests should be addressed to Patrick J. Sherrill, Department of Education, 600 Independence Avenue, S.W., Room 5624, Regional Office Building 3, Washington, DC 20202–4651.

FOR FURTHER INFORMATION CONTACT: Patrick J. Sherrill (202) 708–8196. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Director of the Information Resources Group publishes this notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

Dated: February 27, 1996.

Gloria Parker,

Director, Information Resources Group.

Office of Postsecondary Education

Type of Review: Revision
Title: Applications foe Seven Foreign Language and Area Studies Programs
Frequency: Annually
Affected Public: Individuals or households; Not-for-profit institutions
Annual Reporting and Recordkeeping Hour Burden:
Responses: 575
Burden Hours: 55,640
Abstract: Collect program and budget information to evaluate grant applications by institutions of higher education, nonprofit organizations and individuals. Collected information will be used to make grant awards under seven international education programs.

[FR Doc. 96–4901 Filed 3–1–96; 8:45 am]

BILLING CODE 4000–01–P

National Educational Research Policy and Priorities Board; Meeting

AGENCY: National Educational Research Policy and Priorities Board, Education.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a meeting of the National Education Research Policy and Priorities Board. This notice also describes the functions of the Board. Notice of this meeting is required under Section 10(a)(2) of the Federal Advisory Committee Act and is intended to notify the public of their opportunity to attend.

DATE AND TIME: March 21, 1996, 8 a.m. to 5 p.m.; March 22, 1996, 9 a.m. to 2 p.m.

ADDRESSES: On March 21, the meeting will be held in the Stauffer Auditorium, Hoover Institution, Stanford University, Standford, CA 94305. On March 22, the meeting will be held in the John Hemphill Board Room, Far West Laboratory for Educational Research and Development/WestEd, 730 Harrison Street, San Francisco, CA 94107–1242.

FOR FURTHER INFORMATION CONTACT: John Christensen, Designated Federal Official, National Educational Research Policy and Priorities Board, 555 New Jersey Avenue, NW, Washington, DC 20208–7564. Telephone: (202) 219–2065; Fax: (202) 219–1528. Internet: John—Christensen@ed.gov.

SUPPLEMENTARY INFORMATION: The National Educational Research Policy and Priorities Board is authorized by Section 921 of the Educational Research, Development, Dissemination, and Improvement Act of 1994 (the Act). The Board works collaboratively with the Assistant Secretary for the Office of Educational Research and Improvement (the Office) to forge a national consensus with respect to a long-term agenda for educational research, development, and dissemination, and to provide advice and assistance to the Assistant Secretary in administering the duties of the Office. The Act directs the Board to provide guidance to the Congress in its oversight of the Office; to advise the United States on the Federal educational research and development effort; and to solicit advice from practitioners, policymakers, and researchers to define research needs and suggestions for research topics. The meeting of the Board is open to the public.

The agenda for both days will provide an opportunity for the Board to solicit recommendations from education researchers, teachers, school administrators and others on priorities for the investment of the resources of the Office of Educational Research and Improvement for the next 5-, 10-, and 15-year periods. This meeting continues the Board's program of consultation with the public prior to the publication of a Research Priorities Plan. A final agenda will be available from the Board's office on March 12, 1996.

Records are kept of all Board proceedings, and are available for public inspection at the office of the National Educational Research Policy and Priorities Board, 555 New Jersey Avenue, NW., Washington, DC 20208–7564.

Dated: February 27, 1996.

Sharon P. Robinson,

Assistant Secretary, Office of Educational Research and Improvement.

[FR Doc. 96–4938 Filed 3–1–96; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP94–260–003]

Algonquin Gas Transmission Company; Notice of Amended Application

February 27, 1996.

Take notice that on February 20, 1996, Algonquin Gas Transmission Company (Algonquin), 1284 Soldiers Field Road, Boston, Massachusetts 02135, filed in Docket No. CP94–260–003 an application pursuant to Section 7(c) of the Natural Gas Act to amend its authorized initial rate under Rate Schedule AFT–CL, for service to Canal Electric Company and Montaup Electric Company (collectively referred to as Canal Electric) to reflect increased estimated cost of facilities not yet in service, all as more fully set forth in the application on file with the Commission and open to public inspection.

Algonquin states that on April 19, 1995, the Commission authorized Algonquin to construct and operate approximately 4 miles of 18-inch pipeline, a new meter station and appurtenant facilities and to provide firm transportation service to Canal Electric of up to 75,000 MMBtu per day under a separately-stated incremental rate schedule under Algonquin's Part 284 open-access transportation certificate.[1] Algonquin indicates that the estimated cost of the facilities has risen from approximately $7.5 million to approximately $8.3 million

Algonquin asserts that since it filed its application certain events have contributed to the increased estimated cost for these facilities. Algonquin states that actual experience indicates that company and consulting cost to acquire permits and other approvals will be higher than expected. Algonquin also states that the estimated installation cost is also higher in large part due to changed construction schedules and a change to the proposed in-service date.

Algonquin now seeks to charge an initial rate consisting of a one-part maximum monthly demand charge of $2.4132 per MMBtu, effective upon the commencement of service. Algonquin claims that this initial rate is based upon the same general methodology approved in the April 19, 1995 order and upon the settlement cost of service parameters approved in Algonquin's rate case in Docket No. RP93–14.

Algonquin also states that, in addition to the change for the estimated facility cost, its Exhibit P to the March 2, 1994 application contained an erroneous assumption that results in a minor change to the authorized initial rate, when corrected. Algonquin contends that in the original filing it was assumed that the meter station would be located on land owned in fee instead of under easement. Algonquin further states the Exhibit P included in the amended application contains workpapers showing the effect on the authorized rate if land cost is correctly reflected in the rate calculation.

Additionally, Algonquin states that the pipeline and related facilities are proposed to be placed in service on or around April 1, 1996, to synchronize with Canal Electric's start-up requirements.

Any person desiring to be heard or to make any protest with reference to said amended application should on or before March 19, 1996, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulation Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Algonquin to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 96–4893 Filed 3–1–96; 8:45 am]

BILLING CODE 6717–01–M

[1] 71 FERC ¶ 61,060 (1995).

[Docket No. RP96–147–000]

Equitrans, L.P., Notice of Proposed Changes in FERC Gas Tariff

February 27, 1996.

Take notice that on February 23, 1996, Equitrans, L.P., (Equitrans) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the following proposed tariff sheets, with an effective date on March 1, 1996:

Third Revised Sheet Nos. 41–43
Third Revised Sheet Nos. 47–49
Third Revised Sheet Nos. 53–55
First Revised Sheets No. 220
Original Sheet Nos. 220A–220C
First Revised Sheets Nos. 223–224
Second Revised Sheet No. 225

Equitrans states that it is making this filing in accordance with the Commission's ''Order on Storage Operations Report'' issued on January 23, 1996. 74 FERC ¶ 61,054. Equitrans proposes to implement late winter deliverability ratchets, on the peaking storage services which Equitrans' offers under Rate Schedules 10SS, 30SS, and 60SS. Equitrans states that withdrawals will be reduced first for Rate Schedule 10SS service at a total inventory level of 44,140 MMcf followed by Rate Schedule 30SS withdrawals at an inventory level of 37,000 MMcf, and finally Rate Schedule 60SS withdrawals at a total inventory level of 31,990 MMcf.

Equitrans requests a waiver of the Commission's notice requirements to permit the tariff sheets to take effect on March 1, 1996.

Any person desiring to be heard or to protest this application should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Steet, N.E., Washington, D.C. 20426, in accordance with Sections 385.211 and 385.214 of the Commission's Rules and Regulations. All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. 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. 96–4894 Filed 3–1–96; 8:45 am]

BILLING CODE 6717–01–M

[Project No. 10867–001 Indiana]

Holliday Historic Restoration Associates; Teleconference Meeting Notice

February 27, 1996.

A. Teleconference Meeting for the Holliday Project will be held on March 14, 1996, at 10:00 a.m. to discuss the ownership/leasee relationship between Holliday Historic Restoration Associates and PSI Energy, Inc. as it relates to use of the Holliday dam for project operation.

B. The following parties will participate in the teleconference: FERC staff, Holliday Historic Restoration Associates, PSI Energy, Inc.

C. Any interested party who wants to participate in this teleconference, please call Ms. Mary Golato (202) 219–2804 no later than March 7, 1996.

Lois D. Cashell,

Secretary.

[FR Doc. 96–4891 Filed 3–1–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. MT96–4–001]

Mid Louisiana Gas Company; Notice of Proposed Changes in FERC Gas Tariff

February 27, 1996.

Take notice that on February 16, 1996, Mid Louisiana Gas Company, (Mid Louisiana) filed the following tariff sheets to be included in its FERC Gas Tariff, Third Revised Volume No. 1:

Original Sheet No. 0

Mid Louisiana states that the purpose of the filing of the Revised Tariff Sheet is to correct the Tariff Sheet Revision numbering sequence (pagination error).

Pursuant to Section 154.7(d) of the Commission's Regulations, Mid Louisiana respectfully requests waiver of § 154.207, Notice requirements, as well as any other requirement of the Regulations in order to permit the tendered tariff sheet to become effective January 25, 1996, as submitted.

Mid Louisiana states that, in compliance with § 154.208, paper copies of the Revised Tariff Pages and this filing were served upon its jurisdictional customers and appropriate state regulatory agencies.

Any person desiring to protest said compliance filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. 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 compliance filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 96–4897 Filed 3–1–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. MT96–6–000]

National Fuel Gas Supply Corporation; Notice of Proposed Changes in FERC Gas Tariff

February 27, 1996.

Take notice that on February 15, 1996, National Fuel Gas Supply Corporation (National) tendered for filing to become part of its FERC Gas Tariff, Third Revised Volume No. 1, Third Revised Sheets Nos. 232 and 233, proposed to become effective on March 18, 1996.

National's proposed tariff sheets are filed to comply with the requirement in Section 250.16 of the Commission's Regulations (18 CFR Section 250.16) that pipelines which conduct transportation transactions with affiliated marketing or brokering entities must update and refile, to reflect changes, the tariff provisions required by that regulation.

National states that copies of this filing were served upon the Company's jurisdictional customers and 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, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 214 and 211 of the Commission's Rules of Practice and Procedure (18 CFR Sections 385.214 and 385.211). All such motions to intervene and protests must be filed as provided in Section 154.210 of the Commission's Regulations. 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.

Lois D. Cashell,

Secretary.

[FR Doc. 96–4896 Filed 3–1–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP95–409–004]

Northwest Pipeline Corporation; Notice of Compliance Filing

February 27, 1996.

Take notice that on February 20, 1996, Northwest Pipeline Corporation (Northwest) tendered for filing as part of its FERC Gas Tariff, Third Revision Volume No. 1, the following tariff sheets, to become effective February 1, 1996:

Second Substitute Fifth Revised Sheet No. 375

Second Substitute Fourth Revised Sheet No. 376

Second Substitute Fifth Revised Sheet No. 377

Northwest states that the purpose of this filing is to comply with the Commission's directives in its order on Motion Filing issued February 7, 1996 in Docket No. RP95–409–003. 74 FERC ¶ 61,115. The Commission directed Northwest to file revised tariff sheets within 15 days of this Order to include in its Index of Customers shippers holding permanent capacity acquired through capacity release transactions.

Northwest states that it began including holders of permanent capacity acquired through capacity release transactions in its Index of Shippers (now called the Index of Customers) in 1994. Accordingly, on December 28, 1995, the date that Northwest submitted the last Index of Customers, it believed the composition of the Index of Customers was already in compliance with the Commission's February 7, 1996 Order.

Northwest states that it had incomplete information on two new permanent capacity release agreements at the time that the Index of Customers was being compiled. Northwest is proposing to add these two agreements at this time.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests

will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make the 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. 96–4890 Filed 3–1–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP96–198–000]

Southern Natural Gas Company; Notice of Request Under Blanket Authorization

February 27, 1996.

Take notice that on February 16, 1996, Southern Natural Gas Company (Southern), P.O. Box 2563, Birmingham, Alabama 35202–2563, filed in Docket No. CP96–198–000 a request pursuant to §§ 157.205 and 157.212 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.212) for authorization to construct and operate a delivery point, including measurement and appurtenant facilities for service to Alabama Gas Corporation (Alagasco), under Southern's blanket certificate issued in Docket No. CP82–406–000 pursuant to Section 7 of Natural Gas Act, all as more fully set forth in request that is on file with the Commission and open to public inspection.

Southern proposes to construct and operate certain measurement and other appurtenant facilities to provide transportation service to Alagasco at a new delivery point so Alagasco may provide natural gas service to International Paper's manufacturing plant in Dallas County, Alabama. Southern will locate the facilities around Mile Post 187.265 on its 26-inch South Main Loop Line in Autauga County, Alabama. The estimated cost of the construction and installation of the measurement facilities is $297,200 and will be reimbursed to Southern by Alagasco. Southern states it will transport gas on behalf of Alagasco under its existing Service Agreements pursuant to Southern's Rate Schedules FT and IT. Alagasco will assign a Maximum Daily Delivery Quantity of 2 Mcf per day to the new delivery point from its existing Tuscaloosa Area Delivery Point. Alagasco does not propose to add any transportation demand to its firm service due to the additional delivery point. Southern states that there is sufficient capacity to accomplish deliveries without detriment or disadvantage to its other customers.

Any person or Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within time allowed therefor, 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 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. 96–4892 Filed 3–1–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. EL96–35–000]

Wabash Valley Power Association, Inc. v. Northern Indiana Public Service Company, Inc.; Notice of Filing

February 20, 1996.

Take notice that on February 14, 1996, Wabash Power Association, Inc. (Wabash Valley) tendered for filing its complaint against Northern Indiana Public Service Company (NIPSCO) alleging that NIPSCO's transmission and distribution rates to Wabash are excessive, unjust and unreasonable.

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, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before March 21, 1996. 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. Answers to the complaint shall be due on or before March 21, 1996.

Lois D. Cashell,

Secretary.

[FR Doc. 96–4898 Filed 3–1–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. EG96–47–000, et al.]

NFR Power, Inc., et al.; Electric Rate and Corporate Regulation Filings

February 26, 1996.

Take notice that the following filings have been made with the Commission:

1. NFR Power, Inc.

[Docket No. EG96–47–000]

On February 21, 1996, NFR Power, Inc. (''NFR Power''), 478 Main Street, Buffalo, New York 14202, filed with the Federal Energy Regulatory Commission (''Commission'') an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's Regulations.

Comment date: March 19, 1996, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

2. Louis Dreyfus Electric Power Inc. and Duke/Louis Dreyfus L.L.C.

[Docket No. EC96–12–000]

Take notice that on February 22, 1996, Louis Dreyfus Electric Power Inc. (Louis Dreyfus) and Duke/Louis Dreyfus L.L.C. (Duke/Louis Dreyfus) filed an application for permission to transfer Louis Dreyfus' wholesale power contracts to Duke/Louis Dreyfus.

Comment date: March 18, 1996, in accordance with Standard Paragraph E at the end of this notice.

3. Illinois Power Company

[Docket No. ER96–1101–000]

Take notice that on February 20, 1996, Illinois Power Company (Illinois Power), 500 South 27th Street, Decatur, Illinois 62526, tendered for filing firm and non-firm transmission agreements under which UtiliCorp United Inc. will take transmission service pursuant to its open access transmission tariff. The agreements are based on the Form of Service Agreement in Illinois Power's tariff.

Illinois Power has requested an effective date of January 29, 1996.

Comment date: March 11, 1996, in accordance with Standard Paragraph E at the end of this notice.

4. Wisconsin Public Service Corporation

[Docket No. ER96–1102–000]

Take notice that on February 20, 1996, Wisconsin Public Service Corporation (WPSC), tendered for filing Supplement No. 1 to Supplement No. 10 to Exhibit 1–F to its Service Agreement No. 1 for service to Eagle River, Wisconsin, pursuant to WPSC's Tariff Original

Volume No. 2. The new Supplement No. 1 to Supplement No. 10 makes provision for modification of an existing delivery point for service to Eagle River. WPSC states that the filing proposes no other changes to the terms and conditions under which WPSC provides service to Eagle River.

WPSC asks that the 60 day notice requirement be waived and that Supplement No. 1 to Supplement No. 10 be allowed to retroactively become effective on February 1, 1996. WPSC states that Eagle River consents to and supports this requested effective date. WPSC further states that copies of the filing have been served upon Eagle River and the Wisconsin Public Service Commission.

Comment date: March 11, 1996, in accordance with Standard Paragraph E at the end of this notice.

5. Minnesota Power & Light Company

[Docket No. ER96–1103–000]

Take notice that on February 20, 1996, Minnesota Power & Light Company (MP), tendered for filing Amendment No. 2 to its Electric Service and Interchange Agreement with Dahberg Light and Power Company, a Wisconsin Corporation (Dahberg). MP requests waiver of the Commission's notice requirements to permit an effective date of January 1, 1996.

MP states that the amendment extends the term of the Agreement to December 31, 2010, and a weekday on-peak period to allow Dahberg to more efficiently control and operate its system.

Comment date: March 11, 1996, in accordance with Standard Paragraph E at the end of this notice.

6. Southern Company Services, Inc.

[Docket No. ER96–1104–000]

Take notice that on February 20, 1996, Southern Company Services, Inc., acting on behalf of Alabama Power Company, Georgia Power Company, Gulf Power Company, Mississippi Power Company and Savannah Electric and Power Company (Southern Companies), tendered for filing an Interchange Service Contract between Southern Companies and NoRam Energy Services, Inc. The Interchange Service Contract establishes the terms and conditions of power supply, including provisions relating to service conditions, control of system disturbances, metering and other matters related to the administration of the agreement.

Comment date: March 11, 1996, in accordance with Standard Paragraph E at the end of this notice.

7. Southern Company Services, Inc.

[Docket No. ER96–1105–000]

Take notice that on February 20, 1996, Southern Company Services, Inc., acting on behalf of Alabama Power Company, Georgia Power Company, Gulf Power Company, Mississippi Power Company and Savannah Electric and Power Company (Southern Companies), tendered for filing an Interchange Service Contract between Southern Companies and Western Gas Resources Power Marketing, Inc. The Interchange Service Contract establishes the terms and conditions of power supply, including provisions relating to service conditions, control of system disturbances, metering and other matters related to the administration of the agreement.

Comment date: March 11, 1996, in accordance with Standard Paragraph E at the end of this notice.

8. Southern Company Services, Inc.

[Docket No. ER96–1106–000]

Take notice that on February 20, 1996, Southern Company Services, Inc., acting on behalf of Alabama Power Company, Georgia Power Company, Gulf Power Company, Mississippi Power Company and Savannah Electric and Power Company (Southern Companies), tendered for filing an Interchange Service Contract between Southern Companies and Valero Power Services Company. The Interchange Service contract establishes the terms and conditions of power supply, including provision relating to service conditions, control of system disturbances, metering and other matters related to the administration of the agreement.

Comment date: March 11, 1996, in accordance with Standard Paragraph E at the end of this notice.

9. Interstate Power Company

[Docket No. ER96–1107–000]

Take notice that on February 20, 1996, Interstate Power Company, tendered for filing a Notice of Cancellation of its Municipal Electric Wholesale Agreement with the City of Lawler filed with FERC under Original Volume No. 1.

Comment date: March 11, 1996, in accordance with Standard Paragraph E at the end of this notice.

10. Interstate Power Company

[Docket No. ER96–1108–000]

Take notice that on February 20, 1996, Interstate Power Company, tendered for filing a Notice of Cancellation of its Rate Schedule FERC No. 0110.

Comment date: March 11, 1996, in accordance with Standard Paragraph E at the end of this notice.

11. Pacific Gas and Electric Company

[Docket No. ER96–1109–000]

Take notice that on February 20, 1996, Pacific Gas and Electric Company (PG&E), tendered for filing a Letter of Agreement No. 96SNR00065 (1996 Rate Settlement Agreement) with the Western Area Power Administration (Western). The 1996 Rate Settlement Agreement changes rates for certain transmission services provided to Western under Contracts Nos. 14–06–200–2946A DE–AC65–80WP59000, and DE–MS65–63WP–59055, for the period April 1, 1996 through March 31, 2001.

Comment date: March 11, 1996, in accordance with Standard Paragraph E at the end of this notice.

12. Commonwealth Edison Company

[Docket No. ER96–1110–000]

Take notice that on February 20, 1996, Commonwealth Edison Company (ComEd), submitted two Service Agreements, establishing Delhi Energy Services, Inc. (DESI), dated January 2, 1996, and City of Tallahassee (Tallahassee), dated December 4, 1995, as customers under the terms of ComEd's Power Sales Tariff PS–1 (PS–1 Tariff). ComEd also submitted for filing two Service Agreements, establishing Koch Power Services, Inc. (Koch), dated January 19, 1996, and City of Tallahassee (Tallahassee), dated December 4, 1995, as customers under the terms of ComEd's Flexible Transmission Service Tariff FTS–1 (FTS–1 Tariff). The Commission has previously designated the PS–1 Tariff as FERC Electric Tariff, Original Volume No. 2, and the FTS–1 Tariff as FERC Electric Tariff, Second Revised Volume No. 3.

ComEd requests an effective date of January 20, 1996, for all four Service Agreements and accordingly seeks waiver of the Commission's requirements. Copies of this filing were served upon DESI, Tallahassee, Koch and the Illinois Commerce Commission.

Comment date: March 11, 1996, in accordance with Standard Paragraph E at the end of this notice.

13. Cinergy Services, Inc.

[Docket No. ER96–1111–000]

Take notice that on February 20, 1996, Cinergy Services, Inc. (Cinergy), tendered for filing a service agreement under Cinergy's Non-Firm Point-to-Point Transmission Service Tariff (the Tariff) entered into between Cinergy and Koch Power Services, Inc.

Comment date: March 11, 1996, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

E. 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, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. 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.

Lois D. Cashell,

Secretary.

[FR Doc. 96–4926 Filed 3–1–96; 8:45 am]

BILLING CODE 6717–01–P

[Project No. 2438–007–NY]

Seneca Falls Power Corporation; Notice of Availability of Draft Environmental Assessment

February 27, 1996.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission's) regulations, 18 CFR Part 380 (Order No. 486, 52 FR 47897), the Office of Hydropower Licensing has reviewed the application for a new license for the Waterloo and Seneca Falls Hydroelectric Project, located in Yates, Schuyler, and Ontario Counties, New York, and has prepared a Draft Environmental Assessment (DEA) for the project. In the DEA, the Commission's staff has analyzed the potential environmental impacts of the existing licensed project and has concluded that approval of the project, with appropriate environmental protection measures, would not constitute a major federal action significantly affecting the quality of the human environment.

Copies of the DEA are available for review in the Public Reference Branch, Room 2–A, of the Commission's offices at 888 First Street, N.E., Washington, D.C. 20426.

Any comments should be filed within 30 days from the date of this notice and should be addressed to Lois D. Cashell, Secretary, Federal Energy Regulatory Commission, 888 First Street N.E., Room 1–A, Washington, D.C. 20426. Please affix ''Waterloo and Seneca Falls Hydroelectric Project No. 2438'' to all comments. For further information, please contact Tom Dean at (202) 219–2778.

Lois D. Cashell,

Secretary.

[FR Doc. 96–4895 Filed 3–1–96; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[ASM–FRL–5432–7]

Agency Information Collection Activities Up for Renewal: OMB Control Number 2060–0007

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

REQUEST FOR COMMENTS: Pre-Certification and Testing Exemption Reporting and Record keeping Requirements for motor vehicle and motor vehicle engines.

SUMMARY: In compliance with the paperwork Reduction Act (44 U.S.C. 3506(c)(2)), this notice announces that the Information Collection Request listed below is coming up for renewal. Before submitting the renewal package to the Office of Management and Budget (OMB), EPA is soliciting comments on specific aspects of the collection as described below.

DATES: Comments must be submitted on or before May 3, 1996.

ADDRESSES: Vehicle Programs and Compliance Division, 401 M Street SW., (6405J), Washington, DC 20460.

FOR FURTHER INFORMATION OR COPIES: Interested persons may request a copy of the ICR, without charge, by writing, faxing, or phoning Anthony Tesoriero, Vehicle Programs and Compliance Division, U.S. EPA, 401 M Street SW., (6405J), Washington, DC 20460; (202) 233–9327, Fax (202) 233–9596.

SUPPLEMENTARY INFORMATION:

Affected Entities: Parties potentially affected by this action include: manufacturers of new motor vehicles or engines, manufacturers of parts or equipment that is used on motor vehicles or engines, fuel refiners, manufacturers in the business of importing, modifying, or testing uncertified vehicles for resale, and Independent Commercial Importers (ICIs).

Title: Pre-Certification and Testing Exemptions Reporting and Record keeping Requirements, OMB No. 2060–0007, Expiration Date 3/31/96.

Abstract: Manufacturers of new motor vehicles or engines, manufacturers of vehicle or engine parts, fuel refiners, manufacturers in the business of importing, modifying, or testing uncertified vehicles for resale, and Independent Commercial Importers (ICIs) will report and keep records of applications for pre-certification and testing exemptions. They will submit reports as part of their testing programs when an uncertified vehicle or engine is required. EPA will use this information to ensure that uncertified vehicles or engines from the pre-certification program or the testing exemption program are introduced into commerce only on a temporary basis for legitimate purposes.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a current valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

EPA would like to solicit comments to:

(i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) enhance the quality, utility, and clarity of the information to be collected; and

(iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

BURDEN STATEMENT

[Estimated Avg]

Activity	Burden hours	Cost per response	Frequency	No. of respondents
A. Pre-Certification Exemptions:				
1. Manufacturers	3	$180.00	1	40
2. ICI	5.25	315.50	1	25
B. Testing Exemptions:				
1. Manufacturers	40	2,400.00	1	15
2. NonManufacturers/Importation	3	180.00	1	55
3. NonManufacturers/No Importation	5.25	315.50	1	5

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing, and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Dated: February 23, 1996.

Robin Miles-Mclean,

Acting Director, Office of Mobile Sources.

[FR Doc. 96–4956 Filed 3–1–96; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5433–7]

Agency Information Collection Activities Up for Renewal; Request for Comments: Emission Control System Performance Warranty Regulations and Voluntary Aftermarket Part Certification Program—OMB Control Number: 2060–0060

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3506(c)(2)), this notice announces that the Information Collection Request (ICR) listed below is coming up for renewal. Before submitting the renewal package to the office of Management and Budget (OMB), EPA is soliciting comments on specific aspects of the collection as described below.

DATES: Comments must be submitted on or before May 3, 1996.

ADDRESSES: Requests for a copy of the ICR should be sent to Chestine Payton, U.S. EPA, 401 M Street, S.W. (6405J), Washington, D.C. 20460. Please include a daytime telephone number, and a current mailing address with any request.

FOR FURTHER INFORMATION CONTACT: Chestine Payton, Vehicle Programs and Compliance Division, U.S. EPA, 401 M Street S.W.(6405J), Washington, DC 20460; (202) 233–9328, FAX (202) 233–9596.

SUPPLEMENTARY INFORMATION: Affected entities: Parties potentially affected by this action are those which are automotive manufacturers and builders of automotive after market parts.

Title: Emission Control System Performance Warranty Regulations and Voluntary Aftermarket Part Certification Program, OMB# 2060–0060, Expiration date 4/30/96.

Abstract: The information required is the minimal necessary to ensure that the part to be certified actually performs as required. Without this information EPA would have no way to control and audit fraudulent or marginal submissions. Since information is only collected when the part is tested to be certified, if no information is collected at the time of testing there will be no means of showing later that the part was properly designed. EPA would not be able to control the self-certification of parts and this could, therefore, result in certified parts that cause vehicles to fail emissions standards.

The information collected is part of the requirement of Section 207(a) of the Clean Air Act, and as described in section 40 CFR Part 85, Subpart V. This is a voluntary certification program and there is no requirement that any manufacturer participate.

The total estimated involvement of the aftermarket part industry (replacement and specialty parts) is 2 parts per year.

The estimation of respondent burden in hours is based on Certification burden estimates for vehicle manufacturers compiled in the April l985 Information Collection Report for the basic vehicle certification program (RE: the April l985 report). Estimation of respondent burden will be broken down into three parts: reporting Burden, Testing Burden and Recordkeeping Burden. A total burden estimate will be compiled from these three categories.

The EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Burden Statement: EPA's burden estimated for this information collection are broken down into three parts: reporting, testing, and recordkeeping burden. EPA estimates that the reporting burden will be 116 hours, testing 260 hours and annual recordkeeping 3 hours. No person is required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB contol numbers for EPA's regulations are displayed in 40 CFR Part 9.

Send comments regarding these matters, or any other aspect of the information collection, including suggestions for reducing the burden, to the address listed above.

Dated: February 23, 1996.

Robin Miles-McLean,

Acting Director, Office of Mobile Sources.

[FR Doc. 96–4959 Filed 3–1–96; 8:45 am]

BILLING CODE 6560–50–P

[AMS-FRL–5432–6]

Agency Information Collection Activities Up for Renewal; Emission Defect Information Report; Emission Recall Audit Program; and Emission Control Defect Survey

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that EPA is planning to submit the following proposed and/or continuing Information Collection Requests (ICRs) to the Office of Management and Budget (OMB). Before submitting the ICRs to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collections as described below.

DATES: Comments must be submitted on or before May 3, 1996.

ADDRESSES: Vehicle Programs & Compliance Division (6405J), 401 M Street, SW, Washington, D.C. 20460. Interested persons may request a copy of the ICRs, without charge, by writing, faxing, or phoning the contact persons below.

FOR FURTHER INFORMATION CONTACT: ICR–1: Steve Albrink, Office of Mobile Sources, Vehicle Programs & Compliance Division, (202) 233–9003, (202) 233–9596 fax).

ICR–2: Kerrin Bressant, Office of Mobile Sources, Vehicle Programs & Compliance Division, (202) 233–9291, (202) 233–9596 (fax).

ICR–3: Sonny Kakar, Office of Mobile Sources, Vehicle Programs & Compliance Division, (202) 233–9467, (202) 233–9596 (fax), E-mail address: kakar.sonny@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Request for Comments: This notice requests comments on three different Information Collection Activities (ICRs) related to highway and nonroad motor vehicles and other engines for which the Agency plans to request renewal of their authorizations under the Paperwork Reduction Act. The different ICRs will be referred to as ICR–1, ICR–2 and ICR–3 in the succeeding sections below.

ICR–1: Emission defect information and voluntary emissions recall reporting and record keeping requirements for manufacturers of on-highway light-duty motor vehicles, light-duty trucks, and heavy-duty engines; and large nonroad compression ignition engines; and nonroad spark-ignition engines at and below 19 kilowatts.

ICR–2: Emission recall audit program voluntary request for information to determine whether manufacturers are in compliance with recall procedural regulations, and to determine the cause of ineffectual recall campaigns.

ICR–3: Vehicle emission control defect survey questionnaire reporting and record keeping requirements for owners and repair facilities of on-highway light-duty motor vehicles, light-duty trucks, heavy-duty engines; and large non-road compression ignition engines.

Information Collection Activities Up for Renewal: ICR–1: OMB No. 2060–0048.

ICR–2: OMB No. 2060–0046.

ICR–3: OMB No. 2060–0047.

Affected Entities: ICR–1: Entities potentially affected by this action are manufacturers of on-highway light-duty vehicles, light-duty trucks, and heavy-duty engines; manufacturers of large nonroad compression ignition engines; and manufacturers of small nonroad spark-ignition engines.

ICR–2: Entities potentially affected by this action are individual vehicle owners of on-highway light-duty vehicles and light-duty trucks.

ICR–3: Entities potentially affected by this action are owners and repair facilities of on-highway light-duty vehicles, light-duty trucks, heavy-duty engines, and large non-road compression ignition engines.

Titles: ICR–1: Emission Defect Information Reports and Voluntary Emissions Recall Reports (OMB # 2060–0048, approved through 5/31/96.)

ICR–2: Emission Recall Audit Program Owner Questionnaire (OMB # 2060–0046, approved through 5/31/96.)

ICR–3: Vehicle Emission Control Defect Survey Questionnaire for on-highway light-duty motor vehicles, light-duty trucks, heavy-duty engines, and large non-road compression ignition engines. (OMB # 2060–0047, approved through 5/31/96.)

Abstracts: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

EPA would like to solicit comments to:

(i) Evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the agency's estimate of the burden of the proposed collections of information, including the validity of the methodologies and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collections of information on those who are to respond, including through the use of the appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

ICR–1: Some manufacturers of motor vehicles and certain engines are required to submit two different reports under 40 CFR Part 85, Subpart T, Part 89, Subpart I and Part 90, Subpart I. These reports are only required where certain conditions involving emission defects or voluntary recalls occur. The ''defect information report'' (DIR) contains data regarding the class or engine family and number of vehicles or engines on which a defect has been found, and a description of the defect and its effects on vehicle or engine performance and emissions. The Agency uses the DIR to help identify emission-related defects or classes of vehicles or engines which may not comply with federal emissions standards.

The ''voluntary emission recall'' (VER) report contains data on voluntary recall campaigns conducted by manufacturers, including the procedures used by the manufacturers to conduct voluntary recall campaigns, the identification of vehicles or engines affected by the campaign, and the repair to be completed on recalled vehicles or engines; progress or quarterly updates of the VER reports track the number of vehicles or engines repaired. The Agency uses the VER report and progress reports to ensure that manufacturers are following acceptable procedures when conducting recalls and to track the progress and effectiveness of voluntary recall campaigns.

ICR–2: The Vehicle Compliance Programs Group (VCPG), Vehicle Programs and Compliance Division (VPCD), Office of Mobile Sources (OMS), Office of Air and Radiation (OAR), uses this information collection to enforce the Recall and Defect Reporting Regulations of 40 CFR Part 85, Subparts S and T. Individual owners of on-road light-duty motor vehicles and light-duty trucks may be asked to provide information on vehicles that have been recalled. The Vehicles Compliance Programs Group (VCPG) uses such information to evaluate the effectiveness of various aspects of a recall campaign, to determine whether manufacturers are in compliance with

recall procedural regulations, and to determine the cause of ineffective recall campaigns. The information is obtained from individuals through a questionnaire administered by telephone interviews or in written format. The information collection effort will involve approximately 300 respondents at a cost of $900.00 over a one-year period.

The projected annual cost burden per respondent is as follows: reading or listening to questions, burden cost is $1.60. Responding to questions (verbally or in writing), burden cost is $1.40.

The total annual hour burden for respondents is 75 hours at a total annual cost of $900.

ICR–3: The Vehicle Compliance Programs Group (VCPG) of the Vehicle Programs and Compliance Division (VPCD) and the Engine Compliance Programs Group (ECPG) of the Engine Programs and Compliance Division (EPCD), Office of Mobile Sources (OMS), Office of Air and Radiation (OAR), uses this information collection to gather additional data to supplement in-use testing programs as well as provide possible evidence in support of EPA's position during an administrative hearing. When EPA orders a manufacturer to recall a certain class of motor vehicles (in accordance with Clean Air Act § 207(c)) but the manufacturer disagrees with EPA's findings, the manufacturer may request an administrative hearing. During such a hearing, EPA must make a detailed presentation of facts showing that the class of vehicles in question should indeed be recalled. Facts to be included in such a presentation consist of information on the maintenance and performance history of vehicles belonging to the class. Dealerships, fleets, or individual owners of motor vehicles or engines may be asked to provide information on the vehicles or engines at issue. The information is obtained through a questionnaire administered by telephone interviews with individual vehicle owners, and by telephone or in-person interviews with dealerships or fleets.

Burden Statement: Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjusting the existing ways to comply with any previously applicable instructions and requirements; training personnel to be able to respond to a collection of information; searching data sources; completing and reviewing the collection of information; and transmitting or otherwise disclosing the information.

ICR–1: Tables 1, 2 and 3 below represent the estimated annual burden for this ICR.

TABLE 1.—ON-HIGHWAY LIGHT-DUTY MOTOR VEHICLE, LIGHT-DUTY TRUCK, AND HEAVY-DUTY ENGINE MANUFACTURER BURDEN HOURS AND COSTS

Collection activity	Defect information reports	Voluntary emission recall (VER) reports/records	VER quarterly (progress) reports
Ave. Burden Hours/Response	14	11.5	1.5
Estimated Frequency of Response	2.8	2.9	17.4
Total Burden Hours Per Respondent	39.2	33.4	26.1
Estimated No. of Respondents	15	13	13
Total Burden Hours	588	434.2	339.3
Total Cost Per Respondent ($)	2,290	1,427	1,375
Total Cost ($)	34,350	18,551	17,875

TABLE 2.—LARGE NON-ROAD COMPRESSION IGNITION ENGINE MANUFACTURER BURDEN HOURS AND COSTS

Collection activity	Defect information reports	Voluntary emission recall (VER) reports/records	VER quarterly (progress) reports
Ave. Burden Hours/Response	14	11.5	1.5
Estimated Frequency of Response	1	1	6
Total Burden Hours Per Respondent	14	11.5	9
Estimated No. of Respondents	5	5	5
Total Burden Hours	70	57.5	45
Total Cost Per Respondent ($)	818	492	474
Total Cost ($)	4,090	2,460	2,370

TABLE 3.—SMALL NONROAD SPARK IGNITION ENGINE MANUFACTURER BURDEN HOURS AND COSTS

Collection activity	Defect information reports	Voluntary emission recall (VER) reports/records	VER progress reports
Ave. Burden Hours/Response	14	11.5	1.5
Estimated Frequency of Response	1	1	1
Total Burden Hours Per Respondent	14	11.5	1.5
Estimated No. of Respondents	5	5	5
Total Burden Hours	70	57.5	7.5

TABLE 3.—SMALL NONROAD SPARK IGNITION ENGINE MANUFACTURER BURDEN HOURS AND COSTS—Continued

Collection activity	Defect information reports	Voluntary emission recall (VER) reports/records	VER progress reports
Total Cost Per Respondent ($)	818	492	79
Total Cost ($)	4,090	2,460	395

ICR–2: The projected hour burden is as follows: reading or listening to questions, burden hours = 8 minutes. Responding to questions (verbally or in writing), burden hours = 7 minutes. The frequency of response is once per respondent per year. The estimated number of likely respondents is 300. The total burden for all respondents is 75 hours.

The projected *cost* burden is as follows: reading or listening to questions, burden cost = $1.60. Responding to questions (verbally or in writing), burden cost = $1.40. The total cost for all respondents is $900.

ICR–3: EPA's burden estimates for this collection are broken down according to the respondent burden and cost. EPA may perform two surveys annually, one of manufacturers of on-highway light-duty motor vehicles or light-duty trucks, and the other of heavy-duty engines or large non-road compression ignition engines, which will require either telephone or in-person interviews with one hundred (100) individual vehicle owners or dealerships or fleets per survey. A burden estimate of twenty (20) minutes per individual vehicle owner is based on agency experience with similar questions asked of individuals as part of the in-use recall testing program. A burden estimate of thirty (30) minutes per dealership or fleet is based on contact with dealership and fleets made as part of the in-use recall testing program. The burden estimate is calculated from an average of the two different burdens assuming that one half of the respondents are individual vehicle owners and the other half are dealerships or fleets. Therefore, the total respondent burden will be 2,500 minutes for each survey. Individuals, dealerships, or fleets will be asked to respond to only one survey in any given year. Costs to respondents associated with this ICR are attributed to individual or staff time involved in responding to the information requests. The costs for respondents for reading or listening to and responding to questions (verbally or in writing) are $8.50 per respondent. Therefore, the total respondent cost for each survey will be $850.

Dated: February 23, 1996.

Robin Miles-McLean,

Acting Director, Office of Mobile Sources.

[FR Doc. 96–4961 Filed 3–1–96; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5433–6]

Retrofit/Rebuild Requirements for 1993 and Earlier Model Year Urban Buses; Public Review of Cost Information Related to the Certification of Retrofit/Rebuild Equipment

AGENCY: Environmental Protection Agency.

ACTION: Notice of agency receipt of cost information related to certification of equipment and initiation of 45-day public review and comment period.

SUMMARY: This notice addresses a shortcoming in the current certification of certain equipment certified under the urban bus retrofit/rebuild program. The effective date of certification of Detroit Diesel Corporation's (DDC) equipment for upgrading its 1979 through 1989 model year urban bus engines of model 6V92TA equipped with mechanical unit injection (MUI) is October 2, 1995 (60 FR 51472). That certification was based on reduction in particulate matter (PM) of 25 percent or more, but not on DDC's guarantee to make the equipment available to all operators for less than the applicable life cycle ceiling (hereinafter referred to as ''cost/availability''). Although DDC, in its notification of intent to certify, requested certification on the basis of cost/availability, as stated in the October 2, 1995 Federal Register notice, the Agency at that time saw no advantage to certification on that basis. Upon reconsideration, the Agency believes that it may be beneficial to the program to expand the basis of certification of DDC's upgrade kit to include the basis of cost/availability. Further, in addition to the request in its notification of intent to certify signed March 16, 1995, DDC reiterated its request in a letter to the Agency dated December 15, 1995, that this equipment be certified on the basis of cost/availability. Copies of both DDC's notification and the letter are available for review in the public docket located at the address indicated above.

DDC has submitted to the Agency new information relevant to the certification of urban bus retrofit/rebuild equipment pursuant to 40 CFR Part 85, Subpart O. Pursuant to section 85.1407(a)(7), today's Federal Register notice announces that the information is available for public review and comment, and initiates a 45-day period during which comments can be submitted. The Agency will review this information, as well as comments received, to determine whether certification of the DDC equipment should be expanded to include the basis of cost/availability. If DDC's certification is expanded to include the cost/availability basis, then the certification level of the equipment may be considered when ''post-rebuild'' PM levels are established in mid-1996. The post-rebuild levels to be established in mid-1996 would be used by operators complying with compliance program 2 when calculating average fleet emissions for 1998 and thereafter. Therefore, to expand DDC's certification to include the basis of cost/availability may tend to lower ambient levels of PM emissions from fleets which comply with compliance program 2.

Category VII of Public Docket A–93–42, entitled ''Certification of Urban Bus Retrofit/Rebuild Equipment'' contains the new cost information and DDC's notification of intent to certify, as well as other materials specifically relevant to it. This docket is located at the address below.

Today's notice initiates a 45-day period during which the Agency will accept written comments relevant to whether the certification of DDC's equipment should be expanded to include the basis of cost/availability. Comments should be provided in writing to Public Docket A–93–42, Category VII, at the address below. An identical copy should be submitted to William Rutledge, also at the address below.

DATES: Comments must be submitted on or before April 18, 1996.

ADDRESSES: Submit separate copies of comments to each of the two following addresses:

1. U.S. Environmental Protection Agency, Public Docket A–93–42 (Category VII), Room M–1500, 401 M Street S.W., Washington, DC 20460.
2. William Rutledge, Engine Programs and Compliance Division (mail code 6403J), 401 ''M'' Street S.W., Washington, DC 20460.

The DDC notification of intent to certify, as well as other materials specifically relevant to it, are contained in the public docket indicated above. Docket items may be inspected from 8:00 a.m. until 5:30 p.m., Monday through Friday. As provided in 40 CFR Part 2, a reasonable fee may be charged by the Agency for copying docket materials.

FOR FURTHER INFORMATION CONTACT: William Rutledge, Engine Programs and Compliance Division (6403J), U.S. Environmental Protection Agency, 401 M Street S.W., Washington, DC 20460. Telephone: (202) 233–9297.

SUPPLEMENTARY INFORMATION:

I. Background

On April 21, 1993, the Agency published final Retrofit/Rebuild Requirements for 1993 and Earlier Model Year Urban Buses (58 FR 21359). The retrofit/rebuild program is intended to reduce the ambient levels of particulate matter (PM) in urban areas and is limited to 1993 and earlier model year (MY) urban buses operating in metropolitan areas with 1980 populations of 750,000 or more, whose engines are rebuilt or replaced after January 1, 1995. Operators of the affected buses are required to choose between two compliance options: Program 1 sets particulate matter emissions requirements for each urban bus engine in an operator's fleet which is rebuilt or replaced; Program 2 is a fleet averaging program that establishes specific annual target levels for average PM emissions from urban buses in an operator's fleet. In general, to meet either of the two compliance options, operators of the affected buses must use equipment which has been certified by the Agency.

A key aspect of the program is the certification of retrofit/rebuild equipment. Emissions requirements under either of the two compliance options depend on the availability of retrofit/rebuild equipment certified for each engine model. To be used for Program 1, equipment must be certified as meeting a 0.10 g/bhp-hr PM standard or, if equipment is not certified as meeting the 0.10 PM standard, as achieving a 25 percent reduction in PM. Equipment used for Program 2 must be certified as providing some level of PM reduction that would in turn be claimed by urban bus operators when calculating their average fleet PM levels attained under the program. For Program 1, information on life cycle costs must be submitted in the notification of intent to certify in order for certification of the equipment to initiate (or trigger) program requirements. To trigger program requirements, the certifier must guarantee that the equipment will be available to all affected operators for a life cycle cost of $7,940 or less at the 0.10 g/bhp-hr PM level, or for a life cycle cost of $2,000 or less for the 25 percent or greater reduction in PM emissions. Both of these values are based on 1992 dollars and are increments above costs associated with a standard rebuild. If the Agency determines that the life cycle cost limit is met, then certification would be based on ''cost/availability'' in addition to reducing PM emissions.

Under program 2, operators calculate their average fleet emissions using specified ''pre-rebuild'' and ''post-rebuild'' engine PM emission levels (as well as other factors). The final rulemaking of April 21, 1993, established the pre-rebuild emissions levels, and intended that post-rebuild levels be established at two subsequent points in time, based on the certification levels of equipment certified by those points. Post-rebuild levels were established for the first two years of the program in a Federal Register notice of September 2, 1994 (59 FR 45626), which set 0.30 g/bhp-hr for 6V92TA engines of model years 1979 through 1987. This level was established as required by the final rule, that is, as a ''default'' level for these engines in the event that no equipment was certified by July 1, 1994. As explained in the final rulemaking and the September 2, 1994, Federal Register, EPA determined that this ''default'' level could be attained by rebuilding the engines with the available DDC upgrade kit which, although not certified by July 1, 1994 under the urban bus program, has emissions performance supported by data from the Agency's new-engine certification program.

The post-rebuild level established by the above-mentioned September 2, 1994, Federal Register notice for the 1979–1987 6V92TA engines (0.30 g/bhp-hr) is less than the pre-rebuild level (0.50 g/bhp-hr). That reduction in PM levels, and the assumed rebuild schedule of the regulation [§ 85.1403(c)(1)(iv)], means that operators choosing to comply with compliance program 2 and having 6V92TA MUI engines of certain model years must reduce average fleet PM emissions during calendar years 1995 and 1996 an amount equivalent to rebuilding those model year engines with DDC's upgrade kit.

Section 85.1403(c) requires that final post-rebuild levels be established based on equipment certified by July 1, 1996, to meet the PM standard *and* as being available to all operators for less than an appropriate life cycle cost ceiling. These ''post-rebuild'' levels are to be used in the calculations of fleet target levels for 1998 and thereafter, for engines scheduled for retrofit/rebuild in calendar years 1997 and thereafter. Section 85.1403(c)(1)(iii) requires that post-rebuild emission levels be the *lowest* emission level (greater than 0.1 g/bhp-hr) certified as meeting the emission *and* cost requirements of § 85.1403(b)(2), for any engine model for which no equipment has been certified by July 1, 1996 as meeting the requirements of § 85.1403(b)(1).

The Agency announced certification of the DDC upgrade kit for the 1979–1989 6V92TA engines in the Federal Register on October 2, 1995 (60 FR 51472) based on compliance with the 25% reduction standard, but without determination of compliance with the life cycle cost ceiling. That certification does not restrict use of the upgrade kit by operators under either compliance program 1 or 2, until other equipment is certified which triggers the 0.10 g/bhp-hr standard.

Section 85.1403 of the program regulations requires that the post-rebuild emission levels established in mid-1996 be the *lowest* emission level (greater than 0.10 g/bhp-hr) certified as meeting the emission *and* life cycle cost requirements. The DDC upgrade kit is currently certified to 0.30 g/bhp-hr for the above-mentioned 1979 through 1987 6V92TA engines, but unless certification includes the basis of cost/availability, it would not be considered when we establish the final post-rebuild levels. Other equipment is certified to 0.38 g/bhp-hr for the 1979 through 1987 6V92TA engines and is also certified as available to all operators for no more than the applicable life cycle cost. If no other equipment is certified in the meantime, the ''post-rebuild'' level would probably be set to this 0.38 level.

Additionally, as noted above, the post-rebuild level for the 1979 through 1987 6V92TA engines has already been established at 0.30 g/bhp-hr (the Federal Register notice of September 2, 1994), but only for the first two years of the program. Therefore, if no other equipment is certified prior to July 1, 1996 to a lower level, and lacking any compelling reason not to certify this equipment on the basis of cost/

availability, then it would not be consistent with the Federal Register notice of September 2, 1994 to establish the post-rebuild level higher than 0.30 g/bhp-hr.

II. Information Concerning Cost and Availability

By a notification of intent to certify signed March 16, 1995, and with cover letter dated April 11, 1995, Detroit Diesel Corporation (DDC) applied for certification of equipment applicable to its 6V92TA model engines having mechanical unit injectors (MUI) that were originally manufactured between January 1979 and December 1989. The effective date of certification of that DDC equipment was established in the Federal Register on October 2, 1995 (60 FR 51472). That certification is currently based on reduction in particulate matter (PM) of 25 per cent or more. DDC, in its notification of intent to certify, requests certification on the basis of cost/availability and guarantees to make the equipment available to all operators for less than the applicable life cycle ceiling (hereinafter referred to as ''cost/availability''). As stated in the Federal Register notice of October 2, 1995, however, the Agency saw no advantage to such certification at that time because the emission standard had been triggered earlier by certification of other equipment. As explained above, the Agency upon reconsideration believes that it may be beneficial to the program to expand the basis of certification of DDC's upgrade kit to include the basis of cost/availability.

In its notification, DDC states that the equipment will be offered to all affected urban bus operators for a maximum purchase price of $5,562, and has submitted life cycle cost information. DDC claims that the life cycle cost is less than $2,000 (1992 dollars) incremental to the cost for a standard rebuild. DDC claims that the only incremental cost, compared to a standard rebuild, is the cost of a blower by-pass valve assembly, which DDC states has a suggested price of $97.36 if purchased separately. DDC indicates that there is no incremental installation cost, fuel cost, or maintenance cost compared to that related to a standard engine overhaul.

In addition to its initial request in its notification of intent to certify, DDC reiterated its request that this equipment be certified on the basis of cost/availability in a letter to the Agency dated December 15, 1995, and provided updated information concerning transit pricing level. DDC indicates that the suggested transit list price of the upgrade kit is less than the suggested list price of the individual components, if purchased separately, that are currently replaced or reworked during a standard rebuild. In other words, all of the components of their upgrade kit, with exception of the blower by-pass valve assembly, are non-incremental to a ''standard'' rebuild. Other new information in the docket include a summary of a survey conducted by the American Public Transit Association (APTA) on engine rebuilding practices.

Several public comments concerning cost/availability were received in response to DDC's notification. The following is a summary of the comments, along with the Agency's response, as appropriate:

The People Moving Company of the Greater Bridgeport Transit District states that thirteen of its engines have been rebuilt using DDC's low-emission rebuild kits, and their experience has been positive. They support DDC's claim that the kits provide better fuel economy.

The Muncie Indiana Transit System comments that the DDC kit exceeds the life cycle cost ceiling and does not contain all parts to rebuild an engine, such as rod and main bearings. Muncie, however, does not provide any detailed information to support its claim concerning costs. The comment that the kit does not contain all of the parts necessary to rebuild an engine, may be correct. However, there is no requirement that every part necessary to rebuild an engine be included with equipment certified under the program. The life cycle cost ceiling is meant to reflect costs of certified equipment which are incremental to costs of a standard rebuild. In particular, section 85.1403(b)(2) states that the purchase price of retrofit/rebuild equipment excludes equipment costs incurred for a standard rebuild. Therefore, to the extent that a component (such as a bearing) is replaced in a standard rebuild, it is not necessary to include the component as part of the certified upgrade kit, or to include its cost in the purchase price of the kit.

Muncie also questions whether tune-ups and related emissions-affecting parts are considered warranty items. The emissions performance and defect warranties, required pursuant to section 85.1409, apply to all parts of the certified equipment described in DDC's notification of intent to certify, for the mileage intervals specified in section 85.1409. In its notification, DDC states that the scheduled maintenance and parts necessary to perform the scheduled maintenance are identical before and after rebuild and, therefore, there are no incremental maintenance costs involved.

The Engelhard Corporation provides in-depth comments concerning the life cycle costs. Engelhard states that the DDC upgrade kit will exceed the life cycle cost ceiling, and notes three areas that DDC has not addressed in its life cycle cost analysis. First, Engelhard indicates that an engine must be removed from a bus in order to install the components of the DDC upgrade kit, which would require additional labor hours over an in-frame overhaul. Second, Engelhard states that the DDC kit contains additional components which are not typically replaced during an in-frame overhaul, including camshafts, turbocharger, rollers, injectors, heads, and valves. Third, Engelhard notes that transit operators commonly use aftermarket components which are priced substantially less than DDC components.

With regard to Engelhard's first concern, the preamble to the final rulemaking (April 21, 1993, 58 FR 21367) is clear—the certifier may assume that the engine is removed from the coach during a standard rebuild. It is therefore not necessary for DDC to include cost related to removing an engine for installation of the DDC upgrade kit. Second, the Agency believes that the parts, which Engelhard refers to as ''additional'' and not typically replaced during an in-frame overhaul, are emission-related components. The Agency believes that it is not unreasonable to include emission-related components in a kit because it provides assurance that engines so rebuilt will result in a known condition and a known engine emissions configuration, both of which are important to in-use emissions performance. Further, DDC indicates that all of the parts in its kit, with exception of the blower bypass valve assembly, are normally replaced at engine overhaul.

Third, the cost differential related to use of aftermarket parts is addressed by a cost analysis presented by Engelhard. Engelhard provides an analysis of the cost of a rebuild using aftermarket parts, and compares it to the purchase price of the DDC kit added to the cost of the labor required to remove and install an engine. This comparison indicates that the difference in costs is greater than the life cycle cost ceiling of $2,000. The Agency notes, however, that when the engine removal/installation costs are not included pursuant to the above discussion, the cost differential is less than $2,000. Therefore, this data does not substantiate Engelhard's claim that the life cycle cost ceiling is exceeded.

Copies of the DDC notification, DDC's letter to the Agency dated December 15, 1995, the summary of the APTA survey, and public comments are available for review in the public docket located at the address indicated above.

Today's Federal Register notice announces that information is available for public review and comment, and initiates a 45-day period during which comments can be submitted. The Agency will review this information, as well as comments received, to determine whether certification of the DDC equipment should be expanded to include the basis of cost/availability. If the Agency expands the certification of this equipment to include the basis of cost/availability, then the certification emission levels of the equipment will be considered by the Agency when it establishes final post-rebuild levels as required pursuant to 85.1403(c)(1)(iii). DDC's upgrade kit is certified to emission levels of 0.30 g/bhp-hr for 1979 through 1987 model year 6V92TA MUI engines, and 0.23 g/bhp-hr for 1988 and 1989 model year 6V92TA MUI engines. If either or both of those certification levels are established as post-rebuild values, then operators complying with compliance program 2 would use such levels, as appropriate, in calculations for determining fleet target emissions for 1998 and thereafter.

At a minimum, EPA expects to evaluate this notification of intent to certify, and other materials submitted as applicable, to determine whether there is adequate demonstration of compliance with the cost/availability requirements of § 85.1403(b)(2) and § 85.1407(a)(2), including whether the data provided by DDC complies with the life cycle cost requirements.

The Agency requests that those commenting also consider the regulatory requirements, plus provide comments on experience and/or knowledge related to rebuilding DDC 6V92TA MUI engines, including the specific parts, respective frequency of usage in rebuilds, and costs.

The date of this notice initiates a 45-day period during which the Agency will accept written comments relevant to whether or not the equipment described in the DDC notification of intent to certify should be certified pursuant to the urban bus retrofit/rebuild regulations. Interested parties are encouraged to review the notification of intent to certify and provide comment during the 45-day period. Please send separate copies of your comments to each of the above two addresses.

The Agency will review the cost information related to the notification of intent to certify, along with comments received from interested parties, and attempt to resolve or clarify issues as necessary. During the review process, the Agency may add additional documents to the docket as a result of the review process. These documents will also be available for public review and comment within the 45-day period.

Dated: February 23, 1996.

Richard Wilson,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 96–4954 Filed 3–1–96; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5433–9]

Common Sense Initiative Council (CSIC); Meeting

AGENCY: Environmental Protection Agency.

ACTION: Notification of Public Advisory CSIC Printing Sector Subcommittee Meeting; Common Sense Initiative Council Meeting; and CSIC Petroleum Sector Subcommittee Meeting; Open Meetings.

SUMMARY: Pursuant to the Federal Advisory Committee Act, Public Law 92–463, notice is hereby given that, pending resolution of EPA's FY 1996 appropriation, the Common Sense Initiative Council, and the Printing and Petroleum Sector Subcommittees of the Common Sense Initiative Council will meet on the dates and times described below. All meetings are open to the public. Seating at all three meetings will be on a first-come basis and limited time will be provided for public comment. For further information concerning specific meetings, please contact the individuals listed with the Council and two Sector Subcommittee announcements below.

(1) Printing Sector Subcommittee—March 18 and 19, 1996

Notice is hereby given that the Printing Sector Subcommittee, pending resolution of EPA's FY 1996 appropriation, will hold an open meeting on Monday, March 18, 1996, from 2:30 p.m. EST to 5:00 p.m. EST and Tuesday, March 19, 1996, from 1:00 p.m. EST to 4:00 p.m. EST. The Printing Sector's Workgroups will meet on Monday, March 18, from 10:00 a.m. EST until 2:00 p.m. EST and on Tuesday, March 19, 1996, from approximately 8:30 a.m. EST until noon, EST. The Subcommittee and Workgroup Meetings will be at the Embassy Suites Hotel, 1250 22nd Street, N.W., Washington, DC 20037 (telephone number 857–3388). The purpose of the Subcommittee meeting is to discuss the three projects under consideration by the Subcommittee. The Compliance Tools Workgroup is working on the Multi-Media Flexible Permitting Project, the New York City Education Workgroup is moving ahead with plans for pollution prevention education for small printers, and the Living Lab Workgroup has been looking at information/data collection and management systems. The purpose of the workgroup meetings prior to the Subcommittee meeting is to further develop the workplan for these projects. Agendas will be available March 11, 1996.

For further information concerning this meeting of the Printing Sector Subcommittee, please contact Ginger Gotliffe of EPA's Office of Enforcement and Compliance Assurance at 202–564–7072, or Nancy Cichowicz, EPA, Region III, at 597–2030.

(2) Common Sense Initiative Council Meeting—March 20 and 21, 1996

The Common Sense Initiative Council, pending resolution of EPA's FY 1996 appropriation, will hold an open meeting on Wednesday, March 20, 1996, from 1:30 p.m. EST to 5:30 p.m. EST, and on Thursday, March 21, 1996, from 8:30 a.m. EST to 3:30 p.m. EST. The meeting will be held at the Crystal Gateway Marriott, 1700 Jefferson Davis Highway, Arlington, Virginia (telephone number 703–920–3230).

The Council agenda will focus on a variety of topics including: anticipated second year CSI activities; presentations and discussions with the Council's Operating Principles and Public Health Workgroups; and cross-cutting, broad policy discussions on CSI community-based efforts and alternative regulatory strategies. In addition to these topics, the Iron and Steel Sector Subcommittee will present a Brownfields recommendation for the Council's consideration. Other sector recommendations may be presented to the Council for review and action. Also, EPA will present a preliminary draft workplan (on ensuring stakeholder awareness of and ready access to agency regulatory interpretations and determinations that affect environmental practices of the regulated community) as a followup action to a previously approved Council recommendation.

For further information concerning this Common Sense Initiative Council Meeting, contact Prudence Goforth, DFO on (202) 260–7417.

(3) Petroleum Refining Sector Subcommittee—April 18, 1996

Notice is hereby given that the Environmental Protection Agency, pending resolution of its FY 1996 appropriation, will hold an open meeting of the Petroleum Refining Sector Subcommittee on Thursday, April 18, 1996, from 8:30 a.m. EST until 5:00 p.m. EST. The Petroleum Refining Sector Subcommittee's workgroups will meet the preceding day, Wednesday, April 17, 1996 from 1:00 p.m. EST until 5:00 p.m., EST. The meetings will be held at the Omni Shoreham Hotel, 2500 Calvert Street, N.W., Washington, DC (telephone number 202–234–0700).

On April 18, 1996, the Petroleum Refining Subcommittee will convene to evaluate progress on the ''One-Stop Reporting/Public Access'' project and the proposed workplan for the ''Fugitive Emissions'' project. The group will also determine by consensus whether any recommendations unrelated to these two projects should be sent forward to the Common Sense Initiative Council.

For further information regarding this Petroleum Refining Sector Subcommittee Meeting, please contact either Meg Kelly at EPA, 401 M Street, S.W., Washington, DC. (703–308–8748), or Craig Weeks, EPA, Region VI at 214–665–7505.

INSPECTION OF SUBCOMMITTEE DOCUMENTS: Documents relating to the above Council and Sector Subcommittee announcements, will be publicly available at the meeting. Thereafter, these documents, together with the official minutes for the meetings, will be available for public inspection in room 2821M of EPA Headquarters, Common Sense Initiative Staff, 401 M Street, SW, Washington, DC 20460, telephone number 202–260–7417. Common Sense Initiative information can be accessed electronically through contacting Katherine Brown at brown.katherine@epamail.gov.

Dated: February 27, 1996.

Prudence Goforth,

Designated Federal Officer.

[FR Doc. 96–4957 Filed 3–1–96; 8:45 am]

BILLING CODE 6560–50–P

[OPP–00423; FRL–4990–3]

Testing Guidelines; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: EPA has established a unified library for Test Guidelines issued by the Office of Prevention, Pesticides and Toxic Substances (OPPTS), and is announcing the availability of testing guidelines for the following three series: Series 875–Occupational and Residential Exposure Test Guidelines, Series 880–Biochemicals Test Guidelines, and Series 885–Microbial Pesticide Test Guidelines. The guidelines in these three series have been minimally edited for re-publication, but have not been changed in any substantive way. Issuance of guidelines in these three series initiates the publication of the unified library of OPPTS Test Guidelines. This notice also describes the process of developing this unified library of OPPTS Test Guidelines. The Agency intends to issue Federal Register notices periodically as new test guidelines are added to the OPPTS unified library.

ADDRESSES: The guidelines are available from the U.S. Government Printing Office, Washington, DC 20402 on *The Federal Bulletin Board*. By modem dial (202) 512–1387, telnet and ftp: fedbbs.access.gpo.gov (IP 162.140.64.19), or call (202) 512–1530 for disks or paper copies. The guidelines are also available electronically in ASCII and PDF (portable document format) from the EPA Public Access Gopher (gopher.epa.gov) under the heading ''Environmental Test Methods and Guidelines.''

FOR FURTHER INFORMATION CONTACT: For general information: By mail:

Toxic Substances Control Act (TSCA) information: Contact the TSCA Hotline at: TAIS/7408, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Telephone number: (202) 554–1404; fax (202) 554–5603, e-mail: tsca-hotline@epamail.epa.gov.

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) information: Contact the Communications Branch (7506C), Field Operations Division, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Telephone number: (703) 305–5017; fax is (703) 305–5558.

For technical information on series 875: Alan Nielsen, (703) 305–5242, e-mail: nielsen.alan@epamail.epa.gov.

For technical information on series 880 and series 885: William Schneider, (703) 308–8683, e-mail: schneider.william@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. EPA's Process for Developing a Unified Library of Test Guidelines

EPA's Office of Prevention, Pesticides and Toxic Substances (OPPTS) is close to completion of a multi-year project to harmonize and/or update test guidelines among the Office of Pesticide Programs (OPP), the Office of Pollution Prevention and Toxics (OPPT), and the Organization for Economic Cooperation and Development (OECD). The goals of the project include the formulation of harmonized OPP and OPPT guidelines for those in common between the two programs, the harmonization of OPPT and/or OPP guidelines with those of the OECD, as well as the updating of any guidelines unique to OPP or OPPT programs.

Testing guidelines that are changed substantively in the harmonization process or through other updating/amending activities, or which are new (e.g., for a previously unaddressed testing endpoint) will be made available for public comment by notice in the Federal Register. Additionally, EPA will submit these substantively revised and new test guidelines to peer review by expert scientific panels. Guidelines which are reformatted but not changed in any substantive way will not be made available for public comment or submitted to peer review. Because harmonization and updating is an ongoing task that will periodically result in modified guidelines, some guidelines being made available via GPO and Internet will be subject to revisions in the future. These efforts will ensure that industry is provided with testing guidelines that are current.

All final guidelines will be made available through the GPO Electronic Bulletin Board and the Internet on the EPA Public Access Gopher as a unified library of OPPTS Test Guidelines for use by either program office. Printed versions of the unified library of OPPTS test guidelines will also be available through the GPO. For purposes of this Federal Register notice, ''publication'' of the unified library of guidelines generally describes the availability of these guidelines with the GPO and Internet.

The test guidelines appearing in the unified library will be given numerical designations that are different from the designations provided at 40 CFR parts 158, 795, 796, 797, 798, and 799. OPPTS test guidelines will be published in 10 disciplinary series as follows:

Series 810–Product Performance Test Guidelines

Series 830–Product Properties Test Guidelines

Series 835–Fate, Transport and Transformation Test Guidelines

Series 840–Spray Drift Test Guidelines

Series 850–Ecological Effects Test Guidelines

Series 860–Residue Chemistry Test Guidelines

Series 870–Health Effects Test Guidelines

Series 875–Occupational and Residential Exposure Test Guidelines

Series 880–Biochemicals Test Guidelines

Series 885–Microbial Pesticide Test Guidelines

The Agency intends to issue Federal Register notices periodically as new test guidelines are added to the OPPTS unified library. As each set of guidelines is published, it will be accompanied by a Master List which cross references the new OPPTS guideline numbers to the original OPP and OPPT numbers.

II. Impact on OPP and OPPT

Currently, OPP makes its test guidelines available through the National Technical Information Service (NTIS) as a series of twelve subdivisions. Explicit test requirements for pesticide registration are set out in 40 CFR part 158 which refers to specific guidelines by guideline number. EPA recommends that the test guidelines published through GPO and Internet be consulted instead of those test guidelines that were published through NTIS; studies initiated 45 days or more after final publication should be performed in accordance with the revised guidelines. As test guidelines are published, the Agency will inform industry and the general public by means of PR Notices as well as FR Notices. In addition, Data Call In letters to pesticide registrants will carry a dual numbering system in reference to test guidelines until all test guidelines have been published. Part 158, which is currently under revision, will also carry a dual numbering system for test guidelines when it is proposed and finalized in the Federal Register.

In contrast, OPPT has been publishing its test guidelines in the Code of Federal Regulations (CFR) in 40 CFR parts 795 through 798 and are referenced on a chemical-specific basis in its TSCA section 4 test rules in 40 CFR part 799. Although OPPT is currently evaluating whether to continue to publish its test guidelines in the CFR, OPPT test guidelines and modifications to those test guidelines that have been incorporated by an existing test rule will be retained in the CFR until OPPT announces that it will no longer publish its test guidelines in the CFR. Therefore, to the extent that a manufacturer or processor became subject to a test rule prior to the adoption of a harmonized test guideline, that test rule still requires compliance with the test guideline that was referenced by the test rule and published in the CFR. However, if the manufacturer or processor subject to the test rule is interested in seeking a modification to the requirement to comply with the test guideline that appears in the CFR, and which is incorporated by reference in that test rule, EPA encourages that manufacturer or processor to consult the modification procedures outlined in 40 CFR part 790. EPA has removed, and will continue to remove from the CFR those test guidelines that are no longer incorporated by reference in an existing and applicable test rule.

III. Peer Review of Test Guidelines

The Agency has updated and harmonized test guidelines for Product Properties (830 series) and Residue Chemistry (860 series) (60 FR 44343, August 25, 1995) (FRL–4974–3). EPA submitted the revisions to those series to peer review by the FIFRA Scientific Advisory Panel on September 27, 1995. EPA also made these revisions available to the public for comment through the EPA docket. They will be revised in response to all comments received and published as final guidelines early in 1996.

EPA is also announcing that it intends to make available for public comment prior to peer review meetings the revised test guidelines for Ecological Effects (850 series), Health Effects (870 series), and Fate and Transport (840 series) during 1996.

IV. Notice of Availability of Republished Test Guidelines

This notice announces the availability of OPP unique test guidelines in the 875, 880, and 885 series. The test guidelines in series 875, 880, and 885 have been minimally edited for publication with GPO and Internet, but have not been changed in any substantive way. Guideline Series 880 is drawn from Subdivision M of the Pesticide Assessment Guidelines and pertains to special testing approaches to biochemical pesticides. Only those guidelines from Subdivision M which are truly unique to biochemical pesticides are being published in series 880. The other non-unique tests for biochemical pesticides should be performed using the guidelines for chemical pesticides. Although the Agency is in the process of revising its test guidelines for Post-Application Exposure (875B), the current guidelines are still official and are being published as part of the unified library of OPPTS test guidelines. When EPA has completed the process for revising the Post-Application Exposure guidelines in 1997, the revised guidelines will replace the current guidelines. In the interim, registrants are advised to contact EPA's Occupational and Residential Exposure Branch, within the Office of Pesticide Programs, at (703) 305–6094.

The following is the complete list of guidelines being made available at this time.

SERIES 875—OCCUPATIONAL AND RESIDENTIAL EXPOSURE TEST GUIDELINES

OPPTS Number	Name	Existing Numbers			EPA Pub. no.
		OTS	OPP	OECD	712–C–
	Group A—Applicator Exposure Monitoring Test Guidelines.				
875.1000	Background for application exposure monitoring test guidelines	none	230	none	96–261
875.1100	Dermal exposure—outdoor	none	231	none	96–262
875.1200	Dermal exposure—indoor	none	233	none	96–209
875.1300	Inhalation exposure—outdoor	none	232	none	96–263
875.1400	Inhalation exposure—indoor	none	234	none	96–213
875.1500	Biological monitoring	none	235	none	96–264
875.1600	Application exposure monitoring data reporting	none	236	none	96–265
	Group B—Postapplication Exposure Monitoring Test Guidelines.				
875.2000	Background for postapplication exposure monitoring test guidelines	none	130, 131	none	96–266

SERIES 875—OCCUPATIONAL AND RESIDENTIAL EXPOSURE TEST GUIDELINES—Continued

OPPTS Number	Name	Existing Numbers			EPA Pub. no.
		OTS	OPP	OECD	712–C–
875.2100	Foliar dislodgeable residue dissipation	none	132–1	none	96–267
875.2200	Soil residue dissipation	none	132–1	none	96–243
875.2400	Dermal exposure	none	133–3	none	96–269
875.2500	Inhalation exposure	none	133–4	none	96–270
875.2600	Biological monitoring	none	235	none	96–271
875.2800	Descriptions of human activity	none	133–1	none	96–283
875.2900	Data reporting and calculations	none	134	none	96–272

SERIES 880—BIOCHEMICALS TEST GUIDELINES

OPPTS Number	Name	Existing Numbers			EPA Pub. no.
		OTS	OPP	OECD	712–C–
	Group A—Product Analysis Test Guidelines.				
880.1100	Product identity and composition	none	151–10	none	96–273
880.1200	Description of starting materials, production and formulation process	none	151–11	none	96–274
880.1400	Discussion of formation of impurities	none	151–12	none	96–275
	Group B—Toxicology Test Guidelines.				
880.3550	Immunotoxicity	none	152–18	none	96–280
880.3800	Immune response	none	152–24	none	96–281
	Group C—Nontarget Organisms and Environmental Testing Test Guidelines.				
880.4350	Nontarget insect testing	none	154–11	none	96–285
880.4425	Dispenser water leaching	none	155–5	none	96–286

SERIES 885—MICROBIAL PESTICIDE TEST GUIDELINES

OPPTS Number	Name	Existing Numbers			EPA Pub. no.
		OTS	OPP	OECD	712–C–
885.0001	Overview for microbial pest control agents	none	150A	none	96–290
	Group A—Product Analysis Test Guidelines.				
885.1100	Product identity	none	151A–10	none	96–292
885.1200	Manufacturing process	none	151A–11	none	96–293
885.1300	Discussion of formation of unintentional ingredients	none	151A–01	none	96–294
885.1400	Analysis of samples	none	151A–13	none	96–295
885.1500	Certification of limits	none	151A–15	none	96–296
	Group B—Residues Test Guidelines.				
885.2000	Background for residue analysis of microbial pest control agents	none	153A–1	none	96–299
885.2100	Chemical identity	none	153A–4	none	96–300
885.2200	Nature of the residue in plants	none	153A–6	none	96–302
885.2250	Nature of the residue in animals	none	153A–7	none	96–311
885.2300	Analytical methods—plants	none	153A–8a	none	96–301
885.2350	Analytical methods—animals	none	153A–8b	none	96–305
885.2400	Storage stability	none	153A–9	none	96–306
885.2500	Magnitude of residues in plants	none	153A–10	none	96–307
885.2550	Magnitude of residues in meat, milk, poultry, eggs	none	153A–11	none	96–308
885.2600	Magnitude of residues in potable water, fish, and irrigated crops	none	153A–01	none	96–309
	Group C—Toxicology Test Guidelines.				
885.3000	Background–mammalian toxicity/pathogenicity/infectivity	none	152A–1	none	96–314
885.3050	Acute oral toxicity/pathogenicity	none	152A–10	none	96–315
885.3100	Acute dermal toxicity/pathology	none	152A–11	none	96–316
885.3150	Acute pulmonary toxicity/pathogenicity	none	152A–12	none	96–317

SERIES 885—MICROBIAL PESTICIDE TEST GUIDELINES—Continued

OPPTS Number	Name	Existing Numbers			EPA Pub. no.
		OTS	OPP	OECD	712–C–
885.3200	Acute injection toxicity/pathogenicity	none	152A–13	none	96–318
885.3400	Hypersensitivity incidents	none	152A–15	none	96–320
885.3500	Cell culture	none	152A–16	none	96–321
885.3550	Acute toxicology, Tier II	none	152A–20	none	96–322
885.3600	Subchronic toxicity/pathogenicity	none	152A–21	none	96–323
885.3650	Reproductive/fertility effects	none	152A–30	none	96–324
	Group D—Nontarget Organism and Environmental Expression Test Guidelines.				
885.4000	Background for nontarget organism testing of microbial pest control agents	none	154A–1, 2, 3, 4, 5	none	96–328
885.4050	Avian oral, Tier I	none	154A–16	none	96–329
885.4100	Avian inhalation test, Tier I	none	154A–17	none	96–330
885.4150	Wild mammal testing, Tier I	none	154A–18	none	96–331
885.4200	Freshwater fish testing, Tier I	none	154A–19	none	96–332
885.4240	Freshwater aquatic invertebrate testing, Tier I	none	154A–20	none	96–333
885.4280	Estuarine and marine animal testing, Tier I	none	154A–21	none	96–334
885.4300	Nontarget plant studies, Tier I	none	154A–22	none	96–335
885.4340	Nontarget insect testing, Tier I	none	154A–23	none	96–336
885.4380	Honey bee testing, Tier I	none	154A–24	none	96–337
885.4600	Avian chronic pathogenicity and reproduction test, Tier III	none	154A–26	none	96–342
885.4650	Aquatic invertebrate range testing, Tier III	none	154A–27	none	96–343
885.4700	Fish life cycle studies, Tier III	none	154A–28	none	96–344
885.4750	Aquatic ecosystem test	none	154A–29	none	96–345
	Group E—Environmental Expression Test Guidelines.				
885.5000	Background for microbial pesticides testing	none	155A–1, 2	none	96–056
885.5200	Expression in a terrestrial environment	none	155A–10	none	96–338
885.5300	Expression in a freshwater environment	none	155A–11	none	96–339
885.5400	Expression in a marine or estuarine environment	none	155A–12	none	96–340

List of Subjects

Environmental protection, Test guidelines.

Dated: February 28, 1996.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 96–4964 Filed 2–28–96; 3:49 pm]

BILLING CODE 6560–50–F

[OPP–00413A; FRL–4991–7]

Revision of Prenatal Developmental Toxicity Study and Reproduction and Fertility Effects Testing Guidelines Under FIFRA and TSCA; Notice of Availability and Request for Comments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability and request for comments.

SUMMARY: EPA is making available for public comment revised proposed guidelines for OPPTS 870.3700 Prenatal Developmental Toxicity Study and OPPTS 870.3800 Reproduction and Fertility Effects. When final, these revised guidelines will replace OPP Guidelines 83–3 and 83–4 under 40 CFR 158.340 and OPPT Guidelines under 40 CFR 798.4700 and 798.4900.

DATES: Comments must be received on or before May 3, 1996. If circumstances warrant, EPA may reopen the comment period, by notice in the Federal Register, at a later date.

ADDRESSES: Interested persons are invited to submit written comments in triplicate to: By mail: Public Response and Program Resources Branch, Field Operations Division (7506C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person: bring comments to : Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: guidelines@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number ''OPP–00413A.'' No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found under the ''SUPPLEMENTARY INFORMATION'' caption of this preamble.

Information submitted as a comment in response to this notice may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public docket. Information not marked confidential will be included in the public docket

without prior notice. All statements will be made part of the record and will be taken into consideration by the Agency Scientists.

FOR FURTHER INFORMATION CONTACT: By mail: Susan L. Makris (7509C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: Rm. 816F, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305–5222; e-mail: makris.susan@epamail.epa.gov.

By mail: Katherine Anitole (7509C), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E613B, 401 M St., SW., Washington, DC 20460; telephone: (202) 260–3993; e-mail: anitole.katherine@epamail.epa.gov.

Copies of documents may be obtained by contacting: By mail: Public Docket and Freedom of Information Section, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person or for courier pick-up: Office location and telephone number: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305–5805 or 305–5454. By internet: e-mail requests to: guidelines@epamail.epa.gov or via the EPA Public Access Gopher (gopher.epa.gov) under the heading ''Environmental Test Methods and Guidelines.''

SUPPLEMENTARY INFORMATION: The Agency is revising its test guidelines for Prenatal Developmental Toxicity (870.3700) and Reproduction and Fertility Effects (870.3800). These guidelines would replace FIFRA Subdivision F guidelines 83–3 and 83–4 and TSCA guidelines at 40 CFR 798.4700 and 798.4900. Both draft guidelines were submitted to peer review by the FIFRA Scientific Advisory Panel December 1993 and have been made available to the public for comment.

The current draft revised guidelines are now being made available for additional comment. All interested parties are encouraged to submit comments on the proposed revised guidelines for Prenatal Developmental Toxicity Study and Reproduction and Fertility Effects. Specific comments should reference the specific number and paragraph or subparagraph of the appropriate revised guideline. Recommended technical or scientific changes/modifications should be supported by current scientific/technical knowledge and include supporting references. References may be to the published literature, studies submitted to the Agency in support of registration, and unpublished data. Citations must be sufficiently detailed so as to allow the Agency to obtain copies of the original documents and unpublished data supplied to allow their evaluation.

Comments on the proposed revised guidelines will be considered by the Agency and such modifications of the guidelines considered to be of merit will be incorporated into the final guidelines. The draft modifications and the public comments will be presented to the FIFRA Scientific Advisory Panel and additional experts at a public meeting for its comments before being published as final guidelines. Notice of this meeting will be published in the Federal Register and all interested parties will be offered the opportunity to present written and public comments to the FIFRA Scientific Advisory Panel and additional experts at the public meeting.

A record has been established for this notice under docket number ''OPP–00413A'' (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

guidelines@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this notice, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

List of Subjects

Environmental protection, Test guidelines.

Dated: February 28, 1996.

Lynn R. Goldman,

Assistant Administrator, Office for Prevention, Pesticides and Toxic Substances.

[FR Doc. 96–4967 Filed 2–28–96; 3:49 pm]

BILLING CODE 6560–50–F

[FRL–5434–1]

Risk Assessment and Risk Management Commission

Pursuant to the Federal Advisory Committee Act, Public Law 92–463, notice is hereby given that the Commission on Risk Assessment and Risk Management, established as an Advisory Committee under Section 303 of the Clean Air Act Amendments of 1990, will release its draft report on April 24th from 1:00–300 p.m. at the National Press Club conference rooms on the 13th floor. The Press Building is located at 529 14th Street, NW., Washington, DC 20045. There will be a briefing and the draft report will be available to the public at that time. If you are unable to attend, but wish to receive a copy of the draft report, either fax your request to 202–233–9540, mail your request to the Commission on Risk Assessment and Risk Management, 529 14th Street, NW., Room 452, Washington, DC 20045, or obtain via the internet at http://www.riskworld.com. Be sure to indicate your complete mailing address and a phone number where you can be reached.

Comments on the draft report must be received no later than June 15. Please send you comments to the Commission address listed above.

If you need additional information, please call 202–233–9537. The report will not be available prior to April 24th.

Dated: February 27, 1996.

Gail Charnley,

Executive Director, Commission on Risk Assessment And Risk Management.

[FR Doc. 96–4955 Filed 3–1–95; 8:45 am]

BILLING CODE 6560–50–M

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Sunshine Act Meeting

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

DATE AND TIME: Tuesday, March 12, 1996—2:00 p.m.

PLACE: Conference Room on the Ninth Floor of the EEOC Office Building, 1801 ''L'' Street, N.W., Washington, D.C. 20507.

STATUS: The meeting will be open to the public.

MATTERS TO BE CONSIDERED:

1. Announcement of Notation Votes.
2. Panel Presentation by Invited Experts on Employment Discrimination Issues Affecting Americans with Disabilities.

Note: Any matter not discussed or concluded may be carried over to a later meeting. (In addition to publishing notices on EEOC Commission meetings in the Federal Register, the Commission also provides a recorded announcement a full week in advance on future Commission sessions.) Please telephone (202) 663–7100 (voice) and (202) 663–4074 (TTD) at any time for information on these meetings.

CONTACT PERSON FOR MORE INFORMATION: Frances M. Hart, Executive Officer on (202) 663–4070.

Dated: February 29, 1996.

Frances M. Hart,

Executive Officer, Executive Secretariat.

[FR Doc. 96–5140 Filed 2–29–96; 3:16 pm]

BILLING CODE 6750–06–M

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collections Being Reviewed by the Federal Communications Commission; Comments Requested

February 26, 1996.

SUMMARY: The Federal Communications, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commissions burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before May 3, 1996. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESS: Direct all comments to Dorothy Conway, Federal Communications, Room 234, 1919 M St., NW., Washington, DC 20554 or via internet to dconway@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Dorothy Conway at 202–418–0217 or via internet at dconway@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Number: 3060–0214.

Title: Section 73.3526 Local Public Inspection File of Commercial Stations.

Form Number: None.

Type of Review: Extension.

Respondents: Business or other for-profit.

Number of Respondents: 10,215 commecial radio licensees recordkeepers; 1181 commercial TV licensees recordkeepers; 1181 commercial TV stations making must-carry/retransmission consent elections.

Estimated time per response: 104 hours per year for radio recordkeeping; 130 hours per year for TV recordkeeping; 5 hours per election statement to 150 cable systems per TV station.

Total annual burden: 2,101,640 hours.

Needs and Uses: Section 73.3526 requires that each licensee/permittee of a commercial broadcast station maintain a file for public inspection. The contents of the file vary according to type of service and status. The contents include, but are not limited to, copies of certain applications tendered for filing, a statement concerning petitions to deny filed against such applications, copies of ownership reports and annual employment reports, statements certifying compliance with filing announcements in connection with renewal applications, letters received from members of the public, etc. The data are used by the public and FCC to evaluate information about the broadcast licensee's performance, to ensure that broadcast stations are addressing issues concerning the community to which it is licensed to serve and to ensure that radio stations entering into time brokerage agreements comply with Commission policies pertaining to licensee control and to the Communications Act and the antitrust laws. Broadcasters are required to send each cable operator in the station's market a copy of the election statement applicable to that particular cable operator. Placing these retransmission consent/must-carry elections in the public file provide public access to documentation of station's elections which are used by cable operators in negotiations with television stations and by the public to ascertain why some stations are/are not carried by the cable systems.

OMB Number: 3060–0245.

Title: Section 74.537 Temporary Authorizations.

Form Number: None.

Type of Review: Extension.

Respondents: Business or other for-profit.

Number of Respondents: 50.

Estimated time per response: 2 hours (this time is split 1hour 30 minutes burden for the licensee and 30 minutes cost for a communications attorney).

Total annual burden: 75 hours.

Needs and Uses: Section 74.537 requires licensees of an aural broadcast studio transmitter link (STL) or intercity relay station to file an informal request for special temporary authorization for operations of a temporary nature. The data is used by FCC staff to insure that the temporary operation of an STL or intercity relay station will not cause interference to existing stations.

OMB Number: 3060–0243.

Title: Section 74.551 Equipment Changes.

Form Number: None.

Type of Review: Extension.

Respondents: Business or other for-profit.

Number of Respondents: 25.

Estimated time per response: 1 hour (this hour is split between cost and burden, 30 minutes burden for the licensee and 30 minutes cost for a communications attorney).

Total annual burden: 13 hours.

Needs and Uses: Section 74.551(b) requires licensees of aural broadcast studio transmitter links (STL) or intercity relay stations to notify the Commission in writing of minor equipment changes that can be made without prior Commission authorization upon completion of such changes. The data is used by FCC staff to assure that the changes made comply with the rules and regulations.

OMB Number: 3060–0543.

Title: Section 21.913 Signal booster stations.

Form Number: None.

Type of Review: Reinstatement/revision.

Respondents: Business or other for-profit.

Number of Respondents: 300.

Estimated time per response: 2.5 hours per certification. This includes 0.5 hours for the licensee to convey its desire to install a low power booster station and 2 hours for a consulting engineer to prepare the certification.

Total annual burden: 150.

Needs and Uses: On 6/9/93, OMB approved the Amendment of Parts 1, 2

and 21 of the Commission's Rules Governing Use of the Frequencies in the 2.1 amd 2.5 GHz Bands. That approval contained various rule parts contained in Parts 21 and 74 of the Commission's Rules. Since that time, all rule sections incorporated into that approval have been reapproved under different OMB control numbers expect Section 21.913. Section 21.913(g) permits an MDS or ITFS licensee to install and commence operation of low power signal booster stations without a formal application. Licensees seeking to install a low power signal booster station must, however, submit a certification demonstrating compliance with the various components of Sections 21.913(g). This certification must be submitted within 48 hours of installation of the booster station. The data are used by FCC staff to verify that the licensee has complied with guidelines to use the certification process and that the booster would not cause objectionable interference.

OMB Number: 3060–0280.

Title: Section 90.633(f)&(g) Conventional systems loading requirement.

Form Number: None.

Type of Review: Extension.

Respondents: State or local government; Business or other for-profit; Not-for-profit institutions.

Number of Respondents: 15.

Estimated time per response: 1 hour.

Total annual burden: 15 hours.

Needs and Uses: Section 90.633(f)&(g) provides for the authorization of wide area or ribbon systems upon an appropriate showing of need. The information is used to determine if such systems should be authorized, thus maintaining spectrum efficiency.

OMB Number: 3060–0441.

Title: Section 90.621(b)(4) Selection and assignment of frequencies.

Form Number: None.

Type of Review: Extension.

Respondents: State or local government; Business or other for-profit; Not-for-profit institutions.

Number of Respondents: 33.

Estimated time per response: 1.5 hours.

Total annual burden: 25 hours.

Needs and Uses: Section 90.621(b) requires SMR applicants who wish to locate stations closer than required mileage separation from existing co-channel stations to file additional information and in some instances to request a waiver.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 96–4878 Filed 3–1–96; 8:45 am]

BILLING CODE 6712–01–F

Notice of Public Information Collections Being Reviewed by the Federal Communications Commission

February 28, 1996.

SUMMARY: The Federal Communications, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commissions burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before May 3, 1996. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESS: Direct all comments to Dorothy Conway, Federal Communications, Room 234, 1919 M St., NW., Washington, DC 20554 or via internet to dconway@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Dorothy Conway at 202–418–0217 or via internet at dconway@fcc.gov. Copies may also be obtained via fax by contacting the Commission's Fax on Demand System. To obtain fax copies call 202–418–0177 from the handset on your fax machine, and enter the document retrieval number indicated below for the collection you wish to request, when prompted.

SUPPLEMENTARY INFORMATION:

OMB Approval Number: 3060–0057.

Title: Application for Equipment Authorization, Section 2.911.

Form No.: FCC Form 731.

Type of Review: Extension of existing collection.

Respondents: Businesses or other for-profit; Small businesses or organizations.

Number of Respondents: 8,605.

Estimated Time Per Response: 24 hours.

Total Annual Burden: 206,520 hours.

Needs and Uses: Equipment testing is performed, and data is gathered, to provide information to aid in controlling interference to radio communications. A completed application combined with descriptive information, test data, and occasionally a test sample documents the compliance of the subject with the FCC Rules, and may also be use to aid in enforcement of the Rules.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 96–5042 Filed 3–1–96; 8:45 am]

BILLING CODE 6712–01–F

Sunshine Act Meeting; Deletion of Agenda Item From February 29th Open Meeting

The following item has been deleted from the list of agenda items scheduled for consideration at the February 29, 1996, Open Meeting and previously listed in the Commission's Notice of February 22, 1996.

Item No., Bureau, Subject

4—Common Carrier—Title: Federal-State Joint Board on Universal Service. Summary: Pursuant to the Telecommunica-tions Act of 1996, the Commission will consider referring the issue of the definition of ''universal service'' to the Federal State-Joint Board.

Dated February 28, 1996.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 96–5051 Filed 2–29–96; 1:12 pm]

BILLING CODE 6712–01–F

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

''FEDERAL REGISTER'' CITATION OF PREVIOUS ANNOUNCEMENT: 61 FR 7048–9, February 23, 1996.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10:00 a.m., Wednesday, February 28, 1996.

CHANGES IN THE MEETING: The open meeting has been canceled.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204.

Dated: February 29, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–5102 Filed 2–29–96; 1:12 pm]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Annual Update of the HHS Poverty Guidelines

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice provides an update of the HHS poverty guidelines to account for last (calendar) year's increase in prices as measured by the Consumer Price Index.

EFFECTIVE DATE: These guidelines go into effect on the day they are published (unless an office administering a program using the guidelines specifies a different effective date for that particular program).

ADDRESSES: Office of the Assistant Secretary for Planning and Evaluation, Room 438F, Humphrey Building, Department of Health and Human Services (HHS), Washington, D.C. 20201.

FOR FURTHER INFORMATION CONTACT: For information about how the poverty guidelines are used in a particular program, contact the Federal (or other) office which is responsible for that program.

For general information about the poverty guidelines (but not for information about how they are used in a particular program), contact Gordon Fisher, Office of the Assistant Secretary for Planning and Evaluation, Room 438F, Humphrey Building, Department of Health and Human Services, Washington, D.C. 20201—telephone: (202) 690–6141.

For information about the Hill-Burton Uncompensated Services Program (no-fee or reduced-fee health care services at certain hospitals and other health care facilities for certain persons unable to pay for such care), contact the Office of the Director, Division of Facilities Compliance and Recovery, HRSA, HHS, Room 7–31, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857—telephone: (301) 443–5656 or 1–800–638–0742 (for callers outside Maryland) or 1–800–492–0359 (for callers in Maryland). The Division of Facilities Compliance and Recovery notes that as set by 42 CFR 124.505(b), the effective date of this update of the poverty guidelines for facilities obligated under the Hill-Burton Uncompensated Services Program is sixty days from the date of this publication.

Under an amendment to the Older Americans Act, the figures in this notice are the figures that state and area agencies on aging should use to determine ''greatest economic need'' for Administration on Aging programs. *For information about Administration on Aging programs,* contact Donald Fowles, Administration on Aging, HHS—telephone: (202) 619–0011.

For information about the Department of Labor's Lower Living Standard Income Level (an alternative eligibility criterion with the poverty guidelines for certain Job Training Partnership Act programs), contact Josephine Nieves, Associate Assistant Secretary for Employment and Training, U.S. Department of Labor—telephone: (202) 219–6236.

For information about the number of persons in poverty or about the Census Bureau (statistical) poverty thresholds, contact Income, Poverty, and Labor Force Information Staff, U.S. Bureau of the Census—telephone: (301) 763–8578.

1996 Poverty Guidelines for the 48 Contiguous States and the District of Columbia

Size of family unit	Poverty guideline
1	$7,740
2	10,360
3	12,980
4	15,600
5	18,220
6	20,840
7	23,460
8	26,080

For family units with more than 8 members, add $2,620 for each additional member. (The same increment applies to smaller family sizes also, as can be seen in the figures above.)

1996 Poverty Guidelines for Alaska

Size of family unit	Poverty guideline
1	$9,660
2	12,940
3	16,220
4	19,500
5	22,780
6	26,060
7	29,340
8	32,620

For family units with more than 8 members, add $3,280 for each additional member. (The same increment applies to smaller family sizes also, as can be seen in the figures above.)

1996 Poverty Guidelines for Hawaii

Size of family unit	Poverty guideline
1	$8,910
2	11,920
3	14,930
4	17,940
5	20,950
6	23,960
7	26,970
8	29,980

For family units with more than 8 members, add $3,010 for each additional member. (The same increment applies to smaller family sizes also, as can be seen in the figures above.)

The preceding figures are the 1996 update of the poverty guidelines required by sections 652 and 673(2) of the Omnibus Budget Reconciliation Act (OBRA) of 1981 (Pub.L. 97–35). As required by law, this update reflects last year's change in the Consumer Price Index (CPI-U); it was done using the same procedure used in previous years.

Section 673(2) of OBRA–1981 (42 U.S.C. 9902(2)) requires the use of the poverty guidelines as an eligibility criterion for the Community Services Block Grant program, while section 652 (42 U.S.C. 9847) requires the use of the poverty guidelines as an eligibility criterion for the Head Start program. The poverty guidelines are also used as an eligibility criterion by a number of other Federal programs (both HHS and non-HHS). When such programs give an OBRA–1981 citation for the poverty guidelines, they cite section 673(2). Due to confusing legislative language dating back to 1972, the poverty guidelines have sometimes been mistakenly referred to as the ''OMB'' (Office of Management and Budget) poverty guidelines or poverty line. In fact, OMB has never issued the guidelines; the guidelines are issued each year by the Department of Health and Human Services (formerly by the Office of Economic Opportunity/Community Services Administration). The poverty guidelines may be formally referenced as ''the poverty guidelines updated annually in the Federal Register by the U.S. Department of Health and Human Services under authority of section 673(2) of the Omnibus Budget Reconciliation Act of 1981.''

The poverty guidelines are a simplified version of the Federal Government's statistical poverty thresholds used by the Bureau of the Census to prepare its statistical estimates of the number of persons and families in poverty. The poverty guidelines issued by the Department of Health and Human Services are used for administrative purposes—for instance, for determining whether a person or family is financially eligible for assistance or services under a particular Federal program. The poverty thresholds are used primarily for statistical purposes. Since the poverty guidelines in this notice—the 1996 guidelines—reflect price changes through calendar year 1995, they are approximately equal to the poverty thresholds for calendar year 1995 which the Census Bureau will issue in late summer or autumn 1996. (A preliminary version of the 1995 thresholds is now available from the Census Bureau.)

In certain cases, as noted in the relevant authorizing legislation or program regulations, a program uses the poverty guidelines as only one of several eligibility criteria, or uses a percentage multiple of the guidelines (for example, 130 percent or 185 percent of the guidelines). Some other programs, while not using the guidelines to exclude non-lower-income persons as ineligible, use them for the purpose of giving priority to lower-income persons or families in the provision of assistance or services.

In some cases, these poverty guidelines may not become effective for a particular program until a regulation or notice specifically applying to the program in question has been issued.

The poverty guidelines given above should be used for both farm and nonfarm families. Similarly, these guidelines should be used for both aged and non-aged units. The poverty guidelines have never had an aged/non-aged distinction; only the Census Bureau (statistical) poverty thresholds have separate figures for aged and non-aged one-person and two-person units.

Definitions

There is no universal administrative definition of ''income,'' ''family,'' ''family unit,'' or ''household'' that is valid for all programs that use the poverty guidelines. Federal programs may use administrative definitions that differ somewhat from the statistical definitions given below; the Federal office which administers a program has the responsibility for making decisions about administrative definitions. Similarly, non-Federal organizations which use the poverty guidelines in non-Federally-funded activities may use administrative definitions that differ from the statistical definitions given below. In either case, to find out the precise definitions used by a particular program, one must consult the office or organization administering the program in question. The following statistical definitions (derived for the most part from language used in U.S. Bureau of the Census, Current Population Reports, Series P60–188 and earlier reports in the same series) are made available for illustrative purposes only.

(a) *Family.* A family is a group of two or more persons related by birth, marriage, or adoption who live together; all such related persons are considered as members of one family. For instance, if an older married couple, their daughter and her husband and two children, and the older couple's nephew all lived in the same house or apartment, they would all be considered members of a single family.

(b) *Unrelated individual.* An unrelated individual is a person 15 years old or over (other than an inmate of an institution) who is not living with any relatives. An unrelated individual may be the only person living in a house or apartment, or may be living in a house or apartment (or in group quarters such as a rooming house) in which one or more persons also live who are not related to the individual in question by birth, marriage, or adoption. Examples of unrelated individuals residing with others include a lodger, a foster child, a ward, or an employee.

(c) *Household.* As defined by the Bureau of the Census for statistical purposes, a household consists of all the persons who occupy a housing unit (house or apartment), whether they are related to each other or not. If a family and an unrelated individual, or two unrelated individuals, are living in the same housing unit, they would constitute two family units (see next item), but only one household. Some programs, such as the food stamp program and the Low-Income Home Energy Assistance Program, employ administrative variations of the ''household'' concept in determining income eligibility. A number of other programs use administrative variations of the ''family'' concept in determining income eligibility. Depending on the precise program definition used, programs using a ''family'' concept would generally apply the poverty guidelines separately to each family and/or unrelated individual within a household if the household includes more than one family and/or unrelated individual.

(d) *Family unit.* ''Family unit'' is not an official U.S. Bureau of the Census term, although it has been used in the poverty guidelines Federal Register notice since 1978. As used here, either an unrelated individual or a family (as defined above) constitutes a family unit. In other words, a family unit of size one is an unrelated individual, while a family unit of two/three/etc. is the same as a family of two/three/etc.

(e) *Income.* Programs which use the poverty guidelines in determining eligibility may use administrative definitions of ''income'' (or ''countable income'') which differ from the statistical definition given below. Note that for administrative purposes, in many cases, income data for a part of a year may be annualized in order to determine eligibility—for instance, by multiplying by four the amount of income received during the most recent three months.

For statistical purposes—to determine official income and poverty statistics—the Bureau of the Census defines income to include total annual cash receipts before taxes from all sources, with the exceptions noted below. Income includes money wages and salaries before any deductions; net receipts from nonfarm self-employment (receipts from a person's own unincorporated business, professional enterprise, or partnership, after deductions for business expenses); net receipts from farm self-employment (receipts from a farm which one operates as an owner, renter, or sharecropper, after deductions for farm operating expenses); regular payments from social security, railroad retirement, unemployment compensation, strike benefits from union funds, workers' compensation, veterans' payments, public assistance (including Aid to Families with Dependent Children, Supplemental Security Income, Emergency Assistance money payments, and non-Federally-funded General Assistance or General Relief money payments), and training stipends; alimony, child support, and military family allotments or other regular support from an absent family member or someone not living in the household; private pensions, government employee pensions (including military retirement pay), and regular insurance or annuity payments; college or university scholarships, grants, fellowships, and assistantships; and dividends, interest, net rental income, net royalties, periodic receipts from estates or trusts, and net gambling or lottery winnings.

For official statistical purposes, income does not include the following types of money received: Capital gains;

any assets drawn down as withdrawals from a bank, the sale of property, a house, or a car; or tax refunds, gifts, loans, lump-sum inheritances, one-time insurance payments, or compensation for injury. Also excluded are noncash benefits, such as the employer-paid or union-paid portion of health insurance or other employee fringe benefits, food or housing received in lieu of wages, the value of food and fuel produced and consumed on farms, the imputed value of rent from owner-occupied nonfarm or farm housing, and such Federal noncash benefit programs as Medicare, Medicaid, food stamps, school lunches, and housing assistance.

Dated: February 27, 1996.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 96–4915 Filed 2–29–96; 10:52 am]

BILLING CODE 4150–04–P

Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Aid to Families With Dependent Children, Medicaid, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 1996 Through September 30, 1997

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: The Federal Percentages and Federal Medical Assistance Percentages for Fiscal Year 1997 have been calculated pursuant to the Social Security Act (the Act). These percentages will be effective from October 1, 1996 through September 30, 1997. This notice announces the calculated ''Federal percentages'' and ''Federal medical assistance percentages'' that we will use in determining the amount of Federal matching in State welfare and medical expenditures. The table gives figures for each of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands. Programs under title XIX of the Act exist in each jurisdiction; title IV–A programs exist in all jurisdictions except American Samoa and the Northern Mariana Islands; programs under titles I, X, and XIV operate only in Guam and the Virgin Islands; while a program under title XVI (AABD) operates only in Puerto Rico. The percentages in this notice apply to State expenditures for assistance payments and medical services (except family planning which is subject to a higher matching rate). The statute provides separately for Federal matching of administrative costs.

Sections 1101(a)(8) and 1905(b) of the Act, as revised by section 9528 of Public Law 99–272, require the Secretary of Health and Human Services to publish these percentages each year. The Secretary is to figure the percentages, by formulas in sections 1101(a)(8) and 1905(b) of the Act, from the Department of Commerce's statistics of average income per person in each State and in the National as a whole. The percentages are within upper and lower limits given in those two sections of the Act. The statute specifies the percentages to be applied to Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

The ''Federal percentages'' are for Aid to Families with Dependent Children (AFDC) and aid to needy aged, blind, or disabled persons, and the ''Federal medical assistance percentages'' are for Medicaid. However, under section 1118 of the Act, States with approved Medicaid plans may claim Federal matching funds for expenditures under approved State plans for these other programs using either the Federal percentage or the Federal medical assistance percentage. These States may claim at the Federal medical assistance percentage without regard to any maximum on the dollar amounts per recipient which may be counted under paragraphs (1) and (2) of sections 3(a), 403(a), 1003(a), 1403(a), and 1603(a) of the Act.

DATES: The percentages listed will be effective for each of the 4 quarter-year periods in the period beginning October 1, 1996 and ending September 30, 1997.

FOR FURTHER INFORMATION CONTACT:

Mr. Gene Moyer, Office of Health Policy, Office of the Assistant Secretary for Planning and Evaluation, Room 442E Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, D.C. 20201, Telephone (202) 690–7861.

(Catalog of Federal Domestic Assistance Program Nos. 93.560—Assistance Payments—Maintenance Assistance (State Aid); 93.778—Medicaid Assistance Program)

Dated: February 26, 1996.

Donna Shalala,

Secretary of Health and Human Services.

Federal Percentages and Federal Medical Assistance Percentages, Effective October 1, 1996–September 30, 1997 (Fiscal Year 1997)

State	Federal percentages	Federal medical assistance percentages
Alabama	65.00	69.54
Alaska	50.00	50.00
American Samoa	50.00	*50.00
Arizona	61.70	65.53
Arkansas	65.00	73.29
California	50.00	50.23
Colorado	50.00	52.32
Connecticut	50.00	50.00
Delaware	50.00	50.00
District of Columbia	50.00	50.00
Florida	50.88	55.79
Georgia	57.24	61.52
Guam	50.00	*50.00
Hawaii	50.00	50.00
Idaho	64.41	67.97
Illinois	50.00	50.00
Indiana	57.31	61.58
Iowa	58.83	62.94
Kansas	54.30	58.87
Kentucky	65.00	70.09
Louisiana	65.00	71.36
Maine	59.69	63.72
Maryland	50.00	50.00
Massachusetts	50.00	50.00
Michigan	50.22	55.20
Minnesota	50.00	53.60
Mississippi	65.00	77.22
Missouri	55.60	60.04
Montana	65.00	69.01
Nebraska	54.59	59.13
Nevada	50.00	50.00
New Hampshire	50.00	50.00
New Jersey	50.00	50.00
New Mexico	65.00	72.66
New York	50.00	50.00
North Carolina	59.88	63.89
North Dakota	64.14	67.73
Northern Mariana Islands	50.00	*50.00
Ohio	54.76	59.28
Oklahoma	65.00	70.01
Oregon	56.14	60.52
Pennsylvania	50.00	52.85
Puerto Rico	50.00	*50.00
Rhode Island	50.00	53.90
South Carolina	65.00	70.43
South Dakota	60.99	64.89
Tennessee	60.64	64.58
Texas	58.40	62.56
Utah	65.00	72.33
Vermont	56.72	61.05
Virgin Islands	50.00	*50.00
Virginia	50.00	51.45
Washington	50.00	50.52
West Virginia	65.00	72.60
Wisconsin	54.44	59.00

FEDERAL PERCENTAGES AND FEDERAL MEDICAL ASSISTANCE PERCENTAGES, EFFECTIVE OCTOBER 1, 1996–SEPTEMBER 30, 1997 (FISCAL YEAR 1997)—Continued

State	Federal percentages	Federal medical assistance percentages
Wyoming	55.42	59.88

*For purposes of section 1118 of the Social Security Act, the percentage used under titles I, X, XIV, and XVI and Part A of title IV will be 75 per centum.

[FR Doc. 96–4870 Filed 3–1–96; 8:45 am]

BILLING CODE 4110–60–M

Food and Drug Administration

[Docket No. 96N–0049]

Drug Export; Abbott MATRIX HCV 2.0

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Abbott Laboratories has filed an application requesting approval for the export of the human biological product Abbott MATRIX HCV 2.0 to Australia, New Zealand, and to The Federal Republic of Germany solely for the purpose of further export to Austria, Belgium, Denmark, Finland, Iceland, Ireland, Italy, The Netherlands, Norway, Portugal, Spain, Sweden, and The United Kingdom.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human biological products under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Cathy E. Conn, Center for Biologics Evaluation and Research (HFM–610), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–2006.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of human biological products that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the Federal Register within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Abbott Laboratories, One Abbot Park Rd., Abbott Park, IL 60064, has filed an application requesting approval for the export of the human biological product Abbott MATRIX HCV 2.0 to Australia, New Zealand, and to The Federal Republic of Germany solely for the purpose of further export to Austria, Belgium, Denmark, Finland, Iceland, Ireland, Italy, The Netherlands, Norway, Portugal, Spain, Sweden, and The United Kingdom. The Abbott MATRIX HCV 2.0 is an in vitro immunodot assay which has been developed to qualitatively detect antibodies to putative structural and nonstructural proteins expressed from the HCV genome in human serum or plasma. The application was received and filed in the Center for Biologics Evaluation and Research on January 24, 1996, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by March 14, 1996, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Biologics Evaluation and Research (21 CFR 5.44).

Dated: January 26, 1996.

James C. Simmons,

Director, Office of Compliance, Center for Biologics Evaluation and Research.

[FR Doc. 96–4859 Filed 3–1–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0064]

Drug Export; Acellular Pertussis Toxoid Adsorbed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that AMVAX, Inc., has filed an application requesting approval for the export of the human biological product Acellular Pertussis Toxoid Adsorbed to Denmark for further shipment to Sweden.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human biological products under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Cathy E. Conn, Center for Biologics Evaluation and Research (HFM–610), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–2006.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of human biological products that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the Federal Register within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that AMVAX, Inc., 12103 Indian Creek Ct., Beltsville, MD 20705, has filed an application requesting approval for the export of the human biological

product Acellular Pertussis Toxoid Adsorbed to Denmark for further shipment to Sweden. The Pertussis component is an acellular monocomponent vaccine containing inactivated pertussis toxin. The application was received and filed in the Center for Biologics Evaluation and Research on February 8, 1996, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by March 14, 1996, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Biologics Evaluation and Research (21 CFR 5.44).

Dated: February 16, 1996.

James C. Simmons,

Director, Office of Compliance, Center for Biologics Evaluation and Research.

[FR Doc. 96–4978 Filed 3–1–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96F–0062]

Cytec Industries Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Cytec Industries Inc. has filed a petition proposing that the food additive regulations be amended to correct nomenclature. The amendment would change the two listings for sulfosuccinic acid 4-ester with polyethylene glycol dodecyl ether, disodium salt (CAS Reg. No. 39354–45–5) to polyethyleneglycol alkyl (C10–C12) ether sulfosuccinate, disodium salt (CAS Reg. No. 68954–91–6).

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–606–0202.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (Sec. 409(b)(5) (21 U.S.C. 348(b)(5)), notice is given that a food additive petition (FAP 6B4485) has been filed by Cytec Industries Inc., c/o Keller and Heckman, 1001 G St., NW., suite 500 West, Washington, DC 20001. The petition proposes that the food additive regulations in § § 175.105 Adhesives (21 CFR 175.105) and 178.3400 Emulsifiers and/or surface-active agents (21 CFR 178.3400) be amended to correct nomenclature. The amendment would change the two listings for sulfosuccinic acid 4-ester with polyethylene glycol dodecyl ether, disodium salt (CAS Reg. No. 39354–45–5) to use the nomenclature polyethyleneglycol alkyl (C10–C12) ether sulfosuccinate, disodium salt (CAS Reg. No. 68954–91–6)The agency has determined under 21 CFR 25.24(a)(9) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: February 9, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–4976 Filed 3–1–96; 8:45 am]

BILLING CODE 4160–01–F

Product and Establishment License Applications, Refusal to File; Meeting of Oversight Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting of its standing oversight committee in the Center for Biologics Evaluation and Research (CBER) that conducts a periodic review of CBER's use of its refusal to file (RTF) practices on product license applications (PLA's) and establishment license applications (ELA's). CBER's RTF oversight committee examines all RTF decisions that occurred during the previous quarter to assess consistency across CBER offices and divisions in RTF decisions.

DATES: The meeting will be held in April 1996.

FOR FURTHER INFORMATION CONTACT: Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM–4), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0379.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 15, 1995 (60 FR 25920), FDA announced the establishment and first meeting of CBER's standing oversight committee. As explained in the notice, the importance to the public health of getting new biological products on the market as efficiently as possible has made improving the biological product evaluation process an FDA priority. CBER's managed review process focuses on specific milestones or intermediate goals to ensure that a quality review is conducted within a specified time period. CBER's RTF oversight committee meetings continue CBER's effort to promote the timely, efficient, and consistent review of PLA's and ELA's.

FDA regulations on filing PLA's and ELA's are found in 21 CFR 601.2(a) and 601.3. A sponsor who receives an RTF notification may request an informal conference with CBER, and thereafter may ask that the application be filed over protest, similar to the procedure for drugs described under 21 CFR 314.101(a)(3) (see 57 FR 17950, April 28, 1992).

CBER's standing RTF oversight committee consists of senior CBER officials, a senior official from FDA's Center for Drug Evaluation and Research, and FDA's Chief Mediator and Ombudsman. Meetings, ordinarily, will be held once a quarter to review all of the RTF decisions. The purpose of such a review is to assess the consistency within CBER in rendering RTF decisions.

Because the committee's deliberations will deal with confidential commercial information, all meetings will be closed to the public. The committee's deliberations will be reported in the minutes of the meeting. Although those minutes will not be publicly available because they will contain confidential commercial information, summaries of the committee's deliberations, with all confidential commercial information omitted, may be requested in writing 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. If, following the committee's review, an RTF decision changes, the appropriate division will notify the sponsor.

Dated: February 27, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–4913 Filed 3–1–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0409]

Alternative and Traditional Models for Safety Evaluation of Food Ingredients; Announcement of Study; Request for Scientific Data and Information; Announcement of Open Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB) will undertake a comprehensive discussion of the scientific criteria and principles generally agreed upon by scientists in the food safety community as necessary for demonstrating that a food ingredient is safe. This discussion will include both a description of the data needed to ensure safety or to achieve a reasonable certainty that the ingredient will not cause harm and alternative approaches for achieving that assurance when traditional approaches do not definitively resolve safety questions.

To assist in the preparation of a scientific report, LSRO/FASEB is inviting the submission of scientific data and information regarding this topic. LSRO/FASEB will provide an opportunity for oral presentations at an open meeting.

DATES: LSRO/FASEB has scheduled a 1-day public meeting on this topic for May 15, 1996. Requests to make oral presentations at the open meeting must be submitted in writing and received by April 24, 1996. Submit written presentations of scientific data, information, and views on or before May 10, 1996.

ADDRESSES: Submit written requests to make oral presentations at the open meeting to both the Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20814–3998 and to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of the scientific data, information, and views for presentation should be submitted to each office. The meeting will be held in the Chen Auditorium, Lee Bldg., FASEB (address above).

FOR FURTHER INFORMATION CONTACT: Daniel J. Raiten or Sue Ann Anderson, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20814–3998, 301–530–7030, on the scheduling of presentations at the public meeting and related matters. Other information may be obtained from Victor Frattali, Center for Food Safety and Applied Nutrition (HFS–2), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–1730.

SUPPLEMENTARY INFORMATION: FDA has a contract (223–92–2185) with LSRO/FASEB concerning the analysis of scientific issues that bear on the safety of foods and cosmetics. The objectives of this contract are to provide information to FDA on general and specific issues of scientific fact associated with the analysis of human nutrition.

As one task under the contract, FDA has requested information on matters related to the adequacy of data needed to support decisions on the safety of food ingredients. Currently, FDA provides safety testing guidelines for food ingredients through a publication entitled ''Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food'' (also known as the ''Redbook''). This document gives guidance to petitioners primarily for those situations in which a traditional approach to safety testing is appropriate (i.e., those in which food additives to be used in low concentrations are tested for safety).

However, traditional studies involving administration of substances constituting a large part of an animal's diet may produce adverse effects simply as a result of the unusual diet rather than the inherent toxicity of the test substance. Further, FDA recognizes that the advent of new technologies such as genetic engineering of traditional foods and novel uses of plant products, as well as development of macroingredients, present new situations for which an alternative approach to safety assessment may be needed. While FDA has successfully reached decisions on food ingredients produced with such new technologies on a case-by-case basis, it has become clear that a need exists for information on the criteria that the scientific community believes are appropriate so that both a requirement for new types of safety studies and any elimination or limitation of the role of traditional studies can be justified. Types of food ingredients for which an alternative model may be appropriate include, for example, macroingredient substitutes such as psyllium, ingredients derived from botanicals such as *Stevia rebaudiana Bertoni*, restructured fats such as caprenin, and ingredients derived using biotechnology.

Based on an evolving need to be responsive to the development of food ingredients resulting from new technologies, FDA wishes to have LSRO/FASEB prepare a comprehensive report on the principles and criteria generally agreed upon by the community of food safety experts for determining when the traditional safety model is appropriate. The agency is also interested in a discussion identifying the principles and criteria to be used to determine the safety of a food ingredient when the traditional safety model is not appropriate. FDA is especially interested in a discussion of how different principles and criteria should be ranked and weighted, interrelationships that should be considered, and any situation where a principle or criterion might be considered determinative without regard to other considerations. It would also be desirable to have a discussion about how the new testing approaches may substitute for more traditional testing.

In framing this discussion, FDA has suggested that the following questions be considered. These questions are not intended as a statement of specific tasks. They are intended to be illustrative and to be used as a basis for stimulating thinking regarding the determination of the safe use of food ingredients.

1. In what cases, if any, are animal feeding studies not necessary to ensure safety? For example: Do such studies need to be conducted for ingredients that also occur naturally in foods at similar or higher concentrations? Is it reasonable and necessary to test food-like substances for toxicity and nutritional influences recognizing the potential for confounding results? If so, how?

2. To what extent can chemical and structural similarity to food ingredients known to be safe obviate the need for animal or human testing?

3. What criteria should be used to determine when a treatment-related effect (including effects from nutritional imbalance or interference) is an adverse effect?

4. Are there criteria that can be used to determine whether an adverse effect observed in a study is relevant to human safety as opposed to an effect that is dependent on study design and has no

relevance to safety under actual use conditions?

5. Under what circumstances should clinical studies in humans supplement or replace studies in laboratory animals? How will use of human data affect the need for safety factors? Which parameters should be measured and what study duration is necessary?

6. Is there an agreed-upon basis for determining the maximum level of an additive to be administered in a test diet above which a study should be presumed unacceptable?

7. Can postmarketing surveillance (such as monitoring of use or monitoring of adverse reaction reports by consumers and physicians) be used to ensure safety? For example, can such surveillance be used without compromising safety to verify exposure estimates or to eliminate the need for specific data prior to marketing, thus reducing the need to use worst-case assumptions in a safety evaluation? If so, how could this be accomplished?

The objective of this review is to make recommendations on the set of circumstances under which the scientific community believes that the use of a safety model that is an alternative to the traditional safety model is justified and will ensure the safety of food ingredients. Such discussions would include: (1) Circumstances prompting the need for new types of studies, (2) circumstances in which traditional studies should not be required or should be modified or their use limited, and (3) the appropriate use of safety factors. FDA also requests a description of the principles and criteria that would be used in the nontraditional or alternative situations and a ranking/weighting of these criteria and principles.

The project is divided into two phases. In the first phase, LSRO/FASEB will solicit input from 40 to 60 members of the food safety community. The nature of this input from each individual will be in the form of a 3- to 5-page ''white paper'' which will contain expert opinion on issues related to food ingredient safety evaluations. Individuals will be asked to furnish sufficient background material with their white papers to provide a basis for comment on the issues being addressed by LSRO/FASEB in this contract.

A Phase I Expert Panel composed of five members will be convened by LSRO/FASEB. LSRO/FASEB staff will assemble a background document for the Phase I Expert Panel that consists of a compilation of the previously obtained comments from the scientific community. This background document is intended to provide a perspective for the Phase I Expert Panel in its deliberations; it will not be a preliminary draft of the report to be delivered to FDA in fulfillment of the scope of work for the contract task. Upon approval by the Phase I Expert Panel, the background document will be available on or before April 12, 1996, from LSRO/FASEB (address above). The background document will be on display at LSRO/FASEB and the Dockets Management Branch (addresses above).

In Phase II, the Expert Panel will be expanded to eight members. The Phase II Expert Panel will conduct a comprehensive discussion of the principles and criteria generally agreed upon by the community of food safety experts for determining when the traditional safety model is appropriate. More specifically, based on the deliberations of the Phase II Expert Panel, LSRO/FASEB will organize the scientific concepts of food ingredient safety to yield a set of criteria in a report that the agency could then consider in evaluating the safety of food ingredients. Additionally, based on the discussions of the Phase II Expert Panel, the report will identify a ranking and weighting of such considerations that the scientific community would agree could be used to evaluate whether a new or modified food ingredient should be considered safe.

FDA and LSRO/FASEB are announcing that LSRO/FASEB will hold a public meeting on this topic on May 15, 1996. It is anticipated that the meeting will last 1 day, depending on the number of requests to make oral presentations. Requests to make oral presentations at the open meeting must be submitted in writing and received by April 24, 1996. Participants will be required to submit two copies of the written text of oral presentations of scientific data, information, and views on or before May 10, 1996, to LSRO/FASEB (address above) and two copies to the Dockets Management Branch (address above). The meeting will be held in the Chen Auditorium, Lee Bldg., FASEB (address above).

For individuals not wishing to make an oral presentation, FDA and LSRO/FASEB are also inviting submission in writing of scientific data, information, and views. Two copies of these materials must be submitted on or before May 10, 1996, to both LSRO/FASEB and the Dockets Management Branch (addresses above).

Pursuant to its contract with FDA, LSRO/FASEB will provide the agency with a scientific report on the Phase II review and discussions on or about July 31, 1997.

Dated: February 26, 1996.

William K. Hubbard,

Associate Commissioner for Policy.

[FR Doc. 96–4858 Filed 3–1–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Emergency Medical Services for Children Demonstration Grants

AGENCY: Health Resources and Services Administration HHS.

ACTION: Notice of availability of funds.

SUMMARY: The HRSA in collaboration with the National Highway Traffic Safety Administration (NHTSA) announces that applications will be accepted for fiscal year (FY) 1996 funds for grants authorized under section 1910 of the PHS Act. These discretionary grants will be made to States or accredited schools of medicine to support projects for the expansion and improvement of emergency medical services for children (EMSC). Within the HRSA, EMSC grants are administered by the Maternal and Child Health Bureau (MCHB).

This program announcement is subject to the appropriation of funds. Applicants are advised that this program announcement is a contingency action being taken to assure that should funds become available for this purpose, they can be awarded in a timely fashion consistent with the needs of the program as well as to provide for even distribution of funds throughout the fiscal year. At this time, given a continuing resolution and the absence of FY 1996 appropriations for the EMSC program, the amount of available funding for this specific grant program cannot be estimated.

The NHTSA participated with the MCHB in developing program priorities for the EMSC program for FY 1996. The NHTSA will share the Federal monitoring responsibilities for EMSC awards made during FY 1996 and will continue to provide ongoing technical assistance and consultation in regard to the required collaboration/linkages between applicants and their Highway Safety Offices and Emergency Medical Services Agencies for the State(s). Grantees funded under this program are expected to work collaboratively with the State agency or agencies administering the Maternal and Child Health (MCH) and the Children with Special Health Needs (CSHN) programs under the MCH Services Block Grant, Title V of the Social Security Act (42 U.S.C. 701).

The PHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS led national activity for setting priority areas. The EMSC grant program will directly address the Healthy People 2000 objectives related to emergency medical services and trauma systems linking prehospital, hospital, and rehabilitation services in order to prevent trauma deaths and long-term disability. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report: Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402–9325 (telephone, (202) 783–3238).

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

ADDRESSES: Grant applications for Emergency Medical Services for Children Demonstration Grants (Revised PHS form #5161–1, approved under OMB #0937–0189) must be obtained from and submitted to: Grants Management Branch, Maternal and Child Health Bureau, HRSA, Room 18–12, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Attn: EMSC, telephone 301–443–1440. You must obtain application materials in the mail.

Federal Register notices and application guidance for MCHB programs are available on the World Wide Web via the Internet at address: http://www.os.dhhs.gov/hrsa/mchb. Click on the file name you want to download to your computer. It will be saved as a self-extracting (Macintosh or) Wordperfect 5.1 file. To decompress the file once it is downloaded, type in the file name followed by a <return>. The file will expand to a Wordperfect 5.1 file. If you have difficulty accessing the MCHB Home Page via the Internet and need technical assistance, please contact Linda L. Schneider at 301–443–0767 or ''lschneider@hrsa.ssw.dhhs.gov''.

DATES: The application deadline date is April 26, 1996. Competing applications will be considered to be on time if they are either received on or before the deadline date or postmarked on or before the deadline date and received in time for orderly processing. Applicants should request a legibly dated receipt from a commercial carrier or the U.S. Postal Service, or obtain a legibly dated U.S. Postal Service postmark. Private metered postmarks will not be accepted as proof of timely mailing.

Late competing applications or those sent to an address other than specified in the **ADDRESSES** section will be returned to the applicant.

FOR FURTHER INFORMATION CONTACT: Requests for technical or programmatic information from MCHB should be directed to Jean Athey, Ph.D., or Mark E. Nehring, D.M.D., M.P.H., Division of Maternal, Infant, Child and Adolescent Health, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–39, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443–4026. Requests for technical or programmatic information from NHTSA should be directed to Garry Criddle, R.N., CDR, USCG/USPHS, Department of Transportation, NHTSA EMS Division, NTS–42, 400 Seventh Street SW., Washington, DC 20590, telephone (202) 366–5440. Requests for information concerning business management issues should be directed to: Maria Carter, Grants Management Specialist, Grants Management Branch, Maternal and Child Health Bureau, at the address listed in the ADDRESS section above.

The EMSC program funds three national EMSC resource centers that are available to provide technical assistance and support to applicants, particularly in the areas of: (1) understanding EMSC terminology; (2) developing a manageable approach to EMSC implementation; (3) obtaining local support for the grant application process; (4) facilitating development of community linkages for a collaborative effort; (5) identifying products of previously-funded EMSC projects of interest to potential applicants; (6) offering advice on grant writing; and (7) data collection and analysis. Applicants may contact: James Seidel, M.D., Ph.D., or Deborah Henderson, R.N., M.A., National EMSC Resource Alliance, Research and Education Institute, Harbor/UCLA Medical Center, 1001 West Carson Street, Suite S, Torrance, CA 90502, telephone 310 328–0720; or Jane Ball, R.N., Dr. P.H., EMSC National Resource Center, Children's National Medical Center, Emergency Trauma Services, 111 Michigan Ave., N.W., Washington, DC 20010, telephone 202 745–5188; or J. Michael Dean, M.D., National EMSC Data Analysis Resource Center, University of Utah School of Medicine, 309 Park Building, Salt Lake City, UT 84112, telephone (801) 588–2360.

SUPPLEMENTARY INFORMATION:

Program Background and Objectives

The Emergency Medical Services for Children statute (Section 1910 of the PHS Act, as amended) establishes a program of two-year grants to States, through a State-designated agency, or to accredited medical schools within States, for projects for the expansion and improvement of emergency medical services for children who need treatment for trauma or critical illness. For purposes of this grant program, the term ''State'' includes the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Northern Mariana Islands, Guam, American Samoa, the Republic of Palau, the Republic of the Marshall Islands, and the Federated States of Micronesia. The term ''school of medicine'' is defined as having the same meaning as set forth in Section 799(1)(A) of the PHS Act (42 U.S.C. 295p(1)(A)). ''Accredited'' in this context has the same meaning as set forth in section 799(1)(E) of the PHS Act (42 U.S.C. 295p(1)(E)). It is the intent of this grant program to stimulate further development or expansion of ongoing efforts in the States to reduce the problems of life-threatening pediatric trauma and critical illness. The Department does not intend to award grants which would duplicate grants previously funded under the Emergency Medical Services Systems Act of 1972 or which would be used simply to increase the availability of emergency medical services funds allotted to the State under the Preventive Health Services Block Grant.

Funding Categories

There will be three categories of competition for funding this year: State planning grants, State systems grants, and targeted issue grants. States may apply for only one of the first two categories, but are not restricted in applying for the last category.

Category (1): State Planning Grants

Planning grants are intended for States that have never received an EMSC grant and that are not at a stage of readiness to initiate a full-scale implementation project. States (or medical schools within those States) that have not received prior EMSC implementation grants are the only applicants eligible for this category. Planning grants are designed to enable a State to assess needs and develop a strategy to begin to address those needs.

Funds may be used to hire staff to assist in the assessment of EMSC needs of the State; obtain technical assistance from national, State, regional or local resources; help formulate a State plan for the integration of EMSC services into the existing State EMS plan; and plan a more comprehensive grant proposal based upon a needs assessment performed during the planning grant project period. A comprehensive approach, addressing physical, psychological, and social aspects of EMSC along the continuum of care, should be reflected. An ongoing working relationship with Federal EMSC program staff and resource center staff, beginning with the initiation of a planning grant application, is desirable. The project period is for one year only.

Category (2): State Systems Grants

This category of grants has two subcategories: implementation grants and system enhancement grants. For both subcategories, proposals are sought which include strategies and/or models to ensure that pediatric emergency care is family centered. ''Family centered'' includes the following key elements: maximum possible involvement of families in all phases of the EMSC continuum of care; clear and continuous communication between family members and the emergency care team; attention to the psychological needs of all family members; cultural competence of providers; consumer (parental) involvement in planning and needs assessment; organizational support for the formation of parent involvement groups; and ongoing partnerships with such groups.

Applications will not be accepted for both planning grants and state systems grants simultaneously from the same State.

Subcategory (A): Implementation Grants

Implementation grants will improve the capacity of a State's Emergency Medical Services program to address the particular needs of children. Implementation grants are used to assist States in integrating research-based knowledge and state-of-the-art systems development approaches into the existing State EMS, MCH and CSHN systems, using the experience and products of previous EMSC grantees. The program components of these grants should reflect the goals of the MCHB/NHTSA Five Year Plan for EMSC. This plan outlines the direction of the EMSC program and identifies specific objectives for the program. It builds on the 1993 report for EMSC conducted by a blue ribbon Institute of Medicine panel. The plan will be included with the application kit. Depending upon the appropriation of funds, project periods are up to two years. For this competition, we intend to fund applications from States (and medical schools within those States) that have not as yet received support, or that have received only partial support under this program as part of a regional alliance. This means that approved applications from States (and medical schools within those States) with no or very limited prior EMSC program support will be funded before approved applications from outside this group.

Subcategory (B): System Enhancement Grants

System enhancement grants will fund activities that represent the next logical step or steps to take in institutionalizing EMSC activities within the State EMS, MCH and CSHN systems and achieving program goals outlined in this announcement. The program components of these grants should reflect the goals and objectives of the MCHB/NHTSA Five Year Plan for EMSC. For example, funding might be used to improve linkages between local and regional or State agencies, to develop pediatric standards for a region, or to assure effective field triage of the child in physical or emotional crisis to appropriate facilities and/or other resources. Activities implemented under prior EMSC program funding but not completed or made self-sustaining during the original implementation project period will not be considered suitable. States that have previously received EMSC funds may apply for a system enhancement grant, as long as they will not also be receiving continuation funding for a State implementation grant during the project period of the systems enhancement grant.

Category (3): Targeted Issues Grants

The third funding category is that of targeted issues grants on topics of importance to EMSC. Targeted issues grants are intended to address specific, focused issues related to the development of EMSC capacity. Proposals under this category must have a well-conceived methodology for evaluation of the impact of the activity. The EMSC Five Year Plan identifies several activities judged to be appropriate for support through targeted issues grants for FY 1996. They include the following:

1. Cost-Benefit Analyses Related to EMSC

Very limited information is available on the costs related to different aspects of EMSC, and yet such information is critical to decision making. Projects in this category may include topics such as the following:

- Analyses of the impact of insurance, managed care, and Federal and/or State health care financing policies and protocols on pediatric emergency medical services.
- Analyses of the impact of differing reimbursement policies in contiguous jurisdictions on pediatric patients.
- Assessment of the marginal incremental cost of different approaches to improving EMSC.
- Evaluation of the cost-effectiveness of different EMSC program configurations (such as different approaches to medical control, categorization, and regionalization).

2. Risk-Taking Behaviors of Children and Adolescents

Emergency department health professionals are uniquely positioned to provide interventions to reduce the incidence of repeated episodes when treating a child or adolescent for an injury or medical condition (e.g., noncompliant child or adolescent with a chronic condition, such as diabetes) resulting from risk-taking behavior. Projects in this category can be directed to development and evaluation of materials and strategies for emergency departments in one or more of the following areas:

- Unintentional injury prevention.
- Violence or suicide prevention.
- Integration of mental health services with preventive interventions (injury or medical).

3. Care of Children With Special Health Needs (CSHN)

An organized system of emergency care is needed for children who have special health care needs (children who are respirator dependent, children with tracheostomies, indwelling (broviac) catheters, gastric tubes, etc.) on discharge from acute care settings. Projects in this category can be directed to one or more of the following:

- Development, implementation and evaluation of educational or training programs for families.
- Development, implementation, and evaluation of educational or training programs for health care providers (e.g., prehospital, emergency department, school nurses. etc.).
- Evaluation of models for comprehensive discharge planning.
- Development and evaluation of model injury prevention programs for CSHN.

Projects in this category must demonstrate collaboration and linkages

among EMS and CSHN agencies, as well as families and other agencies and organizations, as appropriate (e.g., schools).

4. EMSC-Related Models for Improving the Care of Culturally Diverse Populations

In emergencies, health care providers are often required to meet the needs of linguistically, culturally and ethnically diverse children and families, but little training is provided in this area. Projects in this category can be directed to one or more of the following:

- Development, implementation and evaluation of education and training programs in cultural sensitivity for prehospital providers, nurses, and physicians.
- Development (or translation), implementation, and evaluation of discharge, injury prevention and health care materials for low literacy populations and for culturally and/or ethnically diverse populations.

Projects in this category must demonstrate collaboration and linkages among EMS or MCH agencies, acute care facilities, and ethnically-oriented community organizations and agencies to assure sensitivity to ethnic and cultural issues.

5. Children's Emergencies in Disasters

Local, regional, and State disaster plans typically do not address the training and equipment necessary to meet the special needs of children in disasters. Projects in this category should address one or more of the seven recommendations identified in the September 21–22, 1995, Workshop on Children's Emergencies in Disasters, co-sponsored by the Maternal and Child Health Bureau, the Federal Emergency Management Agency, and the Substance Abuse and Mental Health Services Administration (a copy of these recommendations is included in the application kit). Examples of projects appropriate for this category include the following:

- Development of a strategy to integrate pediatrics into existing disaster plans, in particular focusing on the following components: Training, equipment, psychosocial support, system access and cost reimbursement, shelter services, and mitigation.
- Identification of key data to be collected, collection, and analysis of data on children's health and mental health needs in disasters.

Proposals may be submitted on emerging issues that are not included in the above list. However, any such proposal must demonstrate relevance to the EMSC Five Year Plan and must make a persuasive argument that the issue is particularly critical. The justification provided should clearly link the activities in the application with the Plan's objectives. Current targeted issues grantees may apply for one additional year of funding.

Prospective applicants are urged to contact EMSC program staff well in advance of submitting their formal applications, so that the work of proposal development can be avoided if the proposed project is inappropriate for submission in this category.

Special Concerns

HRSA's Maternal and Child Health Bureau places special emphasis on improving service delivery to women, children and youth from communities with limited access to comprehensive care. In order to assure access and cultural competence, it is expected that projects will involve individuals from the populations to be served in the planning and implementation of the project. The Bureau's intent is to ensure that project interventions are responsive to the cultural and linguistic needs of special populations, that services are accessible to consumers, and that the broadest possible representation of culturally distinct and historically underrepresented groups is supported through programs and projects sponsored by the MCHB. This same special emphasis applies to improving service delivery to children with special health care needs.

In keeping with the goals of advancing the development of human potential, strengthening the Nation's capacity to provide high quality education by broadening participation in MCHB programs of institutions that may have perspectives uniquely reflecting the Nation's cultural and linguistic diversity, and increasing opportunities for all Americans to participate in and benefit from Federal public health programs, HRSA will place a funding priority on projects from Historically Black Colleges and Universities (HBCU) or Hispanic Serving Institutions (HSI) in all categories and subcategories in this notice for which applications from academic institutions are encouraged. This is in conformity with the Federal Government's policies in support of White House Initiatives on Historically Black Colleges and Universities (Executive Order 12876) and Educational Excellence for Hispanic Americans (Executive Order 12900). An approved proposal from a HBCU or HSI will receive a 0.5 point favorable adjustment of the priority score in a 4 point range before funding decisions are made.

Evaluation Protocol

A maternal and child health discretionary grant project, including any project awarded as part of the Emergency Medical Services for Children Demonstration Grants program, is expected to incorporate a carefully designed and well planned evaluation protocol capable of demonstrating and documenting measurable progress toward achieving the project's stated goals. The protocol should be based on a clear rationale relating the grant activities, the project goals, and the evaluation measures. Wherever possible, the measurements of progress toward goals should focus on health outcome indicators, rather than on intermediate measures such as process or outputs. A project lacking a complete and well-conceived evaluation protocol as part of the planned activities will not be funded.

Public Comment

If time permits, comments from the public will be accepted on the categories, priorities, and preferences described in this notice. Public comments received too late for consideration this year will be considered in the development of program categories, priorities, or preferences for FY 1997. Members of the public should submit any comments to: Chief, Grants Management Branch, MCHB, at the address listed in the **ADDRESS** section.

Project Review and Funding

The Department will review applications in the preceding funding categories as competing applications and will fund those which, in the Department's view, are consistent with the statutory purpose of the program, with particular attention to children from culturally distinct populations and children with special health care needs; and that best meet the purposes of the EMSC program and address achievement of applicable Healthy People 2000 objectives related to emergency medical services and trauma systems.

Review Criteria

The review of applications will take into consideration the following criteria:

- For Category (1) State Planning Grants:

—Evidence of the State's commitment to improve pediatric emergency care services and to continue with EMSC program implementation.

—The adequacy of the applicant's proposed method to identify problems and conduct a needs assessment.
—Evidence of the applicant's understanding of obstacles to EMSC activity in the past, and the completeness of proposed strategies to overcome these obstacles.
—The adequacy of the applicant's proposed planning process for improving EMSC.
—The soundness of the methods the applicant will use to: (1) recruit, select and assemble appropriate participants, including members of culturally distinct populations, with demonstrated expertise and experience in EMS; trauma systems; child health issues; and emergency care for children; and (2) obtain input from potential consumers (i.e., families) of a State EMSC plan.
—Reasonableness of the proposed budget, soundness of the arrangements for fiscal management, effectiveness of use of personnel, and likelihood of project completion within the proposed grant period.

• For Categories (2) and (3) State Systems and Targeted Issues Grants:

—The appropriateness of project objectives and outcomes in relation to the specific nature of the problems identified by the applicant.
—The adequacy of the proposed methodology for achieving project goals and objectives.
—The soundness of the plan for evaluating progress in achieving project objectives and outcomes.
—The adequacy of the plan for organizing and carrying out the project.
—The qualifications and experience of the Project Director and proposed staff.
—The reasonableness of the proposed budget and soundness of the arrangements for fiscal management.
—The extent to which the project gives special emphasis to the issues identified in the Special Concerns section of this notice.

• For Category (2) State Systems Grants only, the following additional criteria:

—The adequacy of the applicant's understanding of the problem of pediatric trauma and critical illness in the grant locale, including the special problems of (a) children with special health needs (CSHN) and their families; and (b) minority children and families (including Native Americans, Native Hawaiians, and Alaska Natives).
—The extent to which the applicant will employ products and expertise of EMSC programs from other States, especially of current and former grantees of the Federal EMSC program.
—The adequacy with which the applicant addresses institutionalization of the proposed project.
—The extent to which the applicant demonstrates the involvement and participation of consumers (e.g., families) and parent advocacy groups in planning, needs assessment, and project implementation.
—The extent to which the applicant demonstrates a multi-disciplinary approach to EMSC system development, including providers at all levels (e.g., physicians, nurses, emergency medical technicians, social workers and others appropriate to project activities).
—Evidence that the applicant will collaborate and coordinate with other participants in the EMSC continuum, e.g., the State EMS agency; the State MCH/CSHN agency; the State Highway Safety Office; other relevant State agencies; tribal nations; state and local professional organizations; private sector voluntary organizations; business organizations; hospital organizations; and any other ongoing Federally-funded projects in EMS, injury prevention, and rural health.
—The adequacy of the applicant's plan to integrate pediatric emergency care into the primary care delivery system.

For Category (3) Targeted Issues Grants only, the following additional criteria:

—The relevance of the proposed project to the MCHB/NHTSA Five Year Plan for EMSC.

Eligible Applicants

No more than one grant under this program will be made in any State (to a State or a school of medicine in the State) in any fiscal year. Applications for funding will be accepted from States and accredited schools of medicine. Applications which involve more than a single State will also be accepted. In developing the proposed project, applicants must seek the participation and support of local or regional trauma centers and other interested entities within the State, such as local government and health and medical organizations in the private sector. If the applicant is a school of medicine, the application must be endorsed by the State. The State's endorsement must acknowledge that the applicant has consulted with the State and that the State has been assured that the applicant will work with the State on the proposed project.

Any State (or medical school within that State) may apply for any category or subcategory of grant, subject to the following considerations based on equitable geographic distribution of EMSC funds, differences in purpose among EMSC grant categories, and variation among States in EMSC program progress:

• For Category (1) Planning Grants, States (or medical schools within those States) that have received prior EMSC state systems grants may not apply for a planning grant.

• For Category (2)(A) Implementation Grants, applications from States (and medical schools within those States) that have not previously received EMSC program funds, or that have received only partial support under this program as part of a regional alliance, will receive preference for funding in this subcategory. This means that approved applications from States (and medical schools within those States) with no or very limited prior EMSC program support will be funded ahead of approved applications from outside this group.

• For Category (2)(B) System Enhancement Grants, States (and medical schools within those States) that have previously received EMSC funds may apply for a system enhancement grant, as long as they will not also be receiving implementation funds during the project period of the system enhancement grant. States that have not previously received EMSC funds are advised to apply first for implementation category funds.

• For Category (3) Targeted Issues Grants, eligibility is not affected by previous receipt of other EMSC funding. Applications will not be considered for both Category (1) State Planning Grants and Category (2) State Systems Grants simultaneously from the same State. Funding of an application for a planning grant or for a Category (2)(A) implementation grant bars a State from future competitions for that category or subcategory.

Allowable Costs

The HRSA may support reasonable and necessary costs of EMSC Demonstration Grant projects within the scope of approved projects. Allowable costs may include salaries, equipment and supplies, travel, contracts, consultants, and others, as well as indirect costs as negotiated and certified. The HRSA adheres to administrative standards reflected in the Code of Federal Regulations, 45 CFR Part 92 and 45 CFR Part 74.

Public Health System Reporting Requirements

This program is subject to the Public Health System Reporting Requirements (approved under OMB No. 0937–0195). Under these requirements, community-based nongovernmental applicants must prepare and submit a Public Health System Impact Statement (PHSIS). The PHSIS is intended to provide information to State and local health officials to keep them apprised of proposed health services grant applications submitted by community-based nongovernmental organizations within their jurisdictions. Community-based non-governmental applicants are required to submit the following information to the head of the appropriate State and local health agencies in the area(s) to be impacted no later than the Federal application receipt due date:

(a) A copy of the face page of the application (SF 424).

(b) A summary of the project (PHSIS), not to exceed one page, which provides:

(1) A description of the population to be served.

(2) A summary of the services to be provided.

(3) A description of the coordination planned with the appropriate State or local health agencies.

The project abstract may be used in lieu of the one-page PHSIS, if the applicant is required to submit a PHSIS.

Executive Order 12372

This program has been determined to be a program which is subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs by appropriate health planning agencies, as implemented by 45 CFR Part 100. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. The application packages to be made available under this notice will contain a listing of States which have chosen to set up such a review system and will provide a single point of contact (SPOC) in the States for review. Applicants (other than federally-recognized Indian tribal governments) should contact their State SPOCs as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC of each affected State. The due date for State process recommendations is 60 days after the application deadline for new and competing awards. The granting agency does not guarantee to ''accommodate or explain'' for State process recommendations it receives after that date. (See Part 148, Intergovernmental Review of PHS Programs under Executive Order 12372 and 45 CFR Part 100 for a description of the review process and requirements).

The OMB Catalog of Federal Domestic Assistance number is 93.127.

Dated: February 27, 1996.

Ciro V. Sumaya,

Administrator.

[FR Doc. 96–4860 Filed 3–1–96; 8:45 am]

BILLING CODE 4160–15–P

Public Health Service

Indian Health Service; Health Professions Recruitment Program for Indians

AGENCY: Indian Health Service, HHS.

ACTION: Notice of Competitive Grant Applications for the Health Professions Recruitment Program for Indians.

SUMMARY: The Indian Health Service (IHS) announces that competitive grant applications are now being accepted for the Health Professions Recruitment Program for Indians established by sec. 102 of the Indian Health Care Improvement Act of 1976 (25 U.S.C. 1612), as amended by Pub. L. 102–573. There will be only one funding cycle during fiscal year (FY) 1996. This program is described at sec. 93.970 in the Catalog of Federal Domestic Assistance and is governed by regulations at 42 CFR sec. 36.310 *et seq.* Costs will be determined in accordance with OMB Circulars A–21, A–87, and A–122 (cost principles for different types of applicant organizations); and 45 CFR part 74 or 45 CFR part 92 (as applicable). Executive Order 12372 requiring intergovernmental review is not applicable to this program. This program is not subject to the Public Health System Reporting requirements.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of *Healthy People 2000,* a PHS-led activity for setting priority areas. This program announcement is related to the priority area of Educational and Community-based programs. Potential applicants may obtain a copy of *Healthy People 2000* (Full Report; Stock No. 017–001–00474–0) or *Healthy People 2000* (Summary Report; Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325 (Telephone 202–783–3238).

Smoke Free Workplace

PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products, and Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

DATES: A. Applicant Receipt Date—An original and two copies of the completed grant application must be submitted with all required documentation to the Grants Management Branch, Division of Acquisition and Grants Operations, Twinbrook Building, Suite 100, 12300 Twinbrook Parkway, Rockville, Maryland 20852, by close of business June 3, 1996.

Applications shall be considered as meeting the deadline if they are either: (1) received on or before the deadline with hand carried applications received by close of business 5 p.m.; or (2) postmarked on or before the deadline and received in time to be reviewed along with all other timely applications. A legibly dated receipt from a commercial carrier or the U.S. Postal Service will be accepted in lieu of a postmark. Private metered postmarks will not be accepted as proof of timely mailing. Late applications not accepted for processing will be returned to the applicant and will *not* be considered for funding.

B. Additional Dates:

1. Application Review: July 17, 1996
2. Applicants Notified of Results: on or about August 1, 1996 (approved, recommended for approval but not funded, or disapproved)
3. Anticipated Start Date: September 1, 1996

FOR FURTHER INFORMATION CONTACT: For program information, contact Robin L. Bristow, Project Officer, Scholarship Branch, Twinbrook Metro Plaza, 12300 Twinbrook Parkway, Suite 100, Rockville, Maryland 20852, (301) 443–6197. For grants application and business management information, contact M. Kay Carpentier, Grants Management Officer, Grants Management Branch, Division of Acquisition and Grants Operations, Indian Health Service, Twinbrook Building, Suite 100, 12300 Twinbrook Parkway, Rockville, Maryland 20852 (301) 443–5204. (The telephone numbers are not toll-free numbers).

SUPPLEMENTARY INFORMATION: This announcement provides information on the general program purpose, eligibility

and preference, program objectives, required affiliation, fund availability and period of support, type of program activities considered for support, and application procedures for FY 1996.

A. General Program Purpose

The purpose of the Health Professions Recruitment program is to increase the number of American Indians and Alaska Natives entering the health professions and to assure an adequate supply of health professionals to the IHS, Indian tribes, tribal organizations, and urban Indian organizations involved in the provision of health care to Indian people.

B. Eligibility and Preference

The following organizations are eligible with preference given in the order of priority to:

1. Indian tribes,
2. Indian tribal organizations,
3. urban Indian organizations and other Indian health organizations; and
4. public and other nonprofit private health or educational entities.

C. Program Objectives

Each proposal must address the following *four* objectives to be considered for funding:

1. To identify Indians with a potential for education or training in Public Health (Masters level) and other health professions (excluding nursing), and to encourage and assist them to enroll in such programs. The Nursing profession is excluded because the IHS Nursing Recruitment Grant Program provides funding to increase the number of nurses who deliver health care services to Indians.

2. To deliver the necessary student support systems to help to ensure that students who are recruited successfully complete their academic training. Support services may include providing career counseling and academic advice; assisting students to identify academic deficiencies and to develop plans to correct those deficiencies; assisting students to locate financial aid; monitoring students to identify possible problems; assisting with the determination of need for and location of tutorial services; and other related activities which will help to retain students in school.

3. To publicize existing sources of financial aid available to Indian students interested in enrolling in or enrolled in an accredited Masters of Public Health program or accredited health professions program (excluding nursing).

4. To work in close cooperation with the IHS, tribes, tribal organizations and urban Indian organizations, in locating and identifying non-academic period placement opportunities and practicum experiences, i.e., the IHS Extern Program authorized under Section 105 of Pub. L. 94–437, as amended; assisting students with individual development plans in conjunction with identified placement opportunities; monitoring students to identify and evaluate possible problems; and monitoring and evaluating all placement and practicum experiences within the IHS to further develop and modify the program.

D. Required Affiliation

If the applicant is an Indian tribe, tribal organization, urban organization or other Indian health organization, or a public or nonprofit private health organization, the applicant must submit a letter of support from at least one accredited school of public health or health professions program (excluding nursing), depending on the type of program for which it proposes to recruit. This letter must document linkage with that educational organization.

When the target population of a proposed project includes a particular Indian tribe or tribes, an official document, i.e., a letter of support or tribal resolution, must be submitted indicating that the tribe or tribes will cooperate with the applicant.

E. Fund Availability and Period of Support

It is anticipated that approximately $250,000 will be available for approximately 3 new grants. The average funding level for projects in FY 1995 was $98,000. The anticipated start date for selected projects will be September 1, 1996. Pursuant to 42 Code of Federal Regulations § 36.313(c), the project period ''will usually be for one to two years.'' However, under this notice, projects will be awarded for a budget term of 12 months, with a maximum project period of up to three (3) years. A maximum project period of three (3) years is required so that key staff, such as project directors, may be recruited, without the financial and career uncertainty of a one or two year budget period and to enable the projects to carry out their recruitment activities without the added activity of applying for a grant every one or two years. Grant funding levels include both direct and indirect costs. Funding of succeeding years will be based on the FY 1996 level, continuing need for the program, satisfactory performance, and the availability of appropriations in those years.

F. Type of Program Activities Considered for Support

Funds are available to develop grant programs to located and recruit students with potential for (1) Masters of Public Health or (2) other health professions degree programs (excluding nursing), and to provide support services to Indian students who are recruited.

G. Application Process

An *IHS Recruitment Grant Application Kit*, including the required PHS 5161–1 (Rev. 7/92) (OMB Approval No. 0937–0189) and the U.S. Government Standard forms (SF–424, SF–424A and SF–424B), may be obtained from the Grants Management Branch, Division of Acquisition and Grants Operations, Indian Health Service, 12300 Twinbrook Parkway, Suite 100, Rockville, Maryland 20852, telephone (301) 443–5204. (This is not a toll free number.)

H. Grant Application Requirements

All applications must be single-spaced, typewritten, and consecutively numbered pages using black type not smaller than 12 characters per one inch, with conventional one inch border margins, on only one side of standard size 8½×11 paper that can be photocopied. The application narrative (not including abstract, tribal resolutions or letters of support, standard forms, table of contents or the appendix) must not exceed 20 typed pages as described above. All applications must include the following in the order presented:

—Standard Form 424, Application for Federal Assistance
—Standard Form 424A, Budget Information—Non-Construction Programs, (pages 1 and 2)
—Standard Form 424B, Assurances—Non-Construction Programs (front and back)
—Certifications, PHS 5161–1, (pages 17–18)
—Checklist, PHS 5161–1, (pages 23–24), NOTE: Each standard form and the checklist is contained in the PHS Grant Application, Form PHS 5161–1 (Revised 7/92)
—Project Abstract (one page)
—Table of Contents
—Program Narrative to include:
—Introduction and Potential Effectiveness of Project
—Project Administration
—Accessibility to Target Population
—Relationship of Objectives to Manpower Deficiencies
—Project Budget, including multi-year narratives, and Budget Justifications
—Appendix to include:

—Tribal Resolution(s) or Letters of Support
—Biographical sketches for key personnel or position descriptions if position is vacant
—Organizational chart
—Workplan
—Completed IHS Application Checklist
—Application Receipt Card, PHS 3038–1 Rev. 5–90.

I. Application Instructions

The following instructions for preparing the application narrative also constitute the standards (criteria or basis for evaluation) for reviewing and scoring the application. Weights assigned each section are noted in parenthesis.

Abstract—An abstract may not exceed one typewritten page. The abstract should clearly present the application in summary form, from a ''who-what-when-where-how-cost'' point of view so that reviewers see how the multiple parts of the application fit together to form a coherent whole.

Table of Contents—Provide a one page typewritten table of contents.

Narrative

1. Introduction and Potential Effectiveness (30 pts.)

a. Describe your legal status and organization.

b. State specific objectives of the project, which are measurable in terms of being quantified, significant to the needs of Indian people, logical, complete and consistent with the purpose of sec. 102.

c. Describe briefly what the project intends to accomplish. Identify the expected results, benefits, and outcomes or products to be derived from each objective of the project.

d. Provide a project specific work plan (milestone chart) which lists each objectives, the tasks to be conducted in order to reach the objective, and the timeframe needed to accomplish each task. Timeframes should be projected in a realistic manner to assure that the scope of work can be completed within each budget period. (A work plan format is provided.)

e. In the case of proposed projects for identification of Indians with a potential for education or training in the health professions (excluding nursing), include a method for assessing the potential of interested Indians for undertaking necessary education or training in such health professions.

f. State clearly the criteria by which the project's progress will be evaluated and by which the success of the project will be determined.

g. Explain the methodology that will be used to determine if the needs, goals, and objectives identified and discussed in the application are being met and if the results and benefits identified are being achieved.

h. Identify who will perform the evaluation and when.

2. Project Administration (20 pts.)

a. Provide an organizational chart (include in appendix). Describe the administrative, managerial and organizational arrangements, and the facilities and resources to be utilized to conduct the proposed project.

b. Provide the name and qualifications of the project director or other individuals responsible for the conduct of the project; the qualifications of the principal staff carrying out the project; and a description of the manner in which the application's staff is or will be organized and supervised to carry out the proposed project. Include biographical sketches of key personnel (or job descriptions if the position is vacant) (include in appendix).

c. Describe any prior experience in administering similar projects.

d. Discuss the commitment of the organization, i.e., although not required, the level of non-Federal support. List the intended financial participation, if any, of the applicant in the proposed project specifying the type of contributions such as cash or services, loans of full or part-time staff, equipment, space, materials or facilities or other contributions.

3. Accessibility to Target Population (20 pts.)

a. Describe the current and proposed participation of Indians (if any) in your organization.

b. Identify the target Indian population to be served by your proposed project and the relationship of your organization to that population.

c. Describe the methodology to be used to access the target population.

4. Relationship of Objectives to Manpower Deficiencies (20 pts.)

a. Provide data and supporting documentation to address the relationship of objectives to manpower deficiencies.

b. Indicate the number of potential Indian students to be contacted and recruited as well as potential cost per student recruited. Those projects that have the potential to serve a greater number of Indians will be given first consideration.

5. Soundness of Fiscal Plan (10 pts.)

a. Clearly define the budget. Provide a justification and detailed breakdown of the funding by category for the project. Information on the project director and project staff should include salaries and percentage of time assigned to the grant. List equipment purchases necessary for the conduct of the project.

b. The available funding level of $250,000 is inclusive of both direct and indirect costs. Pursuant to Public Health Service Grants policy (DHHS Publication No. (OASH) 94–50,000 (Rev.) April 1, 1994), a 'training grant' includes a grant for ''training or other educational purposes'', and the Department of Health and Human Services considers this grant activity as having an educational purpose. Because this project has an educational purpose, and, therefore, is for a training grant, the Department of Health and Human Services' policy limiting reimbursement of indirect cost to the lesser of the applicant's actual indirect costs or 8 percent of total direct costs (exclusive of tuition and related fees and expenditures for equipment) is applicable. This limitation applies to all institutions of higher education other than agencies of State and local government.

c. Projects requiring additional years must include a program narrative and categorical budget and justification for each additional year of funding requested (this is not considered part of the 20-page narrative).

Appendix—to include:

a. Tribal Resolution(s) or Letters of Support
b. Biographical sketches of key personnel or position descriptions if position is vacant
c. Organizational chart
d. Workplan
e. Completed IHS Application Checklist
f. Application Receipt Card, PHS 3038–1 Rev. 5–90

J. Reporting

1. Progress Report—Program progress reports shall be required semiannually. These reports will include a brief description of a comparison of actual accomplishments to the goals established for the period, reasons for slippage and other pertinent information as required. A final report is due 90 days after expiration of the budget/project period.

2. Financial Status Report—Semi-annually financial status reports will be submitted 30 days after the end of the half year. A final financial status report is due 90 days after expiration of the budget/project period. Standard Form 269 (long form) will be used for financial reporting.

K. Grant Administration Requirements

Grants are administered in accordance with the following documents:

1. 45 CFR part 92, HHS, Uniform Administrative Requirements for Grants

and Cooperative Agreements to State and Local Governments, or 45 CFR part 74, Administration of Grants to Non-Profit Recipients.

2. PHS Grants Policy Statement, and

3. Appropriate Cost Principles: OMB Circular A–21, Educational Institutions, OMB Circular A–87, State and Local Governments, and OMB Circular A–122, Non-profit Organizations.

L. Objective Review Process

Applications meeting eligibility requirements that are complete, responsive, and conform to this program announcement will be reviewed by an Objective Review Committee (ORC) in accordance with IHS objective review procedures. The objective review process ensures a nationwide competition for limited funding. The ORC will be comprised of IHS (40% or less) and other federal or non-federal individuals (60% or more) with appropriate expertise. The ORC will review each application against established criteria. Based upon the evaluation criteria, the reviewers will assign a numerical score to each application, which will be used in making the final funding decision. Approved applications scoring less than 60 points will not be considered for funding.

M. Results of the Review

The results of the objective review are forwarded to the Acting Associate Director, Office of Human Resources (OHR), for final review and approval. The Acting Associate Director, OHR, will also consider the recommendations from the Director, Division of Health Professions, Recruitment and Training, and the Grants Management Branch. Applicants are notified in writing on or about August 1, 1996. A Notice of Grant Award will be issued to successful applicants. Unsuccessful applicants are notified in writing of disapproval. A brief explanation of the reasons the application was not approved is provided along with the name of an IHS official to contact if more information is desired.

Dated: February 21, 1996.

Michael H. Trujillo,

Assistant Surgeon General Director.

[FR Doc. 96–4931 Filed 3–1–96; 8:45 am]

BILLING CODE 4160–16–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of an Environmental Assessment and Receipt of an Application for an Incidental Take Permit From Sage Development Company, LLC, Daphne, AL

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: Sage Development Company, LLC, (Applicant), has applied to the Fish and Wildlife Service (Service) for an incidental take permit pursuant to Section 10(a)(1)(B) of the Endangered Species Act (Act). The proposed permit would authorize for a period of 30 years the incidental take of an endangered species, the Alabama beach mouse (*Peromyscus polionotus ammobates*), known to occupy a 25.7-acre tract of land owned by the Applicant on the Fort Morgan Peninsula, Baldwin County, Alabama. The Application proposes to construct a project known as The Dunes, which will include 3 condominium complexes, 38 single family/duplex lots, their associated landscaped grounds and parking areas, recreational amenities, and dune walkover structures (Project).

The Service also announces the availability of an environmental assessment (EA) and habitat conservation plan (HCP) for the incidental take application. Copies of the EA or HCP may be obtained by making requests to the addresses below. This notice is provided pursuant to Section 10© of the Act and National Environmental Policy Act Regulations (40 CFR 1506.6).

DATES: Written comments on the permit application, EA and HCP should be received on or before April 3, 1996.

ADDRESSES: Persons wishing to review the application may obtain a copy by writing the Service's Southeast Regional Office, Atlanta, Georgia. Persons wishing to review the EA or HCP may obtain a copy by writing the Regional Office or the Jackson, Mississippi, Field Office. Requests must be writing to properly process requests. Documents will also be available for public inspection, by appointment, during normal business hours at the Regional Office, or the Field Office. Written data or comments concerning the application, EA, or HCP should be submitted to the Regional Office. Please reference permit under PRT–811416 in such comments.

Regional Permit Coordinator (TE), U.S. Fish and Wildlife Service, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345, (telephone 404/679–7110, FAX 404/679–7081). Field Supervisor, U.S. Fish and Wildlife Service, 6578 Dogwood View Parkway, Suite A, Jackson, Mississippi 39213 (telephone 601/965–4900, FAX 601/965–4340).

FOR FURTHER INFORMATION CONTACT: Mr. Will McDearman at the above Jackson, Mississippi, Field Office.

SUPPLEMENTARY INFORMATION: The Alabama beach mouse (ABM), *Peromyscus polionotus ammobates*, is a subspecies of the common oldfield mouse *Peromyscus polionotus* and is restricted to the dune systems of the Gulf Coast of Alabama. The known change of ABM extends from Fort Morgan eastward to the western terminus of Alabama Highway 182, including the Perdue Unit on the Bon Secour National Wildlife Refuge. The sand dune systems inhabited by this species are not uniform; several habitat types are distinguishable. The species inhabits primary dunes, interdune areas, secondary dunes, and scrub dunes. The depth and area of these habitats from the beach inland varies. Population surveys indicate that this subspecies is usually more abundant in primary dunes that in secondary dunes, and usually more abundant in secondary dunes than in scrub dunes. Optimal habitat consists of dune systems with all dune types. Though fewer ABM inhabit scrub dunes, these high dunes can serve as refugia during devastating hurricanes that overwash, flood, and destroy or alter secondary and frontal dunes. ABM surveys on the Applicant's property reveal habitat occupied by ABM. The Applicant's property contains designated critical habitat for the ABM. Construction of the Project may result in the death of, or injury to, ABM. Habitat alterations due to condominium placement and subsequent human habitation of the project may reduce available habitat for food, shelter, and reproduction.

The EA considers the environmental consequences of several alternatives. One action proposed is the issuance of the incidental take permit based upon submittal of the HCP as proposed. This alternative provides for restrictions that include placing no habitable structures seaward of the designated ABM critical habitat, establishment of walkover structures across designated critical habitat, a prohibition against housing or keeping pet cats, ABM competitor control and monitoring measures, scavenger-proof garbage containers, creation of educational and information brochures on ABM conservation, and

the minimization and control of outdoor lighting. Further, the HCP proposes to provide an endowment to acquire ABM habitat off-site or otherwise perform some other conservation measure for the ABM. The HCP provides a funding source for these mitigation measures. Another alternative is consideration of a different project design that further minimizes permanent loss of ABM habitat. A third alternative is no-action, or deny the request for authorization to incidentally take the ABM.

Dated: February 26, 1996.

Noreen K. Clough,

Regional Director.

[FR Doc. 96–4933 Filed 3–1–96; 8:45 am]

BILLING CODE 4310–55–P

Availability of an Environmental Assessment and Receipt of an Application for an Incidental Take Permit for Timber Management Practices in Conecuh and Monroe Counties, Alabama by MacMillan Bloedel Timberlands, Incorporated

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: MacMillan Bloedel Timberlands, Incorporated, (Applicant) has applied to the Fish and Wildlife Service (Service) for an incidental take permit pursuant to Section 10(a)(1)(B) of the Endangered Species Act (Act). The proposed permit would authorize for a period of 30 years the incidental take of a threatened species, the Red Hills salamander, *Phaeognathus hubrichti*, known to occupy lands owned by the Applicant in Conecuh and Monroe Counties, south-central Alabama.

The Service also announces the availability of an Environmental Assessment (EA) and Habitat Conservation Plan (HCP) for the incidental take application. The Applicant's HCP describes *Phaeognathus hubrichti* conservation measures to be employed to address the anticipated level of incidental take. The EA prepared by the Service describes the environmental consequences of issuing or denying the Applicant's request for an incidental take permit. As stated in the EA, the Service proposes to issue the requested permit. This proposal is based on a preliminary determination that the Applicant has satisfied the requirements for permit issuance and that the HCP provides conservation benefits to *Phaeognathus hubrichti*. This notice also advises the public that the Service has made a preliminary determination that issuing the incidental take permit is not a major Federal action significantly affecting the quality of the human environment within the meaning of Section 102(2)(C) of the National Environmental Policy Act of 1969, as amended. The Finding of No Significant Impact is based on information contained in the EA and HCP. The final determination will be made no sooner than 30 days from the date of this notice. This notice is provided pursuant to Section 10© of the Act and National Environmental Policy Act Regulations (40 CFR 1506.6). Copies of the EA and HCP may be obtained by making a written request to the Regional Office [See **ADDRESSES** below]. Note that requests must be in writing to be properly processed.

DATES: Written comments should be received on or before April 3, 1996.

ADDRESSES: Persons wishing to review the application may obtain a copy by writing the Service's Southeast Regional Office, Atlanta, Georgia. Persons wishing to review the EA or HCP may obtain a copy by writing the Regional Office or the Jackson, Mississippi, Field Office. Documents will also be available for public inspection, by appointment, during normal business hours at the Regional Office, or the Field Office. Written data or comments concerning the application, EA, or HCP should be submitted to the Regional Office. Please reference permit number PRT–811415 in such comments:

Regional Permit Coordinator, U.S. Fish and Wildlife Service, 1875 Century Boulevard, Suite 200, Atlanta, Georgia (404–679–7110, fax 404–679–7081)

Field Supervisor, U.S. Fish and Wildlife Service, 6578 Dogwood View Parkway, Suite A, Jackson, Mississippi 39213 (601–965–4900, fax 601–965–4340)

FOR FURTHER INFORMATION CONTACT: Will McDearman, Jackson, Mississippi Field Office or Rick Gooch at the Atlanta, Georgia Regional Office.

SUPPLEMENTARY INFORMATION: Section 9 of the Act, and implementing regulations, prohibits the take of threatened and endangered species. Take, in part, is defined as an activity that kills, injures, harms, or harasses a listed endangered or threatened species.

Section 10(a)(1)(B) of the Act provides an exemption, under certain circumstances, to the Section 9 prohibition if the taking is incidental to, and not the purpose of an otherwise lawful activities.

Phaeognathus hubrichti is a plethodontid salamander and the sole member of its genus. Its range is confined to a small area of southern Alabama. Portions of the Applicant's lands in the Red Hills physiographic province of south-central Alabama are occupied by this species. According to the surveys identified in the HCP, the Applicant owns approximately 3,800 acres within the species' historic range in Conecuh and Monroe Counties. The Applicant's HCP attempts to define certain management prescriptions according to known occurrences of *Phaeognathus hubrichti* as well as the species' habitat selection preferences. The HCP identifies three habitat classifications: Optimal; Moderately Suitable; and Marginal. The Applicant owns approximately 1,200 acres; 1,300 acres; and 1,300 acres, respectively of each habitat type.

Within the Optimal habitats of the Applicant's properties encompassed by the HCP, either no timber harvests will occur or very limited single tree selections with at least 90 percent hardwood canopy maintained. To minimize impacts to the soil, any trees removed from optimal habitat will be felled by chain saw and pulled from the area by cable, or other applicable method with no heavy machinery permitted in the area.

Within the Moderately Suitable habitats of the Applicant's properties encompassed by the HCP, an increased level of selective cutting (followed by natural regeneration of tree species characteristic of *Phaeognathus hubrichti* habitat), provided hardwood canopy cover is not reduced by more than 35 percent.

Within the Marginal to Unsuitable habitats, options on these areas will include normal silvicultural practices, such as clearcutting, select tree harvest, chemical and mechanical site preparation, replanting, and prescribed burning. Clear-cut areas will be planted with pine or hardwood seedlings. Site preparation methods vary depending on the site but usually will include a combination of herbicides and fire. Although rotation lengths may change in the future due to economic and/or biological considerations, plantations are currently managed on a pulpwood/sawtimber rotation averaging 20–35 years. Prescribed burning rotations range from 3 to 7 years.

Pest or disease infested trees are removed from all habitat classification, if necessary, to prevent further infection of healthy trees. Forested buffers of approximately 50 feet width will be maintained above and below areas classified as *Phaeognathus hubrichti* Optimal habitat. Timber harvesting will be conducted within these buffers with at least 50 percent of the canopy cover maintained.

The HCP also contained funding for the development of an integrated

management plan incorporating the above prescriptions, as well as employee/contractor training, and maintenance of the permit's terms and conditions.

The EA considers the environmental consequences of two alternatives. The no action alternative would probably result in continued insidious and direct habitat loss for *Phaeognathus hubrichti* resulting in further jeopardy to the species and continued exposure of the Applicant under Section 9 of the Act. This action is inconsistent with the purposes and intent of Section 10 of the Act. The proposed action alternative is issuance of the incidental take permit. The issuance of the permit will be predicated on implementation of the Applicant's HCP, and the measures contained in the authorizing permit.

Dated: February 26, 1996.

Noreen K. Clough,

Regional Director.

[FR Doc. 96–4934 Filed 3–1–96; 8:45 am]

BILLING CODE 4310–55–P

Bureau of Land Management

[NV–050–1020–001]

Mojave-Southern Great Basin Resource Advisory Council—Notice of Meeting Locations and Times

AGENCY: Bureau of Land Management, Interior.

ACTION: Resource Advisory Council Meeting Locations and Times.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972 (FACA), 5 U.S.C., the Department of the Interior, Bureau of Land Management (BLM), council meeting of the Mojave-Southern Great Basin Resource Advisory Council will be held as indicated below. The agenda includes a field trip, public meeting, discussion of laws and regulations that pertain to grazing, and a statewide update of standards and guidelines.

All meetings are open to the public. The public may present written comments to the council. Each formal council meeting will have a time allocated for hearing public comments. The public comment period for the council meeting is listed below. Depending on the number of persons wishing to comment, and time available, the time for individual oral comments may be limited. Individuals who plan to attend and need further information about the meetings, or need special assistance such as sign language interpretation or other reasonable accommodations, should contact Michael Dwyer at the Las Vegas District Office, 4765 Vegas Dr., Las Vegas, NV 89108, telephone, (702) 647–5000.

DATES AND TIMES: Dates are March 21 and 22, 1996. The council will meet at the BLM Las Vegas District Office located at 4765 Vegas Drive, Las Vegas, Nevada, at 7:30 a.m. on March 21, 1996, and will depart for a field trip at 8 a.m. Individuals who want to attend the field trip must provide their own transportation and lunch. A schedule for the field trip will be available prior to departure. The council members and BLM support staff will host an open house for public input on the development of Standards and Guidelines for range reform from 5:30 p.m. to 7:30 p.m. at the Caliente Youth Center, U.S. Highway 93, Caliente, NV. On March 22, the council will meet from 8 a.m. to approximately 4 p.m. at the Caliente City Hall in the historic Union Pacific Railroad Station building.

SUPPLEMENTARY INFORMATION: The purpose of the council is to advise the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with the management of the public lands.

FOR FURTHER INFORMATION CONTACT: Lorraine Buck, Public Affairs Specialist, Las Vegas District, telephone: (702) 647–5000.

Michael F. Dwyer,

District Manager.

[FR Doc. 96–4784 Filed 3–1–96; 8:45 am]

BILLING CODE 4310–HC–M

[UT–080–1430–00]

Leasing of Public Land; Uintah and Duchesne Counties, UT

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Realty Action; Leasing of Public Land.

SUMMARY: The following public lands, located in Uintah and Duchesne Counties, Utah may be leased on a non-competitive basis to existing land use permit holders pursuant to Section 302(b) of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1732) and 43 CFR 2920.

Leases would be offered to the adjoining landowners who currently hold short-term, land use permits for the purposes specified below:

Brad Nelson: Permit Serial Number #UTU–65105, agricultural crop production, haystack yards and silage pit.

Salt Lake Meridian, Utah

T. 8 S., R. 17 E.,
Sec. 22: NW¼NW¼SE¼, S½NW¼SE¼, SW¼NE¼SE¼;
Sec. 23: S¼NE¼SW¼, SE¼NW¼SW¼, N¼SW¼SE¼, SW¼SW¼SE¼.

Amounting to 20.00 acres, more or less.

Hunt Oil Company, c/o Ed Webster: Permit Serial Number #UTU–65111, agricultural crop production and corral facility.

Salt Lake Meridian, Utah

T. 11 S., R. 15 E.,
Sec. 31: NW¼SE¼;
Sec. 33: SW¼NW¼SE¼.

Amounting to 11.50 acres, more or less.

H. Lee Wimmer: Permit Serial Number #UTU–63981, agricultural crop production.

Salt Lake Meridian, Utah

T. 11 S., R. 13 E.,
Sec. 21: NE¼SE¼;
Sec. 33: W½NE¼, NW¼NW¼.

Amounting to 25.00 acres, more or less.

Woody Searle: Permit Serial Number #UTU–71224, irrigation system and storage area.

Salt Lake Meridian, Utah

T. 4 S., R. 21 E.,
Sec. 4: NW¼NSW¼SE¼.

Amounting to 1.00 acre, more or less.

This action would convert existing land use permits to long-term leases. The leases would be for a term of from ten to fifteen years from date of issuance. Applications for the leases will be accepted for processing upon completion of the comment period. Leases would be issued for not less than fair market rental and the lessee shall reimburse the United States for reasonable administrative and other costs incurred in the process of converting these permits to leases.

Conversion of these land use permits to leases would be in conformance with Lands and Realty Management Decisions (LR03) and (LR08) described in the December 21, 1994, Record of Decision implementing the Diamond Mountain Resource Area Resource Management Plan.

DATES: On or before April 18, 1996, interested persons may submit comments regarding the proposed leases to Peter Kempenich, Natural Resource Specialist, Bureau of Land Management, Vernal District, 170 South 500 East, Vernal, Utah 84078, (801) 781–4432.

Any adverse comments will be evaluated by the Area Manager for the Diamond Mountain Resource Area who may vacate or modify this notice and issue a final determination. In the absence of any action by the Area Manager, this Notice of Realty Action will become the final determination of the Bureau.

Dated: February 21, 1996.

Paul Andrews,

Acting District Manager.

[FR Doc. 96–4868 Filed 3–1–96; 8:45 am]

BILLING CODE 4310–DQ–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated September 29, 1995, and published in the Federal Register on October 11, 1995, (60 FR 52923), Ciba-Geigy Corporation, Pharmaceuticals Division Regulatory Compliance, 556 Morris Avenue, Summit, New Jersey 07901, made application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of methylphenidate (1724), a basic class of controlled substance listed in Schedule II.

No comments or objections have been received. DEA has considered the factors in Title 21, United States Code, Section 823(a) and determined that the registration of Ciba-Geigy Corporation to manufacture the listed controlled substance is consistent with the public interest at this time. Therefore, pursuant to Section 303 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and Title 21, Code of Federal Regulations, Section 1301.54(e), the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic class of controlled substance listed above is granted.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 96–4946 Filed 3–1–96; 8:45 am]

BILLING CODE 4410–09–M

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated October 19, 1995, and published in the Federal Register on October 25, 1995, (60 FR 54707), Eli Lilly Industries, Inc., Chemical Plant, Kilometer 146 7, State Road 2, Mayaguez, Puerto Rico 00680, made application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of dextropropoxyphene, bulk (non-dosage forms) (9273), a basic class of controlled substance listed in Schedule II.

No comments or objections have been received. DEA has considered the factors in Title 21, United States Code, Section 823(a) and determined that the registration of Eli Lilly Industries, Inc. to manufacture the listed controlled substance is consistent with the public interest at this time. Therefore, pursuant to Section 303 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and Title 21, Code of Federal Regulations, Section 1301.54(e), the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic class of controlled substance listed above is granted.

Dated: February 26, 1996.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 96–4947 Filed 3–1–96; 8:45 am]

BILLING CODE 4410–09–M

Manufacturer of Controlled Substances; Notice of Application

Pursuant to Section 1301.43(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on November 13, 1995, Johnson Matthey, Inc., Custom Pharmaceuticals Department, 2003 Nolte Drive, West Deptford, New Jersey 08066, made application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
2,5-Dimethoxyamphetamine (7396)	I
Difenoxin (9168)	I
Methylphenidate (1724)	II
Codeine (9050)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Meperidine intermediate-A (9232)	II
Meperidine intermediate-B (9233)	II
Meperidine intermediate-C (9234)	II
Methadone (9250)	II
Methadone intermediate (9254)	II
Oxymorphone (9652)	II
Morphine (9300)	II
Oxymorphone (9652)	II
Sufentanil (9740)	II
Carfentanil (9743)	II
Fentanyl (9801)	II

The firm plans to manufacture the listed controlled substances in bulk to supply final dosage form manufacturers.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the above application.

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than May 3, 1996.

Dated: February 26, 1996.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 96–4944 Filed 3–1–96; 8:45 am]

BILLING CODE 4410–09–M

Manufacturer of Controlled Substances; Notice of Application

Pursuant to Section 1301.43(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on December 19, 1995, MD Pharmaceutical, Inc., 3501 West Garry Avenue, Santa Ana, California 92704, made application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Methylphenidate (1724)	II
Diphenoxylate (9170)	II

The firm plans to manufacture the listed controlled substances to make finished dosage forms for distribution to its customers.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objects to the issuance of the above application.

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than May 3, 1996.

Dated: February 26, 1996.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 96–4945 Filed 3–1–96; 8:45 am]

BILLING CODE 4410–09–M

Importer of Controlled Substances; Notice of Registration

By Notice dated December 15, 1995, and published in the Federal Register on December 28, 1995, (60 FR 67141), North Pacific Trading Company, 1505 SE Gideon Street, Portland, Oregon 97202, made application to the Drug Enforcement Administration to be registered as an importer of Marihuana (7360), a basic class of controlled substance listed in Schedule I.

No comment or objections have been received. DEA has considered the factors in Title 21, United States Code, Section 823(a) and determined that the registration of North Pacific Trading Company to import the listed controlled substance is consistent with the public interest at this time. Therefore, pursuant to Section 1008(a) of the Controlled Substances Import and Export Act and in accordance with Title 21, Code of Federal Regulations, Section 1311.42, the above firm is granted registration as an importer of the basic class of controlled substance listed above.

Dated: February 26, 1996.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 96–4948 Filed 3–1–96; 8:45 am]

BILLING CODE 4410–09–M

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated June 29, 1995, and published in the Federal Register on July 6, 1995, (60 FR 35225), Penick Corporation, 158 Mount Olivet Avenue, Newark, New Jersey 07114, made application to the Drug Enforcement Administration to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Dihydromorphine (9145)	I
Pholcodine (9314)	I
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Benzoylecgonine (9180)	II
Ethylmorphine (9190)	II
Hydrocodone (9193)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone-intermediate (9254)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Morphine (9300)	II
Thebaine (9333)	II
Opium extracts (9610)	II
Opium fluid extract (9620)	II
Opium tincture (9630)	II
Opium powdered (9639)	II
Opium granulated (9640)	II
Levo-alphacetylmethadol (9648)	II
Oxymorphone (9652)	II
Alfentanil (9737)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

A registered manufacturer filed a comment requesting that Penick's application for registration be denied for considerations of the public interest. The commenter also questioned whether Penick has the manufacturing and processing capabilities to manufacture the listed controlled substances. DEA has conducted inspection of Penick and determined that Penick has complied with the factors in Title 21, United States Code, Section 823(a). Penick's current application was filed to renew a manufacturer registration which the firm has maintained for several years and under which the firm manufactured controlled substances in the past in conformance with the Controlled Substances Act and its implementing regulations. Therefore, pursuant to section 303 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and Title 21, Code of Federal Regulations, Section 1301.54(e), Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed above is granted.

Dated: February 26, 1996.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 96–4949 Filed 3–1–96; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petitions for Modification

The following parties have filed petitions to modify the application of mandatory safety standards under section 101(c) of the Federal Mine Safety and Health Act of 1977.

1. Mackie J. Coal Company, Inc.

[Docket No. M–95–169–C]

Mackie J. Coal Company, Inc., Route 2, Box 530, Grundy, Virginia 24614 has filed a petition to modify the application of 30 CFR 75.1710–1 (canopies or cabs; self-propelled electric face equipment; installation requirements) to its Mine No. 4 (I.D. No. 44–06051) located in Buchanan County, Virginia. The petitioner proposes to use self-propelled electric face equipment without cabs or canopies in mining heights of 48 inches or less. The petitioner states that application of the standard would result in a diminution of safety to the equipment operator.

2. Marfork Coal Company, Inc.

[Docket No. M–95–170–C]

Marfork Coal Company, Inc., P.O. Box 457, Whitesville, West Virginia 25209 has filed a petition to modify the application of 30 CFR 75.333(d)(1) (ventilation controls) to its Outpost East Mine (I.D. No. 46–08296); its Outpost West Mine (I.D. No. 46–08295); its White Queen Mine (I.D. No. 46–08297); its Brushy Eagle Mine (I.D. No. 46–08315); its Low Gap Mine (I.D. No. 46–08442); and its Birch Fork Mine (I.D. No. 46–08493) all located in Raleigh County, West Virginia. The petitioner proposes to use electronically operated Roll-Down Doors constructed of rubber material similar to those used in conveyor belts to control ventilation within the air course in the main entries instead of using heavy Metal Doors. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

3. Leeco, Inc.

[Docket No. M–95–171–C]

Leeco, Inc., 100 Coal Drive, London, Kentucky 40741 has filed a petition to modify the application of 30 CFR 75.388(a)(1) (boreholes in advance of mining) to its Mine No. 63 (I.D. No. 15–16413); its Mine No. 68 (I.D. No. 15–17497) located in Perry County, Kentucky; its Mine No. 60 (I.D. No. 15–12941); and its Mine No. 66 (I.D. No. 15–17172) located in Leslie County, Kentucky. Instead of drilling boreholes,

the petitioner proposes to advance panels parallel to gob areas maintaining a nominal distance of 35 feet and to second mine the panel; and to mine out the 35 foot barrier to the previous gob as the panel retreats. The petitioner states that this alternative method would only apply to working sections mining within 50 feet of the pillared areas in the same coal mine. The petitioner asserts that application of the standard would result in a diminution of safety to the miners. In addition, the petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

4. Basin Resources, Inc.

[Docket No. M–95–172–C]

Basin Resources, Inc., 14300 Highway 12, Weston, Colorado 81091 has filed a petition to modify the application of 30 CFR 75.1002 (location of trolley wires, trolley feeder wires, high-voltage cables and transformers) to its Golden Eagle Mine (I.D. No. 05–02820) located in Las Animas, Colorado. The petitioner proposes to use high-voltage (2,400 volts) cables to supply power to longwall mining equipment. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

5. Genwal Resources, Inc.

[Docket No. M–95–173–C]

Genwal Resources, Inc., P.O. Box 1420, Huntington, Utah 84528 has filed a petition to modify the application of 30 CFR 75.352 (return air courses) to its Crandall Canyon Mine (I.D. No. 42–01715) located in Emery County, Utah. The petitioner proposes to use belt air in a two-entry mining system and install a low-level carbon monoxide detection system as an early warning fire-detection system in the intake escapeway and the belt entry using specific procedures outlined in its petition for modification. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

6. Bituminous-Laurel Mining, Inc.

[Docket No. M–95–174–C]

Bituminous-Laurel Mining, Inc., 100 Coal Drive, London, Kentucky 40741 has filed a petition to modify the application of 30 CFR 75.388(a)(1) (boreholes in advance of mining) to its Mine No. 4 (I.D. No. 15–11065) located in Leslie County, Kentucky. Instead of drilling boreholes, the petitioner proposes to advance panels parallel to gob areas maintaining a nominal distance of 35 feet and to second mine the panel; and to mine out the 35 foot barrier to the previous gob as the panel retreats. The petitioner states that this alternative method would only apply to working sections mining within 50 feet of the pillared areas in the same coal mine. The petitioner asserts that application of the standard would result in a diminution of safety to the miners. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

7. Philippi Development, Inc.

[Docket No. M–95–175–C]

Philippi Development, Inc., 2708 Cranberry Square, Morgantown, West Virginia 26505 has filed a petition to modify the application of 30 CFR 75.503 (permissible electric face equipment; maintenance) to its Sentinel Mine (I.D. No. 46–04168) located in Barbour County, West Virginia. The petitioner proposes to increase the maximum length of its trailing cables to 900 feet for supplying power to shuttle cars, roof bolters and mobile roof supports. The petitioner has outlined specific procedures in its petition for modification to support its proposed alternative method; and states that proposed revisions to the part 48 training plan would be submitted to the District Manager within 60 days after the Proposed Decision and Order becomes final that would specify task training for all miners designated to examine and verify the short-circuit settings and circuit interrupting device(s). The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

8. Consolidation Coal Company

[Docket No. M–95–176–C]

Consolidation Coal Company, Consol Plaza, 1800 Washington Road, Pittsburgh, Pennsylvania 15241–1421 has filed a petition to modify the application of 30 CFR 75.364(b)(2) (weekly examination) to its Robinson Run No. 95 Mine (I.D. No. 46–01318) located in Harrison County, West Virginia. Due to deteriorating roof and rib conditions and roof falls in certain areas of the intake air course, traveling the area would be unsafe. The petitioner proposes to establish evaluation points to monitor the quantity and quality of air in the affected area. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

9. McElroy Coal Company

[Docket No. M–95–177–C]

McElroy Coal Company, Consol Plaza, 1800 Washington Road, Pittsburgh, Pennsylvania 15241–1421 has filed a petition to modify the application of 30 CFR 75.804(a) (underground high-voltage cables) to its McElroy Mine (I.D. No. 46–01437) located in Marshall County, West Virginia. The petitioner proposes to use a high-voltage cable with an internal ground check conductor smaller than No. 10 (A.W.G.) as part of its 4,160-volt longwall mining system. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

10. Leeco, Inc.

[Docket No. M–95–178–C]

Leeco, Inc., 100 Coal Drive, London, Kentucky 40741 has filed a petition to modify the application of 30 CFR 75.333(a) to its Mine No. 63 (I.D. No. 15–16413) located in Perry County, Kentucky. The petitioner proposes to use semipermanent stoppings in rooms where second mining is projected. The petitioner states that the semipermanent stoppings would be constructed of 6-inch, hollow-core concrete blocks, dry stacked and coated on one side with wood-fiber based plaster; and that application of the standard would result in a diminution of safety to the miners. In addition, the petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

11. White Oak Mining & Construction Company, Inc.

[Docket No. M–95–179–C]

White Oak Mining & Construction Company, Inc., Scofield Route, Helper, Utah 84526 has filed a petition to modify the application of 30 CFR 75.364(b)(4) to its White Oak Mine #2 (I.D. No. 42–01280) located in Carbon County, Utah. Due to deteriorating roof conditions, the Main East intake at the 2nd Right seals and the bleeder entry at the north end of the 2nd & 3rd Left panels cannot be traveled safely. The petitioner proposes to establish evaluation points to monitor the quantity and quality of air in the affected area. The petitioner states that application of the standard would result in a diminution of safety to the miners. In addition, the petitioner asserts that the proposed alternative method would

provide at least the same measure of protection as would the mandatory standard.

12. Performance Coal Company

[Docket No. M–95–180–C]

Performance Coal Company, P.O. Box 69, Naoma, West Virginia 25140 has filed a petition to modify the application of 30 CFR 75.333(d)(1) (ventilation controls) to its Upper Big Branch Mine South (I.D. No. 46–08436) located in Raleigh County, West Virginia. The petitioner proposes to use electronically operated Roll-Down Doors constructed of rubber material similar to those used in conveyor belts to control ventilation within the air course in the main entries instead of using heavy Metal Doors. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

13. Philippi Development, Inc.

[Docket No. M–95–181–C]

Philippi Development, Inc., 2708 Cranberry Square, Morgantown, West Virginia 26505 has filed a petition to modify the application of 30 CFR 75.350 (air course and belt haulage entries) to its Sentinel Mine (I.D. No. 46–04168) located in Barbour County, West Virginia. The petitioner proposes to install a carbon monoxide monitoring system as an early warning fire detection system in all belt entries used as intake air courses. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

14. Jacks Branch Coal Company

[Docket No. M–95–182–C]

Jacks Branch Coal Company, P.O. Box 567, Madison, West Virginia 25130 has filed a petition to modify the application of 30 CFR 75.333(d)(1) (ventilation controls) to its Mine No. 1 (I.D. No. 46–07273) located in Boone County, West Virginia. The petitioner proposes to use electronically operated Roll-Down Doors constructed of rubber material similar to those used in conveyor belts to control ventilation within the air course in the main entries instead of using heavy Metal Doors. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

15. Mountain Coal Company

[Docket No. M–95–183–C]

Mountain Coal Company, P.O. Box 591, Somerset, Colorado 81434 has filed a petition to modify the application of 30 CFR 75.1002–1(a) (location of other electric equipment; requirements for permissibility) to its West Elk Mine (I.D. No. 05–03672) located in Gunnison County, Colorado. The petitioner proposes to use non-permissible electronic testing or diagnostic equipment within 150 feet of pillar workings. The petitioner proposes to use low-voltage or battery operated non-permissible equipment such as, but not limited to, laptop computers, oscilloscopes, vibration analysis machines, and cable fault detectors. The petitioner states that application of the standard would result in a diminution of safety to the miners. In addition, the petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

16. Mountain Coal Company

[Docket No. M–95–184–C]

Mountain Coal Company, P.O. Box 591, Somerset, Colorado 81434 has filed a petition to modify the application of 30 CFR 75.500(d) (permissible electric equipment) to its West Elk Mine (I.D. No. 05–03672) located in Gunnison County, Colorado. The petitioner proposes to use non-permissible electronic testing or diagnostic equipment in or inby the last open crosscut. The petitioner proposes to use low-voltage or battery operated non-permissible equipment such as, but not limited to, laptop computers, oscilloscopes, vibration analysis machines, and cable fault detectors. The petitioner states that application of the standard would result in a diminution of safety to the miners. In addition, the petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

17. Rock of Ages Quarries, Inc.

[Docket No. M–95–12–M]

Rock of Ages Quarries, Inc., P.O. Box 482, Barre, Vermont 05641–0482 has filed a petition to modify the application of 30 CFR 56.19003 (driving mechanism connections) to its Rock of Ages Light Side (I.D. No. 43–00024), U–13 American Hoist, Serial Number H–4121, Model 380/2 located in Washington County, Vermont. The petitioner requests relief from the mandatory standard as it applies to chain drives between the driving mechanism and the gear train of the hoists, allowing the use of chain drives for such application. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

18. Rock of Ages Quarries, Inc.

[Docket No. M–95–13–M]

Rock of Ages Quarries, Inc., P.O. Box 482, Barre, Vermont 05641–0482 has filed a petition to modify the application of 30 CFR 56.19003 (driving mechanism connections) to its Rock of Ages Light Side (I.D. No. 43–00024), U–11 American Hoist, Serial Number H–3783, Model 250/4 located in Washington County, Vermont. The petitioner requests relief from the mandatory standard as it applies to chain drives between the driving mechanism and the gear train of the hoists, allowing the use of chain drives for such application. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

19. Rock of Ages Quarries, Inc.

[Docket No. M–95–14–M]

Rock of Ages Quarries, Inc., P.O. Box 482, Barre, Vermont 05641–0482 has filed a petition to modify the application of 30 CFR 56.19003 (driving mechanism connections) to its Rock of Ages Light Side (I.D. No. 43–00024), W–2 American Hoist, Serial Number 21878, Model 180/3 located in Washington County, Vermont. The petitioner requests relief from the mandatory standard as it applies to chain drives between the driving mechanism and the gear train of the hoists, allowing the use of chain drives for such application. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

20. Rock of Ages Quarries, Inc.

[Docket No. M–95–15–M]

Rock of Ages Quarries, Inc., P.O. Box 482, Barre, Vermont 05641–0482 has filed a petition to modify the application of 30 CFR 56.19003 (driving mechanism connections) to its Rock of Ages Light Side (I.D. No. 43–00024), U–1 American Hoist, Serial Number 22440, Model 180/3 located in Washington County, Vermont. The petitioner requests relief from the mandatory standard as it applies to chain drives between the driving mechanism and the gear train of the hoists, allowing the use of chain drives for such application. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

21. Rock of Ages Quarries, Inc.

[Docket No. M–95–16–M]

Rock of Ages Quarries, Inc., P.O. Box 482, Barre, Vermont 05641–0482 has filed a petition to modify the application of 30 CFR 56.19003 (driving mechanism connections) to its Rock of Ages Light Side (I.D. No. 43–00024), Clyde JJ/Hoist, Serial Number 11430 located in Washington County, Vermont. The petitioner requests relief from the mandatory standard as it applies to chain drives between the driving mechanism and the gear train of the hoists, allowing the use of chain drives for such application. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

22. Swenson Granite Company, Inc.

[Docket No. M–95–17–M]

Swenson Granite Company, Inc., 369 North State Street, Concord, New Hampshire 03301 has filed a petition to modify the application of 30 CFR 56.19003 (driving mechanism connections) to its Gray Quarry (I.D. No. 27–00083), Hilltop Derrick, Timberland Hoist, Serial Number 65–10943, Model 480–2–IR–100E located in Merrimack County, New Hampshire. The petitioner requests relief from the mandatory standard as it applies to chain drives between the driving mechanism and the gear train of the hoists, allowing the use of chain drives for such application. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

23. Swenson Granite Company, Inc.

[Docket No. M–95–18–M]

Swenson Granite Company, Inc., 369 North State Street, Concord, New Hampshire 03301 has filed a petition to modify the application of 30 CFR 56.19003 (driving mechanism connections) to its Gray Quarry (I.D. No. 27–00083), Lower Quarry, Clyde Hoist, Serial Number 21850, Frame 6/2 Drum located in Merrimack County, New Hampshire. The petitioner requests relief from the mandatory standard as it applies to chain drives between the driving mechanism and the gear train of the hoists, allowing the use of chain drives for such application. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

24. Rock of Ages Quarries, Inc.

[Docket No. M–94–37–M]

This notice amends this petition document published in the Federal Register on August 25, 1994 (59 FR 43869), to modify the application of 30 CFR 56.19003. This document is only for the Rock of Ages Light Side (I.D. No. 43–00024), for U–2 American Hoist, Serial Number 5645, Model 180/3 located in Washington County, Vermont. The petitioner requests relief from the mandatory standard as it applies to chain drives between the driving mechanism and the gear train of the hoists, allowing the use of chain drives for such application. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as would the mandatory standard.

Request for Comments

Persons interested in these petitions may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before April 3, 1996. Copies of these petitions are available for inspection at that address.

Date: February 23, 1996.

Patricia W. Silvey,

Director, Office of Standards, Regulations and Variances.

[FR Doc. 96–4866 Filed 3–1–96; 8:45 am]

BILLING CODE 4510–43–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–397]

Washington Public Power Supply System (WPPSS); Notice of Consideration of Issuance of Amendment to Facility Operating License and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF–21, issued to the Washington Public Power Supply System (the Supply System, or the licensee), for operation of the WPPSS Nuclear Project No. 2, located in Benton County, Washington.

The proposed amendment would modify the technical specifications (TS) to reflect replacement of the existing reactor recirculation (RRC) flow control system with an adjustable speed drive (ASD) system. The current system relies on operation of the RRC pumps at two discrete speeds, using flow control valves to vary the flow in the RRC system. Following the design change, the flow control valves and the existing pump controllers would be deactivated in place. The existing analog-hydraulic flow control system will be replaced with dual channel, variable frequency ASDs and a digital recirculation flow control system that would vary RRC flow by varying RRC pump speed. The proposed TS changes would reflect the new RRC flow control system.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

By March 29, 1996, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Richland Public Library, 955 Northgate Street, Richland, Washington 99352. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) the nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible

effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1–(800) 248–5100 (in Missouri 1–(800) 342–6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to William H. Bateman, Director, Project Directorate IV–2, MS O–13–E–18, Washington, D.C. 20555: petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this Federal Register notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to M.H. Philips, Jr., Esq., Winston & Strawn, 1400 L Street, N.W., Washington, D.C., 20005–3502, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1) (i)–(v) and 2.714(d).

If a request for a hearing is received, the Commission's staff may issue the amendment after it completes its technical review and prior to the completion of any required hearing if it publishes a further notice for public comment of its proposed finding of no significant hazards consideration in accordance with 10 CFR 50.91 and 50.92.

For further details with respect to this action, see the application for amendment dated October 26, 1995, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Richland Public Library, 955 Northgate Street, Richland, Washington 99352.

Dated at Rockville, Maryland, this 27th day of February 1996.

For the Nuclear Regulatory Commission.

James W. Clifford,

Senior Project Manager, Project Directorate IV–2, Division of Reactor Projects—III/IV, Office of Nuclear Reactor Regulation.

[FR Doc. 96–4943 Filed 3–1–96; 8:45 am]

BILLING CODE 7590–01–P

[Docket Nos. 50–424 and 50–425]

Georgia Power Company, et al.; Vogtle Electric Generating Plant, Units 1 and 2 Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of amendments to Facility Operating License Nos. NPF–68 and NPF–81, issued to Georgia Power Company, et al. (the licensee) for operation of the Vogtle Electric Generating Plant (Vogtle), Units 1 and 2, located at the licensee's site in Burke County, Georgia.

Environmental Assessment

Identification of Proposed Action

This Environmental Assessment has been prepared to address potential environmental issues related to the licensee's application dated May 1, 1995, as supplemented by letters dated August 3 and 9, September 22, November 20, and December 21, 1995, and January 26 and 30, 1996. The proposed action will replace the existing Vogtle Technical Specifications (TS) in their entirety with a new set of TS based on Revision 1 to NUREG–1431, ''Standard Technical Specifications Westinghouse Plants,'' and the existing VEGP TS.

The Need for the Proposed Action

It has been recognized that nuclear safety in all plants would benefit from improvement and standardization of TS. The ''NRC Interim Policy Statement on Technical Specification Improvements for Nuclear Power Reactors,'' (52 FR 3788, February 6, 1987), and later the Final Policy Statement (58 FR 39132, July 22, 1993), formalized this need. To facilitate the development of individual improved TS, each reactor vendor owners group (OG) and the NRC staff developed standard TS (STS). For Westinghouse plants, the STS are published as NUREG–1431, and this document was the basis for the new Vogtle TS. The NRC Committee to Review Generic Requirements (CRGR) reviewed the STS and made note of the safety merits of the STS and indicated its support of conversion to the STS by operating plants.

Description of the Proposed Change

The proposed revision to the TS is based on NUREG–1431 and on guidance provided in the Final Policy Statement. Its objective is to completely rewrite, reformat, and streamline the existing TS. Emphasis is placed on human factors principles to improve clarity and understanding. The Bases section has

been significantly expanded to clarify and better explain the purpose and foundation of each specification. In addition to NUREG–1431, portions of the existing TS were also used as the basis for the improved TS (ITS). Plant-specific issues (unique design features, requirements, and operating practices) were discussed at length with the licensee, and generic matters with the OG.

The proposed changes from the existing TS can be grouped into four general categories, as follows:

1. Non-technical (administrative) changes, which were intended to make the ITS easier to use for plant operations personnel. They are purely editorial in nature or involve the movement or reformatting of requirements without affecting technical content. Every section of the Vogtle TS has undergone these types of changes. In order to ensure consistency, the NRC staff and the licensee have used NUREG–1431 as guidance to reformat and make other administrative changes.

2. Relocation of requirements, which includes items that were in the existing Vogtle TS but did not meet the criteria set forth in the Final Policy Statement for inclusion in the TS. In general, the proposed relocation of items in the Vogtle TS to the Final Safety Analysis Report (FSAR), appropriate plant-specific programs, procedures and ITS Bases follows the guidance of the Westinghouse STS (NUREG–1431). Once these items have been relocated by removing them from the TS to licensee-controlled documents, the licensee may revise them under the provisions of 10 CFR 50.59 or other NRC staff-approved control mechanisms, which provide appropriate procedural means to control changes.

3. More restrictive requirements, which consist of proposed Vogtle ITS items that are either more conservative than corresponding requirements in the existing Vogtle TS, or are additional restrictions that are not in the existing Vogtle TS but are contained in NUREG–1431. Examples of more restrictive requirements include: placing a Limiting Condition of Operation (LCO) on plant equipment that is not required by the present TS to be operable; more restrictive requirements to restore inoperable equipment; and more restrictive surveillance requirements.

4. Less restrictive requirements, which are relaxations of corresponding requirements in the existing Vogtle TS that provide little or no safety benefit and place unnecessary burdens on the licensee. These relaxations were the result of generic NRC actions or other analyses. They have been justified on a case-by-case basis for Vogtle as will be described in the staff's Safety Evaluation to be issued with the license amendments, which will be noticed in the Federal Register.

In addition to the changes described above, the licensee proposed certain changes to the existing TS that deviated from the STS in NUREG–1431. Each of these additional proposed changes is described in the licensee's application and in the staff's Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Opportunity for a Hearing (60 FR 46633). These changes have been justified on a case-by-case basis for Vogtle as will be described in the staff's Safety Evaluation to be issued with the license amendments.

Environmental Impacts of the Proposed Action

The Commission has completed its evaluation of the proposed action and concludes that the proposed TS conversion would not increase the probability or consequences of accidents previously analyzed and would not affect facility radiation levels or facility radiological effluents.

Changes that are administrative in nature have been found to have no effect on the technical content of the TS, and are acceptable. The increased clarity and understanding these changes bring to the TS are expected to improve the operator's control of the plant in normal and accident conditions.

Relocation of requirements to licensee-controlled documents does not change the requirements themselves. Future changes to these requirements may be made by the licensee under 10 CFR 50.59 or other NRC-approved control mechanisms, which ensures continued maintenance of adequate requirements. All such relocations have been found to be in conformance with the guidelines of NUREG–1431 and the Final Policy Statement, and, therefore, are acceptable.

Changes involving more restrictive requirements have been found to be acceptable and are likely to enhance the safety of plant operations.

Changes involving less restrictive requirements have been reviewed individually. When requirements have been shown to provide little or no safety benefit or to place unnecessary burdens on the licensee, their removal from the TS was justified. In most cases, relaxations previously granted to individual plants on a plant-specific basis were the result of a generic NRC action, or of agreements reached during discussions with the OG and found to be acceptable for Vogtle. Generic relaxations contained in NUREG–1431 as well as proposed deviations from NUREG–1431 have also been reviewed by the NRC staff and have been found to be acceptable.

In summary, the proposed revision to the TS was found to provide control of plant operations such that reasonable assurance will be provided so that the health and safety of the public will be adequately protected.

These TS changes will not increase the probability or consequences of accidents, no changes are being made in the types of any effluent that may be released offsite, and there is no significant increase in the allowable individual or cumulative occupational radiation exposure. Therefore, the Commission concludes that there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential nonradiological impacts, the proposed action involves features located entirely within the restricted area as defined in 10 CFR Part 20. It does not affect nonradiological plant effluents and has no other environmental impact. Accordingly, the Commission concludes that there are no significant nonradiological environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

Since the Commission has concluded there is no measurable environmental impact associated with the proposed amendments, any alternatives with equal or greater environmental impact need not be evaluated. The principal alternative to this action would be to deny the request for amendments. Such action would not reduce the environmental impacts of plant operations.

Alternative Use of Resources

This action did not involve the use of any resources not previously considered in the Final Environmental Statement related to the operation of the Vogtle Electric Generating Plant.

Agencies and Persons Consulted

In accordance with its stated policy, on February 8, 1996, the staff consulted with the Georgia State official, Mr. James Hardeman of the Environmental Protection Division, Georgia Department of Natural Resources, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

Based upon the environmental assessment, the Commission concludes

that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed amendments.

For further details with respect to this action, see the licensee's letter dated May 1, 1995, and supplemental letters dated August 3 and 9, September 22, November 20, and December 21, 1995, and January 26 and 30, 1996, which are available for public inspection at the Commission's Public Document Room, The Gelman Building, 2120 L Street NW., Washington, DC, and at the local public document room located at the Burke County Library, 412 Fourth Street, Waynesboro, Georgia.

Dated at Rockville, Maryland, this 27th day of February 1996.

For the Nuclear Regulatory Commission.

Leonard A. Wiens,

Acting Director, Project Directorate II–2, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 96–4942 Filed 3–1–96; 8:45 am]

BILLING CODE 7590–01–P

Notice of Organization of Agreement States Technical Workshop

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) and Agreement State staffs plan to hold a public meeting with various vendors for the purpose of discussing and clarifying an NRC draft Information Notice on how radiography licensees can verify that their associated equipment meets the requirements of 10 CFR 34.20. Vendors are being invited to provide procedures for identifying associated equipment they manufacture. Agreement States are States which have assumed regulatory authority over certain radioactive materials. NRC expects to use the findings from this meeting to finalize an Information Notice on identification of associated equipment. This meeting will be held a day in advance of the previously announced March 5–6, 1996 Organization of Agreement States technical meeting, in which Agreement State Program issues, including this issue, will be discussed with Agreement State technical representatives (61 FR 5414).

DATES: The meeting will be held from 2:00 p.m. til 5:00 p.m on March 4, 1996.

ADDRESSES: The meeting will be held at the Red Lion Inn at the Quay, 100 Columbia Street, Vancouver, Washington, 360/694–8341. Vancouver is located directly across the Columbia River from Portland, Oregon, and is served by the Portland airport.

FOR FURTHER INFORMATION CONTACT: James H. Myers, Office of State Programs, Mail Stop OWFN–3–D–23, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone 301/415–2328.

CONDUCT OF THE MEETING: The meeting will be conducted in a manner that will expedite the orderly conduct of business. The following procedures apply to public attendance at the meeting:

1. Questions or statements will be entertained as time permits on a first-come, first-served basis, following discussion and summary.

2. Seating will be on a first-come, first-served basis.

Dated at Rockville, Maryland, this 26th day of February, 1996.

For the Nuclear Regulatory Commission.

Richard L. Bangart,

Director, Office of State Programs.

[FR Doc. 96–4941 Filed 3–1–96; 8:45 am]

BILLING CODE 7590–01–P

Notice of Spent Fuel Storage and Transportation Public Workshop

The Nuclear Regulatory Commission will conduct a public workshop on May 17, 1996, to discuss the NRC's Spent Fuel Storage and Transportation Program. This program focuses the agency's efforts on the important issues associated with interim storage and transportation of spent fuel from the nation's nuclear power generators. The purpose of the workshop is to provide applicants, licensees, and other interested parties with an understanding of staff initiatives and to provide an opportunity for interested parties to obtain both NRC and licensee perspectives on issues associated with spent fuel management.

The workshop will focus on participant experience gained through the licensing and inspection programs for dry cask storage. The NRC staff will discuss current and planned staff initiatives, including the development of staff guidance for both the licensing and inspection programs. The staff will also be interested in obtaining feedback on its ''Draft Standard Review Plan For Independent Spent Fuel Storage Casks.'' A tentative agenda is provided below in the Supplementary Information section.

TIME AND LOCATION: The workshop will be held on May 17, 1996, from 8:30 am to 4:30 pm, at the NRC Auditorium. The NRC Auditorium is located in the Two White Flint North Building at 11545 Rockville Pike, Rockville, MD. The White Flint Metro Station is located at the intersection of Marinelli Drive and Rockville Pike. The NRC complex is directly across Marinelli Drive from the Metro Station.

REGISTRATION: To ensure availability of adequate copies of workshop materials, pre-registration is requested by April 15, 1996, to Mr. James Schneider via mail to the U.S. Nuclear Regulatory Commission, Mail Stop O–6–F–18, Washington, DC 20555–0001; telephone (301) 415–8523; or facsimile (301) 415–8555. When registering, please provide the full name of attendee(s), name of organization, mailing address, daytime telephone number, and facsimile number.

SUPPLEMENTARY INFORMATION:

Tentative Agenda

8:30 Introduction
- The Licensing Process
  - —10 CFR Parts 71 and 72
  - —10 CFR Part 50 Interface
- NRC Experience with Dry Cask Storage
  - —Licensing and Inspection Observations and Lessons Learned
- Break
- NRC Experience with Dry Cask Storage (cont'd)
  - —NRC Action Plan
  - —Change Processes (10 CFR 50.59 and 10 CFR 72.48)
  - —Quality Assurance and Inspections

12:00 Lunch

1:00 Industry Experience With Dry Cask Storage
- Break
- Staff Initiatives and Feedback
  - —Development and Implementation—Standard Review Plan and Inspection Procedures
  - —Communications—NRC, Industry, and the Public Workshop Summary

4:30 Adjournment

Note: Time for questions and discussion has been allotted at the end of each presentation.

For further information contact Mark S. Delligatti, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards, Mail Stop 0–6–G–22, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–8518.

Dated at Rockville, Maryland, this 27th day of February 1996.

For the Nuclear Regulatory Commission.

William D. Travers,

Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 96–4939 Filed 3–1–96; 8:45 am]

BILLING CODE 7590–01–P

Sunshine Act Meeting

NUCLEAR REGULATION COMMISSION

DATE: Thursday, March 7, 1996.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public

MATTERS TO BE CONSIDERED:

Thursday, March 7

4:00 p.m.

Affirmation Session (Public Meeting)

a. Cleveland Electric Illuminating Co.—Licensee's Petition for Review of LBP–95–17

(Contact: Andrew Bates, (301) 415–1963)

The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (Recording)—(301) 415–1292.

CONTACT PERSON FOR MORE INFORMATION: Bill Hill (301) 415–1661.

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to it, please contact the Office of the Secretary, Attn: Operations Branch, Washington, D.C. 20555 (301–415–1963).

In addition, distribution of this meeting notice over the internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to alb@nrc.gov or gkt@nrc.gov.

Dated: February 28, 1996.

William M. Hill, Jr.,

Secy Tracking Officer, Office of the Secretary.

[FR Doc. 96–5101 Filed 2–29–96; 1:12 pm]

BILLING CODE 7590–01–M

Regulatory Guide; Issuance, Availability

The Nuclear Regulatory Commission has issued a new guide in its Regulatory Guide Series. This series has been developed to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the Commission's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and data needed by the staff in its review of applications for permits and licenses.

Regulatory Guide 1.162, ''Format and Content of Report for Thermal Annealing of Reactor Pressure Vessels,'' describes a format and content acceptable to the NRC staff for the Thermal Annealing Report to be submitted to the NRC for describing the licensee's plan for thermal annealing a reactor vessel. This guide also describes the Thermal Annealing Results Report that must be submitted after the thermal annealing.

Comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time. Written comments may be submitted to the Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

Regulatory guides are available for inspection at the Commission's Public Document Room, 2120 L Street NW., Washington, DC. Single copies of regulatory guides may be obtained free of charge by writing the Office of Administration, Attention: Distribution and Services Section, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; or by fax at (301) 415–2260. Issued guides may also be purchased from the National Technical Information Service on a standing order basis. Details on this service may be obtained by writing NTIS, 5285 Port Royal Road, Springfield, VA 22161. Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

(5 U.S.C. 552(a))

Dated at Rockville, Maryland, this 15th day of February 1996.

For the Nuclear Regulatory Commission.

David L. Morrison,

Director, Office of Nuclear Regulatory Research.

[FR Doc. 96–4940 Filed 3–1–96; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35–26479]

Filings Under the Public Utility Holding Company Act of 1935, as Amended (''Act'')

February 26, 1996.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by March 21, 1996, to the Secretary, Securities and Exchange Commission, Washington, DC 20549, and serve a copy of the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

The Columbia Gas System, Inc. (70–8791)

Notice of Proposal to Issue Common Stock; Order Authorizing Solicitation of Proxies

The Columbia Gas System, Inc. (''Columbia''), 20 Montchanin Road, Wilmington, Delaware, 19807, a registered holding company, has filed a declaration under sections 6(a), 7, 12(c) and 12(e) of the Act and rules 42, 62 and 65 thereunder.

Columbia proposes to adopt, subject to shareholder approval at the annual meeting of shareholders to be held on April 26, 1996 (''1996 Annual Meeting''), The Columbia Gas System, Inc. Long-Term Incentive Plan (''Plan''). The Columbia Board of Directors (''Board'') approved the Plan on December 20, 1995. Columbia states that the purpose of the Plan is to provide incentives to specific individuals to attract, retain and motivate certain employees and directors and to align the interests of these individuals with the shareholders' interests.

The Plan provides long-term incentives to (1) officers and key employees (''Employees'') of Columbia and its subsidiaries (the ''System'') who, in the opinion of the Compensation Committee of Columbia's Board (''Committee''), may be able to make substantial contributions to the System by their ability and efforts; and (2) members of the Board who are not employees (''Outside Directors''). The Plan authorizes as incentive awards: stock options, including incentive and nonqualified stock options; stock appreciation rights (''SARs''); contingent stock; restricted stock; and awards in other forms, including a combination of the foregoing, that the Committee may

deem appropriate and consistent with the Plan's purpose. Employees could receive any form of award, while Outside Directors are eligible only for nonqualified stock option awards in accordance with a formula contained in the Plan.

Up to three million shares of common stock, $10 par value, may be granted under the Plan, subject to equitable adjustment in certain instances to prevent dilution or enlargement of the participants' rights. No more than 20% of the total shares authorized for issuance under the Plan, or 600,000 shares, may be awarded pursuant to the contingent and restricted stock award provisions. The maximum number of shares that may be awarded to any individual during the life of the Plan will be 20% of the total shares authorized for issuance under the Plan, or 600,000 shares. Shares issued under the Plan may be authorized and unissued shares or treasury shares. Shares of common stock subject to options and awards that expire or terminate for reasons other than the exercise of a SAR would be available again for awards under the Plan.

The Board may suspend, terminate or amend the Plan; the Board may not, however, without Commission authorization, if required, and shareholder approval, adopt an amendment that would: (1) Materially increase the benefits accruing to participants; (2) materially increase the maximum number of shares that may be issued under the Plan; (3) materially modify the Plan's eligibility requirements; or (4) change the basis on which awards are granted to Outside Directors. Columbia reserves the right to terminate all or part of the Plan for any reason, so long as participants are equitably compensated for their interests.

The portion of the Plan applicable to Employees will be administered by the Committee, which is composed of Outside Directors who qualify as ''disinterested persons'' under Rule 16b–3 of the Securities Exchange Act of 1934, as amended (''Exchange Act''), and as ''outside directors'' under Section 162(m) of the Internal Revenue Code of 1986, as amended (''IRC''), and the regulations thereunder. In administering the Plan for Employees, the Committee will have full and final authority in its discretion to interpret the provisions of the Plan conclusively and to decide all questions of fact arising in its application; to determine the Employees to who awards shall be made and the type of award to be made and the amount, size and terms of each such award; to determine the time when awards will be granted; to make all other determinations necessary or advisable for the administration of the Plan; and to accelerate the exercise period of an option or the restriction/contingency period of restricted and continent stock awards.

The Committee also will administer the portions of the Plan applicable to Outside Directors, but only with respect to ministerial matters. Columbia states that the Plan is designed to be a ''formula plan'' for Outside Directors meeting the requirements of Exchange Act Rule 16b–3(c)(2) and, accordingly, is intended to be self-governing. The Committee will have no discretion with respect to the amount, price and timing of awards to Outside Directors. The Plan may not be amended more than once every six months except as may be consistent with Exchange Act Rule 16b–3(c)(2)(ii)(B).

Nonqualified stock option awards will be made to Outside Directors if Columbia's total shareholder return (market appreciation and dividends declared in a year) for a fiscal year exceeds the median of the total shareholder return for the peer group of companies utilized for comparison purposes in Columbia's annual proxy statement. If Columbia's total shareholder return falls within the third quartile (between 50% and 75%) or the fourth quartile (between 75% and 100%) of the peer group, then options will be granted to each Outside Director to purchase 3,000 or 6,000 shares of Columbia common stock, respectively. No award options will be made to Outside Directors if total shareholder return is at or below the median.

Outside Director's nonqualified stock option awards would be granted effective as of 90 days after the close of Columbia's fiscal year for total shareholder return performance for the preceding fiscal year. Grants to Outside Directors would vest one-third upon the date of the grant, one-third upon the first anniversary of the grant, and one-third upon the second anniversary of the grant. The purchase price per share of stock for Outside Directors' awards would be 100% of the fair market value of the stock on the day the option is granted, less any dividends paid as long as the option is outstanding, but no less than par value. Fair market value is the average of the high and low sales prices per share of Columbia's common stock on the New York Stock Exchange as reported in the Wall Street Journal for a given date. In all other respects and to the extent consistent with Exchange Act Rule 16b–3(c)(2), Outside Director stock options will be governed by the provisions of the Plan governing Employee options.

Options will be evidenced by stock option agreements with, in substance, the following terms and conditions. The purchase price per share deliverable upon the exercise of an incentive stock option will be 100% of the fair market value of the stock on the day the option is granted. The purchase price per share deliverable upon the exercise of a nonqualified stock option will be 100% of the fair market value of the stock on the day the option is granted, less any dividends paid while the option is outstanding, but no less than the par value of the stock. The option period will not start earlier than six months or end not more than ten years after the date of the grant of the option. The Committee may permit an acceleration of the previously determined exercise terms, subject to the terms of the Plan and to the extent permitted by Exchange Act Rule 16b–3(c). If an optionee ceases to be an Employee of the System or an Outside Director of Columbia for any cause other than death, disability or retirement or a change in control, the optionee may be able to exercise the option during its term within a period of three months after such termination. Incentive stock option agreements may contain such terms, conditions and provisions as the Committee may determine to be necessary or desirable to qualify the option as a tax-favored option under the IRC. Stock purchased pursuant to an option agreement is to be paid for in full at the time of purchase, either in the form of cash, common stock of Columbia at fair market value or in a combination thereof, as determined by the Committee.

SARS may be granted in connection with options and will entitle the grantee to receive all or a portion of the excess of (1) the fair market value of a specified number of shares of Columbia's common stock at the option's surrender, over (2) 100% of the fair market value of the same number of shares at the time the option was granted, less any dividends paid while the option was outstanding but unexercised. SARs will be granted for a period of not less than six months nor more than 10 years. No SAR will exercisable during the first six months from the date of the grant or after a grantee's employment by the System is terminated, except that the Committee may permit an SAR to be exercisable for up to three months after the grantee's employment is terminated. If the termination was due to death, retirement or disability, however, the grantee or his successor may be able to exercise the SAR within 24 months after the date of the termination. The

Committee may reserve the right to accelerate previously determined exercise terms.

In contingent stock awards, the stock is not issued until the right to receive the stock is vested. For restricted stock awards, shares will be issued in the name of the recipient, but the recipient will not receive them until the specified restrictions lapse, or if he receives them, the shares will bear a legend referring to all applicable restrictions. Attempts to dispose of such stock in contravention of the restrictions will be ineffective. Recipients of restricted stock awards will have all the rights of a stockholder during the restricted period.

Under contingent and restricted stock awards, Employees are given the right to receive shares of stock when the specified contingencies and/or restrictions are satisfied. The Committee may determine such restrictions and, except for an initial six month period, may accelerate any applicable contingency or restriction period. Termination of employment for any reason prior to the lapse of contingencies or restrictions and unless otherwise provided for in the Plan or award agreement will result in the forfeiture by the participant to Columbia, without payment or any other consideration, of all rights to the shares as to which there remain unlapsed contingencies or restrictions. If a recipient of a contingent or restricted stock award is terminated but continues to receive a salary because of an agreement, severance program or other arrangement, then contingencies and restrictions that are or could have been satisfied during the period the salary payments are continued will be deemed to have been satisfied and the applicable shares will be issued and delivered to the recipient before the salary payments are ended.

Upon a change in control, all contingent, restricted and stock option awards (including SARs) automatically vest and all restrictions or contingencies will be deemed to have been satisfied. A change in control will occur upon: (1) the acquisition by any party or parties of the beneficial ownership of 25% or more of the voting shares of Columbia; (2) the occurrence of a transaction requiring shareholders' approval for the acquisition of Columbia through purchase or exchange of stock or assets, or by merger or otherwise; or (3) the election during a period of 24 months or less of 30% or more of the members of the Board, without the approval of a majority of the Board as constituted at the beginning of the period.

Columbia proposes to submit the Plan for consideration and action by its stockholders at the annual meeting to be held on April 26, 1996, and in connection therewith, to solicit proxies from its stockholders. Consequently, Columbia requests that the effectiveness of its declaration with respect to such solicitation of proxies be permitted to become effective as soon as practicable as provided in rule 62(d).

It is stated that no state or federal commission, other than this Commission, has jurisdiction over the proposed transactions.

It appearing to the Commission that Columbia's declaration regarding the proposed solicitation of proxies should be permitted to become effective forthwith, pursuant to rule 62:

It is Ordered, that the declaration regarding the proposed solicitation of proxies be, and it hereby is, permitted to become effective forthwith, pursuant to rule 62 and subject to the terms and conditions prescribed in rule 24 under the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–4883 Filed 3–1–96; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–36892; File No. 4–388]

Symposium on Intangible Assets

AGENCY: Securities and Exchange Commission.

ACTION: Notice of symposium.

SUMMARY: The Securities and Exchange Commission (''Commission'') is announcing that it will hold a symposium on issues related to the financial accounting and reporting of intangible assets. The symposium will have various panels that will address such topics as the nature and types of intangible assets, including intellectual property, human capital, research and development, software and related items. Discussion at the symposium also will center upon the types of companies that utilize intangible assets, the importance of disclosure relating to these assets from the perspective of investors and other users of financial reporting, and the sources of information relating to intangible assets. Invited panelists also will discuss issues related to the measurement of intangible assets by preparers of financial reports, concerns about disclosures related to intangible assets, academic research pertaining to such assets, and the experience of U.S. and foreign standards setters with regard to accounting and disclosure of intangible assets. The symposium will conclude with a general discussion of issues raised by the various panels and measures that might be taken to address these issues.x

Invited panelists will include academics engaged in the study of intangible assets, representatives of U.S. and foreign companies that utilize intangibles, and various representatives of the accounting profession and standard setting community. A list of the panelists will be published at a later date.

DATES: The symposium will be held on Thursday, April 11, 1996 from 1:00 p.m. to 5:30 p.m., and on Friday, April 12, 1996 from 9:00 a.m. to 4:30 p.m..

ADDRESSES: The symposium will take place in Room 1C–30 at the Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549.

FOR FURTHER INFORMATION CONTACT: The symposium is open to the public. Members of the public planning to attend the symposium are encouraged to contact Terry Warfield at (202) 942–4400 or Andre Owens at (202) 942–0800.

Dated: February 27, 1996.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–4886 Filed 3–1–96; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–36888; File No. SR–Amex–96–07]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the American Stock Exchange, Inc. Relating to Minor Corrections to the Exchange's Company Guide

February 26, 1996.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on February 5, 1996, the American Stock Exchange, Inc. (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. On February 15, and February 26, 1996, the Exchange submitted Amendments No. 1 and 2 to the proposed rule change to the Commission.[2] The Commission is

[1] 15 U.S.C. 78s(b)(1).

[2] Amendment No. 1 corrected the proposed renumbering of existing Item 6 of Section 212 of the *Company Guide* and redesignated the proposed rule change as a ''noncontroversial'' filing under Section

Continued

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 is proposing to make several minor corrections to its *Company Guide.* The text of the proposed rule change is available at the Office of the Secretary, the Amex, and at the Commission.

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 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 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 Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to make several minor corrections to its *Company Guide.* First, Section 108 is being amended to delete its prohibition against listing voting trust certificates. With the adoption of the uniform voting rights policy on December 19, 1994, which eliminated the Exchange's prohibition against listing non-voting stock, the Exchange believes that it is no longer appropriate to retain this restriction as to voting trust certificates because such certificates may be eligible for listing if the issuer is otherwise in conformance with the policy. Due to an oversight, Section 108 was not amended at the time Section 122 was amended to adopt the uniform voting rights policy.[3]

Second, Section 140 of the *Company Guide* is being amended to delete the reference to ''long-term'' warrants. All warrants listed on the Exchange are subject to the same fee schedule, and the inadvertent inclusion of the phrase ''long-term'' is confusing to issuers.

Third, Section 212 of the *Company Guide* is being corrected to delete several superfluous items. The Exchange no longer requires that the information referenced in Items 3(a), 4 and 5 be included in a listing application because such information is contained in other documents submitted by listing applicants in connection with the application. The requirement that this information be reiterated on the listing application is unduly confusing to listing applicants. Additionally, the requirement in Item 6 that the applicant's corporate seal be affixed to the certificate submitted in connection with the application is being deleted because the use of a corporate seal is not necessary to authenticate the officer's signature on the certificate, and some companies no longer have corporate seals.

Finally, as a result of the above deletions to Section 212, two additional changes are being made. First, the requirement that applicants for listing indicate the number of shares outstanding of any class of stock that is not being listed, the quantity of shares reserved for future issuance, and the purpose for which such shares have been reserved is being moved from Item 3(b) to Item 1. Second, Item 6 is being renumbered as Item 3.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act[4] in general and furthers the objectives of Section 6(b)(5)[5] in particular in that it is designed to foster cooperation and coordination with persons engaged in regulating and processing information with respect to transactions in securities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose 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 Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) the Exchange provided the Commission with written notice of its intent to file the proposed rule change at least five business days prior to the filing date, it has become effective pursuant to Section 19(b)(3)(A) of the Act[6] and Rule 19b–4(e)(6) thereunder.[7]

A proposed rule change filed under Rule 19b–4(e)[8] does not become operative prior to thirty days after the date of filing or such shorter time as the Commission may designate if such action is consistent with the protection of investors and the public interest. In order for the Exchange to include the proposed rule changes in its pending printing of the *Company Guide,* the Amex has requested that the Commission accelerate the implementation of the proposed rule change so that it may take effect prior to the thirty days specified under Rule 19b–4(e)(iii).[9] The Commission finds that the proposed rule change is consistent with the protection of investors and the public interest and therefore has determined to make the proposed rule change operative as of the date of this order.

19(b)(3)(A) and Rule 19b–4(e)(6)(iii) thereunder. *See* Letter dated February 15, 1996, from Claudia Crowley, Special Counsel, Amex, to Glen Barrentine, Senior Counsel/Team Leader, SEC. Amendment No. 2 further amends Section 212 by moving from Item 3(b) to Item 1 the requirement that applicants for listing indicate the number of shares outstanding of any class of stock that is not being listed, the quantity of shares reserved for future issuance, and the purpose for which such shares have been reserved. *See* Letter dated February 26, 1996, from Claudia Crowley, Special Counsel, Amex, to Glen Barrentine, Senior Counsel/Team Leader, SEC.

[3] The Commission notes that the Amex would have to apply its voting rights policy in Section 122 to voting trusts.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78s(b)(3)(A).

[7] 17 CFR 240.19b–4(e)(6).

[8] 17 CFR 240.19b–4(e).

[9] 17 CFR 240.19b–4(e)(6)(iii).

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Intersted persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six opies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 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 at the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Also, copies of such filing will be available for inspection and copying at the principal office of the Amex. All submissions should refer to File No. SR–Amex–96–07 and should be submitted by March 25, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–4884 Filed 3–1–96; 8:45 am]

BILLING CODE 8010–01–M

[10] 17 CFR 200.30–3(a)(12).

[Release No. 34–36885; International Series Release No. 939; File No. SR–AMEX–95–50]

Self-Regulatory Organizations; American Stock Exchange, Inc.; Order Approving Proposed Rule Change Relating to the Listing and Trading of Commodity Indexed Securities

February 26, 1996

I. Introduction

On December 11, 1995, the American Stock Exchange, Inc. (''Amex'' or ''Exchange'') submitted to the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade commodity indexed preferred or debt securities (''ComPS''), whose value will be linked to the price of a single commodity.

Notice of the proposed rule change was published for comment and appeared in the Federal Register on January 3, 1996.[3] No comments were received on the proposal. This order approves the proposal.

II. Description of Proposal

Under Section 107 of the Amex Company Guide, the Exchange may approve for listing and trading securities which cannot be readily categorized under the listing criteria for common and preferred stocks, bonds, debentures and warrants. The Amex now proposes to list for trading ComPS, which will conform to the Amex's listing guidelines under Section 107 of the Company Guide.[4] Accordingly, all issuances of ComPS must have: (1) A public distribution of one million trading units; (2) 400 holders; and (3) a market value of not less than $4 million. The Exchange also will require that the issuer have a minimum tangible net worth of $150 million. In addition, the Exchange will require that the total original issue price of the notes (when combined with all of the issuer's commodity linked notes which are listed on a national securities exchange or traded through the facilities of NASDAQ), shall be greater than 25% of the issuer's tangible net worth at the time of issuance.

Holders of ComPS generally will receive a dividend or interest as applicable on the face value of their securities. The frequency and rate of the dividend or interest payment will vary from issue to issue based upon prevailing interest rates and other factors. In addition, investors will receive at maturity a payment linked to the price of a single commodity in accordance with the following formula:

Fact Amount * (Ending Commodity Price/Beginning Commodity Price)

Commodity prices will be determined in a manner as described in greater detail below. In addition, commodity prices for the purpose of determining the payment to holders at maturity will be determined by reference to prices for a linked commodity over at least a ten business day period. The securities will have a term of from two to ten years. Holders of the securities have no claim to any of the underlying physical linked commodities. Under the proposal, the Exchange may only link different issues of ComPS to the following commodities: West Texas Intermediate (''WTI'') crude oil, natural gas, unleaded gasoline, hearing oil, alumium (''Al''), copper (''Cu''), zinc (''Zn''), nickel (''Ni''), gold, silver and platium.

The prices for the commodities linked to the proposed ComPS will be based upon: (i) London Metal Exchange (''LME'') closing prices for the futures contracts expiring the third Wednesday of March, June, September and December (with respect to the linked base metals); (ii) New York Mercantile Exchange (''NYMEX'') official settlement prices for the near term futures contract expiring every month (with respect to the linked energy commodities); (iii) NYMEX official settlement prices for the platium contract expiring January, April, July and October; (iv) Commodity Exchange (''COMEX'') official settlement prices for the gold contract expiring February, April, June, August and December; and (v) COMEX official settlement prices for the silver contract expiring March, May, July, September and December.

These prices are widely reported by vendors of financial information and the press. The following charts describe the linked contracts:

[1] 15 U.S.C. § 78s(b)(1) (1988).

[2] 17 CFR § 240.19b–4 (1993).

[3] *See* Securities Exchange Act Release No. 36639 (Dec. 27, 1995), 61 FR 196.

[4] The proposed underwriter of ComPS has advised the Exchange that the securities will comply with the ''hybrid exemption'' of the Commodity Futures Trading Commission (''CFTC'') under 17 CFR Part 34. The underwriter has further advised the Exchange that it has presented a description of the structure and sample term sheet of ComPS to the staff of the CFTC, who have raised no objection to the structure.

Official Commodity Name and Units	Exchange	Units per contract	Contract used for ComPS
1. Aluminum $/MT (Metric Tons)	LME	25 tons	Third Wednesday of Mar, Jun, Sep and Dec.
2. Copper $/MT	LME	25 tons	Third Wednesday of Mar, Jun, Sep and Dec.
3. Nickel $/MT	LME	6 tons	Third Wednesday of Mar, Jun, Sep and Dec.
4. Zinc $/MT	LME	25 tons	Third Wednesday of Mar, Jun, Sep and Dec.
5. Heating Oil #2 $/gal	NYMEX	42,000 gal	Every month.
6. Natural Gas $/MM BTU	NYMEX	10,000 MM BTU	Every month.
7. Unleaded Gas $/gal	NYMEX	42,000 gal	Every month.
8. WTI Light Sweet Crude $/BBL	NYMEX	1,000 bbl	Every month.
9. Platinum $/troy oz	NYMEX	50 troy oz	Jan, Apr, Jul, Oct.
10. Gold	COMEX	100 troy oz	Feb, Apr, Jun, Aug and Dec.
11. Silver	COMEX	5,000 troy oz	Mar, May, Jul, Sep and Dec.

Commodity	Avg. daily volume (in contracts)	Avg. open interest (in contracts)
A1	58,417	257,886
Cu	68,945	207,748
Ni	13,620	58,515
ZN	21,212	100,518
Heating Oil	36,184	159,614
Natural Gas	25,495	130,255
Unleaded Gas	30,331	93,225
WTI	107,654	411,483
Gold	33,860	155,347
Silver	23,954	120,027
Platinum	3,572	23,239

The value of the linked commodities will be calculated using one of three pricing methodologies, as described below; (1) Excess Return, (2) Total Return or (3) Price Return methodologies.

1. Excess Return

When the Excess Return methodology is employed to value ComPS, it is anticipated that holders of the proposed ComPS will realize a return on their investment equivalent to a trading strategy that holds a fully collateralized near term commodity futures contract for the linked commodity and, near the expiration of the contract, rolls the position into the next nearest designated contract. Accordingly, this methodology can be characterized as the sum of ''price'' return and ''roll'' return.

Price return is the return that arises solely from changes over time in the price of the nearby contract. Thus, if on the first day of a given month the price of the nearby contract is $15.00, and on the 30th day of such month the price of the contract is $15.50, the investor in such contract has earned a price return of 3.3% ($0.50/$15 or 3.33%). Roll return represents the yields which are potentially available as a result of the differential between the prices for shorter-dated commodity future positions and the prices for longer-dated commodity futures positions. The price of the longer-dated position may be higher or lower than the price of the shorter-dated position based on a variety of factors, including the cost of transportation, storage and insurance of commodities, the expectations of market participants with respect to future price trends and general supply and demand trends.

To minimize possible pricing volatility arising from conducting the ''roll'' on a single business day, the substitution of the new contract for the old will be accomplished over a five business day period in increments of 20% of the index value. For example, the index change on the day immediately following the first roll is 80% of the old contract change plus 20% of the new contract change. On the next day, the index change is 60% old contract and 40% new contract and so forth until after the last roll day the index change is now 100% the new contract change. For energy commodities, the ''roll'' will be conducted each month. For base and precious metals, due to the absence of a designated contract for each month, the ''roll'' will be conducted periodically into the designated contract. Rolls for all commodities will begin on the fifth business day of the month. If a market disruption (*e.g.,* a limit price move, no trading or limited trading) occurs on a roll day, then the affected commodity will not roll on that day, and the volume to roll will accumulate and roll on the next available day.

Many commodity markets, including those for base metals and energy products, have historically been in backwardation for extended periods (*i.e.,* the nearby futures contracts are more expensive than longer dated contracts). This creates an opportunity to increase the return available through an investment in such commodities by establishing longer-dated positions in the commodities and continuously ''rolling'' such positions forward as they approach expiration. With the passage of time, longer-dated positions replace expiring shorter-dated positions. Positions that were formerly longer-dated but which have become shorter-dated positions are rolled forward and sold, with the proceeds used to purchase longer-dated replacement contracts. This process results in the realization of the roll return. However, if the prices for shorter-dated positions are less than the prices for longer-dated positions (a condition referred to as ''contango'') the investor may bear a cost with rolling futures positions forward, even where prices for shorter-dated positions remain constant or increase. This potential cost arises from the fact that as longer-dated contracts become shorter-dated contracts and then approach expiration, the prices of such contracts may decrease relative to the prices for the same contract when it was further away from expiration. Thus, as the maturing contracts are sold and rolled into longer-dated positions, the investor realizes a relatively smaller amount of proceeds, and must purchase

the newly acquired longer dated futures contract at a higher price.

The example that follows illustrates the calculation of Excess Return as the sum of price and roll return. In the example, spot prices move from $15 to $15.50 over one month, and the second nearby monthly contract moves from $14.40 to $15 (*i.e.*, the price curve remains in a constant $0.50 backwardation). Holding period Excess Return, therefore, is $15.50–$14.50)/$14.50 or 6.9%.

	Aug 1st	Sept 1st
Calculating excess return in a backwardated market:		
1st Nearby Contract and Price	Sep @ $15.00	Oct @ $15.50.
2nd Nearby Contract and Price	Oct @ $14.50	Nov @ $15.00.
P/L on Oct Position Initiated Aug 1st		$1.00.
Holding Period Spot Return		3.3% (on Sep contract).
Holding Period Excess Return		6.9% (on Oct contract).

2. Total Return

As stated above, the proposed securities also may use a ''Total Return'' methodology to value the linked commodities. The Total Return methodology simply adds the element of return arising from an investment in U.S. Treasury bills to the value of the linked commodity as calculated by the Excess Return methodology described above. The element of return arising from an investment in Treasury bills is referred to as collateral return (''collateral return''). Thus, Total Return equals Excess Return plus an interest rate equivalent to the U.S. Treasury bill rate. If the Total Return methodology is used, securities will not have a separate dividend or interest payment, or if they do have a separate dividend or interest payment, it will be substantially less than if the Excess Return methodology were used. The return based upon the Treasury bill rate will be calculated using a 13 week T-bill yield, compounded daily at the decompounded discount rate of the most recent weekly U.S. Treasury bill auction as found in the H.15 (519) report published by the Board of Governors of the Federal Reserve System, on the full value of the commodity. Interest will accrue on an actual day basis over weekends and holidays at the previous day's rate.

3. Price Return

If a Price Return methodology is employed, the value of the linked commodity at maturity of the ComPS will be determined by reference to the price of a specified near term futures contract. The use of the Price Return methodology eliminates the elements of roll and collateral return from the valuation of the linked commodities. If the Price Return methodology is used to determine the value of the linked commodity, the holders of the proposed ComPS generally will receive a dividend or interest payment on the face value of their securities, the frequency and rate of which will vary from issue to issue depending upon prevailing interest rates and other factors.

It is anticipated that the futures contract underlying a particular ComPS will remain unchanged during the term of the instrument. Certain developments, however, may necessitate changes with respect to the underlying futures contract.[5] Decisions regarding such changes will be determined by a policy committee consisting of employees of the commodities and research areas of the underwriter or its affiliates as well as independent industry and academic experts. Employees of the underwriter or its affiliates will be restricted to an advisory, non-voting membership on the committee. Members of the policy committee will be prohibited from trading ComPS.

If it becomes necessary to choose a replacement futures contract, the ''new'' replacement contract will meet the following criteria: (i) it will be priced in U.S. dollars, or if priced in a foreign currency, the exchange on which the contract is traded must publish an official exchange rate for conversion of the price into U.S. dollars and such currency must be freely convertible into U.S. currency, (ii) it will be traded on a regulated futures exchange in the U.S., Canada, U.K, Japan, Singapore or an O.E.C.D. country,[6] and (iii) at the time of replacement, it will have a minimum annual volume of 300,000 contracts or $500 million. The underwriter will immediately notify the Exchange and vendors of financial information in the event that there is a chance in the futures contract underlying a particular series of ComPS.[7]

The Amex represents that it is able to obtain market surveillance information, including customer identity information, with respect to transactions occurring on the LME pursuant to its information sharing arrangements with the Securities and Futures Authority (''SFA'') in the United Kingdom through the Intermarket Surveillance Group (''ISG'').[8] The Exchange also is able to obtain market surveillance information, including customer identity information, with respect to transactions occurring on NYMEX or COMEX pursuant to its information sharing agreement with NYMEX. In addition, the Exchange is able to obtain market surveillance information, including customer identity information, regarding transactions on several other futures exchanges in the U.S. and abroad through the ISG.[9]

In the event that the policy committee determines that the futures contract underlying a ComPS should be changed, and it identifies an appropriate benchmark replacement contract, the substitution of the new contract for the old only will be done where: (1) the Exchange has established a comprehensive information sharing agreement with the market or self-

[5] Such developments could include, among other things, changing liquidity conditions or the discontinuation of existing contracts or the emergence of new ''benchmark'' contracts for the particular linked commodity.

[6] The O.E.C.D. (Organization of Economic Cooperation and Development) consists of the following countries: the U.S., Japan, Germany, France, Italy, U.K., Canada, Australia, Austria, Belgium, Denmark, Finland, Greece, Iceland, Ireland, Luxembourg, Mexico, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland and Turkey.

[7] The Amex would also have to have suitable surveillance arrangements for any replacement contract, as discussed above.

[8] The ISG was formed on July 14, 1983 to, among other things, coordinate more effectively surveillance and investigative information sharing arrangements in the stock and options markets. *See* Intermarket Surveillance Group Agreement, July 14, 1983. The most recent amendment to the ISG Agreement, which incorporates the original agreement and all amendments made thereafter, was signed by ISG members on January 29, 1990. *See* Second Amendment to the Intermarket Surveillance Group Agreement, January 29, 1990. The domestic members of the ISG are the Amex; the Boston Stock Exchange, Inc.; the Chicago Board Options Exchange, Inc.; the Chicago Stock Exchange, Inc.; the National Association of Securities Dealers, Inc.; the New York Stock Exchange, Inc.; the Pacific Stock Exchange, Inc.; and the Philadelphia Stock Exchange, Inc. The SFA is an affiliate member of ISG.

[9] *See infra* note 10.

regulator for the replacement contract,[10] or (2) the SEC has established suitable alternative arrangements with an appropriate regulator of the market for the replacement contract.[11] When there is no suitable benchmark replacement contract or, there is a suitable benchmark contract but the Exchange's or the Commission's information sharing arrangements do not meet the above criteria, then the affected ComPS either will be called by the issuer or the payment to be made to holders at maturity will be fixed as of a certain time and in a manner established by the underwriter, and thereafter the principal amount will not fluctuate throughout the term of the instrument as a result of the price of a linked commodity.

The underwriter intends to retain the services of an independent calculation agent to compute the value of the linked commodities in accordance with the protocols described above if a Total Return or an Excess Return methodology is employed since the value of the linked commodities will vary from the prices of the relevant futures contracts then trading as a result of the incorporation of roll and collateral return (in the case of Total Return methodology). With respect to ComPS overlying the linked energy and precious metal commodities (*i.e.,* those commodities traded in the U.S.), the value of such ComPS will be calculated every 60 seconds and disseminated to vendors of financial data via the Exchange's Network B. With respect to ComPS overlying base metals (*i.e.,* those traded on the LME), the value of such ComPS will be continuously disseminated on Network B, but will be updated only once per day during U.S. market hours as the market for the relevant underlying contracts does not trade in a continuous fashion when the U.S. securities markets are open.

Since commodity returns historically have been negatively correlated with financial assets, the Exchange believes that the ownership of ComPS (although their return is uncertain) will help to diversify a portfolio of financial instruments. According to the Exchange, ComPS also will benefit the producers, consumers and dealers of the underlying commodities by permitting them, through the issuance of ComPS, to raise low cost capital.

Returns to investors in ComPS are unleveraged with neither a cap nor a floor. There is an element of derivative pricing, however, with respect to the calculation of the final payment. The Exchange, accordingly, will require members, member organizations and employees thereof to make a determination with respect to customers whose accounts have not previously been approved to trade futures or options that a transaction in the proposed securities is suitable for such customer. In addition, members, member organizations or employees thereof recommending a transaction in ComPS will be required: (1) to determine that the transaction recommended is suitable for the customer and (2) to have a reasonable basis for believing that the customer can evaluate the special characteristics of, and is able to bear the financial risks of, the recommended transaction. The Exchange will distribute a circular to its membership prior to trading ComPS providing guidance with regard to member firm compliance responsibilities (including suitability recommendations) when handling transactions in such securities and highlighting the special risks and characteristics thereof.

ComPS will be subject to the equity margin and trading rules of the Exchange that, where ComPS are issued as debt in denominations with a face value of $1,000 or greater, they will be traded subject to the Exchange's debt trading rules (although they will still remain subject to equity margin rules).

III. Commission Findings and Conclusions

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, and, in particular, the requirements of Section 6(b)(5). In particular, the Commission believes that the availability of exchange-traded ComPS will provide an instrument for investors to achieve desired investment objectives (*e.g.,* commodity exposure and portfolio diversification) through the purchase of an exchange-traded securities product linked to one of the single commodities noted above.[12] For the reasons discussed below, the Commission has concluded that the Amex listing standards applicable to ComPS are consistent with the Act.

ComPS are similar in structure to a previous Amex proposed product, Commodity Indexed Notes (''COINs''), which the Commission approved in March 1995.[13] COINs, similar to ComPS, were proposed to be listed pursuant to Section 107 of the Amex Company Guide. The principal value of COINs was to be derived from the performance of a commodity index comprised of futures contracts overlying certain selected physical commodities.

Like COINs, the value of ComPS will be affected partially by certain risks that are associated with the purchase and sale of exchange-traded futures contracts. Furthermore, the Commission notes that the prices of commodities, including the eleven individual commodities which may underlie a particular ComPS issuance, may be subject to volatile price movements caused by numerous factors.[14] Accordingly, an investment in ComPS may also be subject to volatile price movements due to price changes in the underlying commodities and related futures contracts. In addition, ComPS possess many complex features, such as the incorporation of roll return and collateral return into their pricing methodologies.

In order to address the complex and risky nature of ComPS, the Amex has proposed special suitability, disclosure, and compliance requirements. First, the Exchange will require members to make a determination with respect to customers whose accounts have not previously been approved to trade futures or options that a transaction in the proposed securities is suitable for such customer.[15] This is important given the embedded derivative component of ComPS. Second, the

[10] The Exchange currently has information sharing arrangements that qualify as comprehensive information sharing agreements with the following futures markets and self-regulators: Chicago Board of Trade, Chicago Mercantile Exchange, London International Financial Futures and Options Exchange, Montreal Exchange, New York Futures Exchange, New York Mercantile Exchange and the U.K. Securities and Futures Authority. From time to time, moreover, the Exchange enters into new information sharing arrangements that qualify as comprehensive information sharing agreements with securities and futures markets and self-regulators other than those with which the Exchange currently has such agreements.

[11] Amex will notify the Commission staff prior to the commencement of a ComPS replacement contract change. Telephone conversation between Michael Bickford, Amex, and Michael Walinskas, SEC, on February 21, 1996.

[12] Pursuant to Section 6(b)(5) of the Act the Commission must predicate approval of exchange trading for new products upon a finding that the introduction of the product is in the public interest. Such a finding would be difficult with respect to a product that served no investment, hedging or other economic function, because any benefits that might be derived by market participants would likely be outweighed by the potential for manipulation, diminished public confidence in the integrity of the markets, and other valid regulatory concerns.

[13] *See* Securities Exchange Act Release No. 35518 (March 21, 1995).

[14] Such factors include, but are not limited to, international economic, social and political conditions and levels of supply and demand for the individual commodities.

[15] Such a requirement is more than the duty to know and approve customers, but entails an obligation to make a determination that the transaction is suitable for the customer.

Amex will require that members who make recommendations in ComPS determine that the transaction recommended is suitable for the customer and have a reasonable basis for believing that the customer can evaluate the special characteristics of, and is able to bear the financial risks of, the recommended transaction. Third, because ComPS are cash-settled, holders will not receive, nor be required to liquidate, the underlying physical commodities or overlying futures contracts. The Commission notes that this provision will effectively terminate a ComPS investor's exposure to commodity market risk at the security's maturity and limit an investor's loss to the amount of his initial investment. Finally, the Exchange plans to distribute a circular to its membership calling attention to the specific risks associated with ComPS.[16] This will assist members in determining the customers eligible to trade ComPS, formulating recommendations in ComPS, and in monitoring customer and firm transactions in ComPS.

The Commission also believes that several factors significantly minimize the potential for manipulation of ComPS. First, each of the futures contracts overlying the commodities is relatively actively traded, and has considerable open interest. Second, the majority of futures contracts overlying the component commodities trade on exchanges that impose position limits on speculative trading activity, which are designed, and serve, to minimize potential manipulation and other market impact concerns. Third, as discussed below, the Amex has entered into certain surveillance sharing agreements with each of the futures exchanges upon which the underlying designated futures contracts trade. These agreements should help to ensure the availability of information necessary to detect and deter potential manipulations and other trading abuses, thereby making ComPS less readily susceptible to manipulation.[17] Fourth, the price of ComPS (with respect to those commodities traded in the U.S.) will be calculated every 60 seconds and disseminated to vendors of electronic financial information via the Exchange's Network B.[18] Fifth, adequate procedures are in place to prevent the misuse of information by members of the policy committee responsible for replacements with respect to the underlying contract.[19] Accordingly, for the reasons discussed above, the Commission believes that ComPS are not readily susceptible to manipulation and that in any event, the surveillance procedures in place are sufficient to detect and deter potential manipulation.

The Commission notes the ComPS, unlike standardized options, do not contain a clearinghouse guarantee but are instead dependent upon the individual credit of the issuer. This heightens the possibility that a purchaser of ComPS may not be able to receive any cash payment due upon maturity. To some extent this credit risk is minimized by the Exchange's listing guidelines requiring ComPS issuers to possess at least $100 million in assets and stockholders' equity of at least $10 million. In any event, financial information regarding the issuer will be disclosed or incorporated in the prospectus accompanying the offering of ComPS.

Based on the above, the Commission finds that the proposal to trade ComPS is consistent with the Act, and, in particular, the requirements of Section 6(b)(5).[20]

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[21] that the proposed rule change is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[22]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–4887 Filed 3–1–96; 8:45 am]

BILLING CODE 8010–01–M

[16] The ComPS circular will be submitted to the Commission for its review and should include, among other things, a discussion of those risks which may cause commodities to experience volatile price movements in addition to details on the pricing methodology to be used for that particular issuance.

[17] The Amex has comprehensive surveillance sharing agreements with all of the exchanges upon which the futures contracts relating to a particular ComPS trade. Specifically, Amex is able to obtain market surveillance information, including customer identity information, for transactions occurring on NYMEX and Comex. Furthermore, under the ISG information sharing agreement, SFA will be able to provide, upon Amex request, surveillance information with respect to trades effected on the LME, including client identity information. Finally, if the underlying commodity for an issuance of ComPS changes or if a different market is utilized for purposes of calculating the value of a designated futures contract, the Amex will ensure that it has entered into a surveillance sharing agreement with respect to the new relevant market.

[18] For commodities traded on the LME, as discussed above, prices for ComPS will be continuously disseminated on Network B, however, they will only be updated once per day during U.S. hours.

[18] As discussed above, members of the policy committee are expressly prohibited from trading ComPS and from communicating any knowledge concerning changes in the value of the underlying commodities. Amex will also have surveillance procedures in place to periodically review activity in the securities.

[20] The Commission notes that a Rule 19b–4 filing might be required in order to list any other derivative product based upon a commodity interest that differs from the proposed ComPS or previously approved COINs products.

[21] 15 U.S.C. § 78s(b)(2) (1982).

[22] 17 CFR § 200.30–3(a)(12) (1994).

[Release No. 34–36884; File No. SR–Amex–96–02]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the American Stock Exchange, Inc. Relating to a Gratuity Fund Interpretation

February 23, 1996.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on January 16, 1996 the American Stock Exchange, Inc. (''Amex'' or ''Exchange'') filed with the Securities and 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 Board of the American Stock Exchange, Inc. has made an interpretation of Article IX of the Exchange Constitution with respect to the Gratuity Fund eligibility of individuals who inherited their regular memberships.

The text of the proposed rule change is available at the Office of the Secretary, the Amex, and at the Commission.

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 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 self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Effective May 16, 1995, the Commission approved various amendments to the Exchange Constitution and Rules relating to the Gratuity Fund.[2] These changes, among other things, include options principal members and options principal and regular member lessees in the Gratuity Fund, increase the Gratuity Fund benefit to $125,000, subject to a ''phase-in'' schedule for new Gratuity Fund Participants (''Participants''), and include a two-year ''active'' requirement for participation.[3] The changes also include a grandfathering provision, which provides that all individuals who were regular members or regular member lessors on June 10, 1993 are grandfathered with respect to the ''active'' requirement (i.e., they are deemed to have met it, even though they were never active for a two-year period).[4]

Except for those who are grandfathered, inactive owners of memberships are not Gratuity Fund Participants, and thus are generally not subject to assessments upon the death of a Participant.[5] The Constitution, however, does require that each membership pay at least one assessment upon the death of a Gratuity Fund Participant.[6] Accordingly, a non-Participant does have to pay an assessment when there is no lessee or nominee on the seat who is a participant.[7]

An ambiguity arose making it appropriate to interpret these provisions. Pursuant to Article II, Section 2 of the Exchange Constitution, the Exchange's Board of Governors has the authority to interpret the Exchange Constitution and Rules.

It has for many years been the case that an individual who inherited a regular seat (after collecting a Gratuity Fund benefit) would not be eligible to participate in the Gratuity Fund himself or herself unless he or she fulfilled all membership requirements (except taking the Floor examinations), including paying the $2,500 transfer fee. This was considered analogous to the beneficiary selling the inherited seat and purchasing a new one.[8]

There are currently ten beneficiaries who inherited their memberships prior to June 10, 1993, and chose to retain the memberships and lease them out. Of the ten, five beneficiaries qualified for membership and paid the $2,500 transfer fee, and five did not. The five who did not take steps to qualify for membership and pay the $2,500 transfer fee were still required to pay a Gratuity Fund assessment every time that a regular member or regular member lessor died.[9]

The question has now arisen whether the beneficiaries who did not take steps to qualify for membership must still pay Gratuity Fund assessments in light of the Gratuity Fund provisions which were adopted in May 1995.[10] It is arguably inappropriate for the Exchange to continue to assess these non-Participants for contributions since other non-Participants do not have to pay assessments if there is a Participant affiliated with a seat.

On December 14, 1995 the Exchange's Board of Governors adopted an interpretation of Article IX of the Exchange Constitution regarding the situation described above. This interpretation provides that the Exchange will continue to take the position that each of the five individuals is not a Gratuity Fund Participant, but that the Exchange should treat them equally with other owners who are non-Participants, and not subject them to assessments, so long as the membership is leased to (or has a nominee who is) a Participant in the Gratuity Fund. This interpretation is retroactive to May 16, 1995, the date that the new rules were implemented.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act[11] in general and furthers the objectives of Section 6(b)(5)[12] in particular in that it is designed to promote just and equitable principles of trade and to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose 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 Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change constitutes a stated policy, practice, or interpretation with respect to the meaning, administration, or enforcement of an existing rule and, therefore, has become effective pursuant to Section 19(b)(3)(A) of the Act[13] and subparagraph (e) of Rule 19b–4 thereunder.[14]

At any time within sixty days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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, N.W.,

[2] *See* Securities Exchange Act Release No. 35723 (May 16, 1995), 60 FR 27353 (May 23, 1995) (Order approving File No. SR–Amex–95–08).

[3] *Id.*

[4] Individuals who owned options principal memberships on May 16, 1995 were given a one-time opportunity to elect to ''opt-in'' or ''opt-out'' of the Gratuity Fund, and those who choose to ''opt-in'' are grandfathered with respect to the ''active'' requirement as well. *See* Securities Exchange Act Release No. 36585 (Dec. 13, 1995), 60 FR 65701 (Dec. 20, 1995) (Order approving File No. SR–Amex–95–49). An election to ''opt-out'' is irrevocable for the rest of the person's life, unless he or she subsequently buys a regular membership. *Id.* In addition, those individuals who were either regular or options principal member lessees on May 16, 1995 have the right to ''opt-out'' of the Gratuity Fund for the duration of their lease. *Id.*

[5] Inactive members are those that do not meet all Exchange requirements to be active on the Floor. *See* Para. 9176 of the Amex Guide (''Membership Requirements and Admissions Procedures'').

[6] *See* Amex Constitution, Article IX, Section 4.

[7] *Id.*

[8] It is the Exchange's understanding that the New York Stock Exchange treats individuals who inherit memberships in the same manner.

[9] Note that under the new rules, the ambiguity being dealt with here is not likely to arise. Pursuant to Article IX, Section 23(a), an individual must be a regular member or regular member lessor on June 10, 1993 to be grandfathered from the requirement that one must have been an ''active'' member to be a Gratuity Fund Participant. A previously active exchange member, however, would again become a participant in the Gratuity Fund upon becoming a lessor so long as no more than five years has elapsed since such individual last participated in the fund. Typically, however, it can be expected that those who inherit seats upon the death of the owner will not have previously been active Exchange members themselves, so that if they hold on to the seats as owners they will not be eligible to be Participants under the new rules, and thus will not be subject to assessments unless there is no lessee or nominee Participant on the seat.

[10] *See* Securities Exchange Act Release No. 35723, *supra*, note 2.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4.

Washington, D.C. 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 at the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filing also will be available for inspection and copying at the principal office of the American Stock Exchange. All submissions should refer to File No. SR–Amex–96–02 and should be submitted by March 25, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[15]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–4888 Filed 3–1–96; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–36883; File No. SR–PSE–96–01]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Pacific Stock Exchange, Inc. Relating to Its Options Firm Quote Rule

February 23, 1996.

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 January 16, 1996, the Pacific Stock Exchange, Inc. (''PSE'' of ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the PSE. 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 Options Firm Quote Rule (Rule 6.86, the ''rule'') in order to codify some related floor policies and also to clarify certain provisions of the rule.

The text of the proposed rule change is available at the Office of the Secretary, the PSE, and at the Commission.

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 Exchange 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 PSE 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

1. Purpose

The Exchange is proposing to modify its Options Firm Quote Rule as follows:

Order Identification

Subsection (a) of the rule currently provides that members and member organizations who enter orders for execution on the Options Floor must ascertain the account origin of such orders and provide a notation of the account origin on the order ticket. The Exchange is proposing to modify this provision to provide that such members and member organizations would be required to communicate such account information to the executing member organization. Accordingly, the member or member organization entering the order must indicate to the executing member organization whether the order is for the account of a customer, firm or market maker.

The proposal would also set forth the duty of executing floor brokers to inquire personally as to the account origin of each eligible order upon receipt thereof or prior to its execution and to note such information on the order ticket.

Finally, under the proposal, the executing member organization and the clearing member organization would bear greater responsibility with respect to the proper identification of orders that are executed on behalf on non-members of the Exchange.

Commentary .05

Proposed Commentary .05 sets forth certain types of orders that are subject to the rule and the extent to which the rule applies to such orders. The rule specifically addresses the treatment of combination orders, spread orders, straddle orders and contingency orders. With respect to combination orders, market Makers in a trading crowd would only be responsible for providing an aggregate of 20 contracts on one side of the market; however, Market Makers would be required to provide a depth of twenty contracts on both sides of the market for spread and straddle orders.

The proposed Commentary also enumerates the types of contingency orders that are subject to the rule, *i.e.,* ''minimum'' orders of 20 contracts or less and market not-held, limit not-held and delta orders that can be executed immediately. The types of contingency orders that are not subject to the rule include: ''minimum'' orders for more than 20 contracts, buy-writes, all-or-none orders for more than 20 contracts, delta orders traded with stock and contingency orders that have been partly executed.

The proposed Commentary also provides that in executing contingency orders pursuant to the rule, the order ticket must be time stamped upon being taken into the trading crowd. The Commentary also states that such orders are entitled to 20 contracts on the market disseminated at that time.

Commentary .06

Proposed Commentary .06 provides that Market Makers must be afforded a ''reasonable'' opportunity to update their disseminated markets for the execution of consecutive eligible customers orders in options on the same underlying security. The Commentary further provides that orders shall be executed on a time priority basis so that the order with the earliest time stamp will receive a guaranteed fill of 20 contracts.

Commentary .07

Proposed Commentary .07 provides that a Floor Broker may be held liable for an entire order if such Floor Broker attempts to solicit a better price than the limit price stipulated on the order ticket and such attempt creates a change in the market that does not result in an immediate execution.

Commentary .08

Proposed Commentary .08 designates those Market Makers to whom the Order Book Official may, pursuant to current Subsection (d), allocate the balance of contracts necessary to provide an execution of 20 contracts when the response of the members present at the trading post is insufficient to provide a depth of 20 contracts. Specifically, such allocations may be made to Market Makers who: (1) Are present at the trading post at the time of a call for a

[15] 17 CFR 200.30–3(a)(12).

market; and either (2) hold an appointment in the option classes at the trading post or (3) regularly effect transactions in person for their trading accounts at that trading post.

In addition, this proposed Commentary provides that Market Makers who have logged on to the Automatic Execution system, but who are not present in the trading crowd will not be eligible for an allocation by the Order Book Official pursuant to current Subsection (d).

2. Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act, in general, and furthers the objectives of Section 6(b)(5) in particular, in that it facilitates transactions in securities and promotes just and equitable principles of trade.

B. Self-Regulatory Organization's Statement on Burden on Competition

The PSE does not believe that the proposed rule change will impose any inappropriate 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 solicited or received with respect to the proposed rule change.

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 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 and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20459. 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, N.W., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the PSE. All submissions should refer to File No. SR–PSE–96–01 and should be submitted by March 25, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[1]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–4885 Filed 3–1–96; 8:45 am]

BILLING CODE 8010–01–M

[1] 17 CFR 200.30–3a(a)(12).

DEPARTMENT OF STATE

[Public Notice 2349]

Notice Convening an Accountability Review Board for the Attack on the Headquarters of the Office of Program Manager, Saudi Arabian National Guard in Riyadh, in Which Five Americans Were Killed

Pursuant to section 301 of the Omnibus Diplomatic Security and Antiterrorism Act of 1986 (22 U.S.C. 4831 *et seq.*), I have determined that the November 13, 1995, car-bomb attack on the headquarters of the Office of Program Manager, Saudi Arabian National Guard in Riyadh, Saudi Arabia, involved loss of life related to a U.S. mission abroad. Therefore, I am convening an Accountability Review Board, as required by that statute, to examine the facts and circumstances of the attack and report to me such findings and recommendations as it deems appropriate, in keeping with the attached mandate.

I have appointed Ambassador Alfred L. Atherton as chairman of the Board. He will be assisted by former Ambassador Peter Sebastian; Brigadier General Thomas J. Konitzer, USA; Mr. William Piekney; and Mr. James A. Brooke. Mr. Andrew Winter will act as Executive Secretary. The members will bring to their deliberations distinguished backgrounds in government service and the private sector.

I have asked the Board to submit its conclusions and recommendations to me within sixty days of its first meeting, unless the chairman determines a need for additional time. Appropriate action will be taken and reports submitted to the Congress on any recommendations made by the Board.

Anyone with information relevant to the Board's examination of this incident should contact the Board promptly at (202) 647–3300.

Dated: February 22, 1996.

Strobe Talbott,

Deputy Secretary of State.

Attachment

Mandate

Accountability Review Board Mandate

A. *Review and Report.* The Accountability Review Board shall examine the facts and circumstances surrounding the November 13, 1995, car bomb attack on the headquarters of the Office of Program Manager, Saudi Arabian National Guard (OPM/SANG) in Riyadh, Saudi Arabia, which killed five American and two third country national employees and wounded over thirty others, and shall submit a detailed written report to the Deputy Secretary of State within 60 days of its first meeting. If the chairman determines that more than 60 days are necessary to complete the Board's review, he shall notify the Deputy Secretary of State of that fact and the amount of additional time needed.

B. *Findings.* In accordance with section 304(a) of the Omnibus Diplomatic Security and Antiterrorism Act of 1986 (''the Act''), the Board shall make written findings in its report to include at least the following matters:

(1) The extent to which the incident with respect to which the Board was convened was security-related;

(2) whether in this case the security systems and security procedures at the mission were adequate;

(3) whether the security systems and security procedures were properly implemented in this case;

(4) the impact of intelligence and information availability in this case; and

(5) such other facts and circumstances in this case which may be relevant to the appropriate security management of United States missions abroad.

C. *Program Findings and Recommendations.* The Board shall submit its findings (which may be classified to the extent deemed necessary by the Board) to the Deputy Secretary of State, together with recommendations as appropriate to improve the security and efficiency of any program or operation which the Board has reviewed.

D. *Personnel Findings and Recommendations.* If the Board finds reasonable cause to believe that an employee of the United States Government or member of the uniformed services, as defined by section 303(a)(1)(B) of the Act, has breached his or her duty, the Board shall:

(1) Notify the individual concerned;

(2) transmit the finding of reasonable cause, together with all information relevant

to such finding, to the head of the appropriate Federal agency or instrumentality; and

(3) recommend that such agency or instrumentality initiate an appropriate investigatory or disciplinary action.

E. *Termination.* The Board shall terminate 30 days after submission of its report to the Deputy Secretary of State, unless the Deputy Secretary of State within that time requests that further proceedings be held by the Board and specifies a new termination date.

Strobe Talbott,

Deputy Secretary of State.

[FR Doc. 96–4862 Filed 3–1–96; 8:45 am]

BILLING CODE 4710–10–M

[Public Notice 2340]

Notice To Seek Public Comment on Entering Into Bilateral Agreements With Parties to the Basel Convention on the Transboundary Movement of Hazardous Wastes and Their Disposal To Allow Those Countries To Export Wastes to the United States Consistent With the Convention

LEAD AGENCY: Department of State, Washington, DC.

COOPERATING AGENCIES: Environmental Protection Agency (EPA), U.S. Department of Commerce, Office of the U.S. Trade Representative.

SUMMARY: The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal prohibits a Party to the Convention from trading in Basel-covered wastes (i.e., hazardous and other wastes) with a non-Party, absent an agreement or arrangement consistent with Article 11 of the Convention. The United States is not a Party to the Convention, and there is interest in agreements or arrangements to allow the import of hazardous wastes from Convention Parties to the United States. The United States Government is seeking public comment to evaluate the need for additional waste agreements or arrangements.

SUPPLEMENTARY INFORMATION:

I. Background on the Convention

The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal was adopted in 1989, and entered into force in 1992. The Convention's general objective is to protect human health and the environment against adverse effects of wastes under its scope by minimizing their generation and transboundary movement, and ensuring their environmentally sound management. Wastes covered by the Convention include certain wastes exhibiting hazardous characteristics set forth in the Convention, as well as ''other wastes'' (consisting of household wastes and residues from incineration of household wastes).

Among other provisions, the Convention establishes conditions under which transboundary movements of Basel-covered wastes may occur. These conditions include a requirement that the exporting Party obtain the prior written informed consent of the importing Party before a shipment can proceed, as well as requirements that the waste be managed in an environmentally sound manner. The Convention, along with a detailed explanation of its provisions and an outline of the history of its development, is contained in Federal Register Notice, 57 FR 20602 (May 13, 1992).

Currently, 97 States and the European Community are Parties to the Convention. The United States was among the original signatories of the Basel Convention, and the U.S. Senate subsequently gave its advice and consent to ratify it. However, for the United States to meet the obligations of the Convention, additional statutory authorities are needed. Administrations have sought without success since 1991 to obtain these statutory authorities. As a consequence, the United States has not ratified the Convention. However, the United States has continued to participate actively, as a non-Party observer, in meetings and Conferences of the Basel Parties.

The Convention specifies particular controls on trade between Basel Parties and non-Parties. Parties are prohibited from trading in Basel-covered wastes with non-Parties, except in cases in which a Party concludes an agreement or arrangement pursuant to Article 11 of the Convention. Article 11(1) enables Parties to enter into bilateral, multilateral or regional agreements or arrangements for the transboundary movement of Basel-covered wastes with Parties or non-Parties, provided that such agreements or arrangements do not derogate from the environmentally sound management of Basel-covered wastes as required by the Convention. It also provides that agreements or arrangements entered into by Basel Parties shall stipulate provisions which are not less environmentally sound than those provided for by the Convention.

Because the United States is not currently a Party to the Convention, several Basel Parties and U.S. firms have expressed an interest in the United States entering into Article 11 bilateral agreements/arrangements in order to enable continued export of Basel-covered waste to the United States for recycling or disposal. The Department of State, on behalf of the U.S. government recently concluded such a bilateral agreement with Malaysia covering exports of hazardous wastes into the United States, and is developing agreements with several other Basel Parties.

The requirements for agreements or arrangements developed by States prior to the entry into force of the Convention are somewhat different, and apply to three pre-existing agreements and arrangements of which the United States is a Party. Article 11(2) provides that the provisions of the Basel Convention shall not affect transboundary movements which take place pursuant to such agreements provided that such agreements are compatible with the environmentally sound management of hazardous wastes and other wastes as required by the Convention. The U.S. has bilateral waste agreements with Canada and Mexico which predate entry into force of the Convention. In addition, a decision by the Organization for Economic Cooperation and Development (OECD, of which the United States is a Party), covering trade of hazardous wastes between OECD states for recycling only, is considered an arrangement under Article 11.

Today's notice seeks comment on entering into bilateral agreements or arrangements for imports of Basel-covered waste into the United States for disposal and recycling. These agreements would not address Basel-covered waste exports from the United States to Basel Parties. The Administration may address export bilaterals in a future Federal Register notice.

The import agreements under consideration would have to meet the requirements of Article 11 of the Basel Convention. Only Parties to the Basel Convention, and not the United States, have the obligation under the Convention to meet the Convention's requirements. Thus, each exporting Party will ultimately need to determine for itself whether an agreement meets its Basel Convention obligations. At the same time, the United States would only negotiate and conclude agreements that the U.S. Government believes will meet the Convention's requirements, as stipulated under Article 11.

The U.S. import of Basel-covered wastes pursuant to Basel-consistent agreements should not pose environmental difficulties for the United States. Wastes imported into the United States will be managed in an environmentally sound manner pursuant to U.S. laws and regulations,

and may often be better managed than in the country of origin. It may be more economically efficient to export wastes to the United States for management in existing U.S. facilities, particularly for specialized waste streams and substances, than to construct new facilities in the country of origin. In many cases, advanced facilities in the United States enable the environmentally sound recovery of valuable secondary materials.

Under the type of import agreements described in this notice, the Environmental Protection Agency (EPA), the designated competent authority of the U.S. Government, will be able to express its consent, conditional consent, or objection to proposed imports of hazardous wastes. EPA will exercise its prerogative to consent or object to imports consistent with its statutory and regulatory authority. Current U.S. Government policy is to withhold consent only if it has reason to believe a shipment may not be managed in accordance with applicable U.S. laws and regulations.

Based on experience to date, the negotiation of each agreement is likely to take some time (several months). Administration resources are limited, and it is not expected that additional resources will be available for these purposes. In addition, the notice and consent procedures referred to above will impose an increased administrative burden on the U.S. Government. Once the U.S. Government evaluates the demand for these agreements, it will consider how many agreements to enter into, and how to prioritize requests, if necessary.

Public Comment

The Department of State is seeking the comment from the public on the potential demand for additional agreements for the movements of Basel-covered waste to the United States, and would be interested in the following specific information, where applicable, from firms and others with an interest in such agreements:

(a) Expected country of export, expected amount and frequency of such exports to the United States;

(b) whether more than one generator produces wastes which could be handled under an agreement;

(c) types of waste (including whether the wastes are considered to be hazardous under the Convention and/or under the laws and regulations of the United States or the exporting party);

(d) whether such wastes are for final disposal or treatment or recovery, and whether a substantially increased proportion is likely to be recovered in the future;

(e) whether such wastes are being exported because of a lack of adequate management capabilities and/or pressing environmental conditions in the exporting country;

(f) whether destinations closer than the United States to the generation of the waste would also provide environmentally sound and efficient management;

(g) whether U.S. waste management capabilities are superior to those in the exporting country; and

(h) whether acceptance of such wastes by the United States would reasonable be expected to provide a disincentive to the future development of adequate environmental facilities in the exporting country;

(i) whether any other conditions require that such wastes be exported to the United States for disposal or recovery.

The State Department will use this information to determine whether, given available resources, it will be necessary to develop criteria for entering into and prioritizing among proposed bilateral agreements. The State Department welcomes public input regarding such criteria.

Individuals or organizations are invited to provide written comments to: U.S. Department of State, OES/ENV, ATTN: Mr. Trigg Talley, 2201 ''C'' Street, N.W., Washington, D.C. 20520, TEL: (202) 647–5808, FAX: (202) 647–5947.

Comments and suggestions should be received no later than 60 days following the date of publication of this notice in order to be considered.

Dated: February 16, 1996.

Trigg Talley,

Environmental Affairs Officer, Department of State, OES/ENV.

[FR Doc. 96–4864 Filed 3–1–96; 8:45 am]

BILLING CODE 4710–09–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

[CGD08–96–004]

Eighth Coast Guard District Industry Day Meeting

AGENCY: Coast Guard, DOT.

ACTION: Notice of meeting.

SUMMARY: The Commander, Eighth Coast Guard District, is sponsoring a Marine Safety Industry Day to discuss various topics of interest to the marine community. The meeting will be open to the public.

DATES: The meeting will be held on May 15, 1996, from 8:30 a.m. to 4 p.m.

ADDRESSES: The meeting will be held at the Fairmont Hotel, 123 Baronne Street (at University Place), New Orleans, LA. The telephone number for the hotel is (504) 529–7111.

FOR FURTHER INFORMATION CONTACT: CDR S.P. Glenn, U.S. Coast Guard, c/o Commander (mep), Eighth Coast Guard District, Hale Boggs Federal Bldg., Room 1341, 501 Magazine Street, New Orleans, LA 70130–3396; telephone number (504) 589–3656; fax number (504) 589–4999.

SUPPLEMENTARY INFORMATION: For this year's industry day, we plan to present a series of speakers representing all segments of the industry followed by panel sessions in the afternoon. These presentations, among other topics, will include: Prevention Through People, New Spill Doctrine, Offshore Issues, Spill Management, Maritime Law Issues, Licensing, and Commercial Vessel Safety.

The agenda is:

May 15, 1996—Fairmont Hotel
- 8:30 a.m. Registration
- 9:30 a.m. Welcome and Introductions Speaker presentations (plenary)
- 12:00 a.m. Luncheon with keynote speaker
- 2:00 p.m. Panel sessions
- 4:00 p.m. Industry Day concludes

Attendance is open to the public. Preregistration for the program is required to assure adequate space. The conference and luncheon fee will be $30.00. Contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section to obtain registration forms and luncheon menu. Reservations must be received no later than April 30, 1996.

Dated: February 12, 1996.

R.C. North,

Rear Admiral, U.S. Coast Guard Commander, Eighth Coast Guard District.

[FR Doc. 96–4923 Filed 3–1–96; 8:45 am]

BILLING CODE 4910–14–M

Surface Transportation Board [1]

[STB Finance Docket No. 32869]

Cimarron Valley Railroad, L.C.; Acquisition and Operation Exemption; Cimarron Valley and Manter Branches of The Atchison, Topeka and Santa Fe Railway Company

Cimarron Valley Railroad, L.C. (CVR), a noncarrier, has filed a verified notice

[1] The ICC Termination Act of 1995, Pub. L. No. 104–88, 109 Stat. 803 (the Act), which was enacted on December 29, 1995, and took effect on January 1, 1996, abolished the Interstate Commerce

of exemption under 49 CFR 1150.31 to acquire and operate the Cimarron Valley and the Manter Branches, including overhead trackage rights, from The Atchison, Topeka and Santa Fe Railway Company (''Santa Fe'') as follows: (1) 151.04 miles of the Cimarron Valley Branch extending from East Ensign, KS, at milepost 3.76, to east of Boise City, OK, at milepost 154.80; (2) incidental overhead trackage rights to permit interchange on Santa Fe's C.V. Subdivision between milepost 154.80 and milepost 158.33, on Track No. 2 of Santa Fe's Boise City Subdivision between milepost 158.33 and milepost 159.74, and on Track Nos. 11, 12, 13 and 14 of Santa Fe's Boise City Yard near Boise City, OK; (3) 103.83 miles of the Manter Branch from Satanta, KS, at milepost 0.06 to east of Springfield, CO, at milepost 91.03 together with the Pritchett Industrial Spur from North Junction, north of Springfield, CO, at milepost 96.84, to near Pirtchett, CO, at milepost 109.70; and (4) incidental overhead trackage rights to permit interchange on Santa Fe's Manter Subdivision between milepost 91.03 and the west end of Santa Fe's Manter Subdivision at South Junction, CO, near milepost 95.00, and on Santa Fe's Boise City Subdivision between milepost 172.60 and milepost 174.40, and on the siding of Santa Fe's Boise City Subdivision at Springfield, CO.

Consummation was expected to occur on or shortly after February 23, 1996.

This proceeding is related to *David L. Durbano—Continuance in Control Exemption—Cimarron Valley Railroad, L.C.*, STB Finance Docket No. 32870, wherein David L. Durbano has concurrently filed a verified notice to continue to control CVR, upon its becoming a Class III rail carrier.

If the verified notice contains false or misleading information, the exemption is void *ab initio*. Petitions to reopen the proceeding to revoke the exemption under 49 U.S.C. 10502(d) [formerly section 10505(d)] may be filed at any time. The filing of a petition to reopen will not automatically stay the transaction. An original and 10 copies of all pleadings, referring to STB Finance Docket No. 32869, must be filed with the Office of the Secretary, Surface Transportation Board, Case Control Branch, 1201 Constitution Avenue, NW., Washington, DC 20423. In addition, a copy of each pleading must be served on Walter T. Merrill, Durbano & Associates, 3340 Harrison Boulevard, Suite 200, Ogden, UT 84403.

Decided: February 27, 1996.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 96–4929 Filed 3–1–96; 8:45 am]

BILLING CODE 4915–00–P

[STB Finance Docket No. 32870]

David L. Durbano—Continuance in Control Exemption—Cimarron Valley Railroad, L.C.

David L. Durbano (Applicant), a noncarrier, has filed a verified notice under 49 CFR 1180.2(d)(2) to continue in control of Cimarron Valley Railroad, L.C. (CVR), upon CVR's becoming a Class III rail carrier. Consummation was expected to occur on or shortly after February 23, 1996.

CVR, a noncarrier, has concurrently filed a verified notice of exemption under 49 CFR 1150.31 in *Cimarron Valley Railroad, L.C.—Exemption to Acquire and Operate—Cimarron Valley and Manter Branches of The Atchison, Topeka and Santa Fe Railway Company,* STB Finance Docket No. 32869, in which CVR seeks to acquire and operate 151.04 miles of the Cimarron Valley Branch rail line and 103.83 miles of the Manter Branch rail line both of which are owned by The Atchison, Topeka and Santa Fe Railroad Company. CVR's acquisition of the rail lines was expected to have been consummated on or shortly after February 23, 1996.

Applicant controls four other Class III rail carriers: Wyoming and Colorado Railroad Company, Inc. (WYCO); Oregon Eastern Railroad Company, Inc. (OER); Arizona Central Railroad, Inc. (AZCR); and Southwestern Railroad Company, Inc. (SWR).

The transaction is exempt from the prior approval requirements of 49 U.S.C. 11323 [formerly section 11343] because Applicant states that: (1) CVR, WYCO, OER, AZCR, and SWR will not connect with each other; (2) the continuance in control is not part of a series of anticipated transactions that would connect the railroads with each other; and (3) the transaction does not involve a Class I carrier.

As a condition to this exemption, any employees adversely affected by the transaction will be protected under *New York Doc Ry.—Control—Brooklyn Eastern Dist.,* 360 I.C.C. 60 (1979).

If the verified notice contains false or misleading information, the exemption is void *ab initio*. Petitions to reopen the proceeding to revoke the exemption under 49 U.S.C. 10502(d) [formerly section 10505(d)] may be filed at any time. The filing of a petition to reopen will not automatically stay the transaction. An original and 10 copies of all pleadings, referring to STB Finance Docket No. 32870, must be filed with the Office of the Secretary, Surface Transportation Board, Case Control Branch, 1201 Constitution Avenue, N.W., Washington, DC 20423. In addition, a copy of each pleading must be served on Walter T. Merrill, Durbano & Associates, 3340 Harrison Boulevard, Suite 200, Ogden, UT 84403.

Decided: February 27, 1996.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 96–4928 Filed 3–1–96; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Minority Veterans

The Department of Veterans Affairs' notice that a meeting of the Advisory Committee on Minority Veterans, authorized by P.L. 103–446, to be held from March 11, 1996 to March 13, 1996, is hereby canceled. The notice appeared in the Federal Register on February 14, 1996, Vol. 61, No. 31, page 5837.

If you have any questions, please contact Mr. Anthony T. Hawkins, Associate Director, Center for Minority Veterans, (phone 202–273–6708).

Dated: February 26, 1996.

By direction of the Secretary:

Heyward Bannister,

Committee Management Officer.

[FR Doc. 96–4882 Filed 3–1–96; 8:45 am]

BILLING CODE 8320–01–M

Rehabilitation Research and Development Service Scientific Merit Review Board, Notice of Meeting

The Department of Veterans Affairs gives notice under Public Law 92–463 (Federal Advisory Committee Act) as amended, by section 5(c) of Pubic Law 94–409 that a meeting of the

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Commission (ICC) and transferred certain functions to the Surface Transportation Board (Board). This notice relates to functions that are subject to Board jurisdiction pursuant to 49 U.S.C. 10901.

[1] The ICC Termination Act of 1995, Pub. L. No. 104–88, 109 Stat. 803, which was enacted on December 29, 1995, and took effect on January 1, 1996, abolished the Interstate Commerce Commission (ICC) and transferred certain functions to the Surface Transportation Board (Board). This notice relates to functions that are subject to Board jurisdiction pursuant to 49 U.S.C. 11323.

Rehabilitation Research and Development Service Scientific Merit Review Board will be held at the Vista International Hotel, 1400 ''M'' Street NW, Washington, DC on July 16 through July 18, 1996.

The session on July 16, 1996 is scheduled to begin at 6:30 p.m. and end at 9:30 p.m. The sessions on July 17 and July 18, 1996, are scheduled to begin at 8 a.m. and end at 5 p.m. The purpose of the meeting is to review rehabilitation research and development applications for scientific and technical merit and to make recommendations to the Director, Rehabilitation Research and Development Service, regarding their funding.

The meeting will be open to the public up to the seating capacity of the room for the July 16 session for the discussion of administrative matters, the general status of the program, and the administrative details of the review process. On July 16–18, 1996 the meeting is closed during which the Board will be reviewing research and development applications.

This review involves oral comments, discussion of site visits, staff and consultant critiques of proposed research protocols, and similar analytical documents that necessitate the consideration of the personal qualifications, performance and competence of individual research investigators. Disclosure of such information would constitute a clearly unwarranted invasion of personal privacy. Disclosure would also reveal research proposals and research underway which could lead to the loss of these projects to third parties and thereby frustrate future agency research efforts.

Thus, the closing is in accordance with 5 U.S.C. 522b(c)(6), and (c)(9)(B) and the determination of the Secretary of the Department of Veterans Affairs under Sections 10(d) of Public Law 92–463 as amended by Section 5(c) of Public Law 94–409.

Due to the limited seating capacity of the room, those who plan to attend the open session should write to Ms. Victoria Mongiardo, Program Analyst, Rehabilitation Research and Development Service, Department of Veterans Affairs, 103 South Gay Street, Baltimore, Maryland 21202 (Phone: (410–962–2563) at least five days before the meeting.

Dated: February 26, 1996.

By Direction of the Secretary.

Heyward Bannister,

Committee Management Officer.

[FR Doc. 96–4881 Filed 3–1–96; 8:45 am]

BILLING CODE 8320–01–M

Wage Committee, Notice of Meetings

The Department of Veterans Affairs (VA), in accordance with Public Law 92–463, gives notice that meetings of the VA Wage Committee will be held on:

Wednesday, April 24, 1996, at 2:00 p.m.
Wednesday, May 22, 1996, at 2:00 p.m.
Wednesday, June 5, 1996, at 2:00 p.m.
Wednesday, June 19, 1996, at 2:00 p.m.

The meetings will be held in Room 1225, Department of Veterans Affairs, Tech World Plaza, 801 I Street, NW, Washington, DC 20001.

The Committee's purpose is to advise the Under Secretary for Health on the development and authorization of wage schedules for Federal Wage System (blue-collar) employees.

At these meetings the Committee will consider wage survey specifications, wage survey data, local committee reports and recommendations, statistical analyses, and proposed wage schedules.

All portions of the meetings will be closed to the public because the matters considered as related solely to the internal personnel rules and practices of the Department of Veterans Affairs and because the wage survey data considered by the Committee have been obtained from officials of private business establishments with a guarantee that the data will be held in confidence. Closure of the meetings is in accordance with subsection 10(d) of Public Law 92–463, as amended by Public Law 94–409, and as cited in 5 U.S.C. 552b(c)(2) and (4).

However, members of the public are invited to submit material in writing to the Chairperson for the Committee's attention.

Additional information concerning these meetings may be obtained from the Chairperson, VA Wage Committee, Room 1225, 801 I Street, NW, Washington, DC 20001.

Dated: February 26, 1996.

By Direction of the Secretary.

Heyward Bannister,

Committee Management Officer.

[FR Doc. 96–4880 Filed 3–1–96; 8:45 am]

BILLING CODE 8320–01–M

federal register

Monday
March 4, 1996

Part II

Department of Transportation

Research and Special Programs Administration

49 CFR Parts 171, 173, and 178
Restructuring of Cylinder Specifications Requirements; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 171, 173, and 178

[Docket HM–220B; Notice No. 96–2]

RIN 2137–AC81

Restructuring of Cylinder Specifications Requirements

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: RSPA is proposing to revise the Hazardous Materials Regulations (HMR) by restructuring the cylinder specification requirements. The intended effect of this rulemaking is to reduce the size of the HMR through consolidation of repetitive requirements and other formatting changes. This action will eliminate pages of regulations without substantially changing the regulatory requirements or affecting safety. It is in response to President Clinton's March 4, 1995 Regulatory Reinvention Initiative memorandum to heads of departments and agencies calling for a review of all agency regulations. RSPA is also proposing to make corresponding reference changes throughout the HMR.

DATES: Comments must be received on or before April 26, 1996.

ADDRESSES: Please address written comments to the Dockets Unit (DHM–30), Research and Special Programs Administration, U.S. Department of Transportation, 400 7th Street, SW., Washington, DC 20590–0001. Comments may also be faxed to (202) 366–3753. Comments should identify the docket (Docket No. HM–220B). The Dockets Unit is located in Room 8421 of the Nassif Building, 400 Seventh Street SW., Washington, DC 20590–0001. Office hours are 8:30 a.m. to 5:00 p.m., Monday through Friday, except on public holidays when the office is closed.

FOR FURTHER INFORMATION CONTACT: John A. Gale, (202) 366–8553; Office of Hazardous Materials Standards, RSPA, Department of Transportation, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION:

I. Background

On March 4, 1995, President Clinton issued a Regulatory Reinvention Initiative memorandum to heads of departments and agencies calling for a review of all agency regulations and elimination or revision of those regulations that are outdated or in need of reform. RSPA has performed an extensive review of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171–180) and associated procedural rules (49 CFR Parts 106 and 107) in response to the President's directive.

The President also directed that front line regulators ''* * * get out of Washington and create grassroots partnerships'' with people affected by agency regulations. On April 4, 1995, RSPA published in the Federal Register (60 FR 17049) a Notice of Public Meetings and request for comment on its hazardous materials safety program. Comments were requested on ways to improve the HMR and the kind and quality of services its customers want. RSPA held seven public meetings and received over 50 comments in response to the notice. On July 28, 1995, RSPA published a second Notice of Public Meetings in the Federal Register (60 FR 38888) which announced five more public meetings that were held from September through January 1996.

One area identified by RSPA in its review of the HMR was the need to reform the cylinder specifications in 49 CFR Part 178. RSPA estimates that by consolidating duplicative requirements in 23 cylinder specifications, that it will eliminate at least 40 pages from the CFR. By reformatting the specifications, RSPA proposes to eliminate over 450 sections from Part 178 of Title 49. The combined effect of these changes will be to make the regulations shorter and easier to use and help RSPA move toward a goal of being able to issue the HMR in one volume of the Code of Federal Regulations, rather than two.

This rulemaking also serves as the model for a more comprehensive rulemaking, being developed by RSPA in cooperation with the Compressed Gas Association, for which a notice of proposed rulemaking is anticipated later this year. In this latter rulemaking, under Docket HM–220, RSPA intends to propose substantive changes to the cylinder specifications to accommodate contemporary manufacturing techniques, eliminate obsolete requirements, contemporize regulatory language and make safety enhancements to the regulations.

II. Proposed Changes

In this NPRM, RSPA is proposing to revise the HMR by restructuring the cylinder specification requirements in 49 CFR Part 178. The proposed restructuring of the cylinder specifications would: (1) consolidate similar sections; (2) reformat subpart C of Part 178 for consistency with the format of the rest of Part 178; and (3) revise section references throughout the HMR to correspond to the revised sections. RSPA intends to streamline the cylinder specification requirements without making substantive changes to them.

Sections that have been identified by RSPA for consolidation are the sections of each specification addressing compliance, authorized inspectors, duties of the inspector, the inspector's report, record retention, defects, safety relief devices, and marking. These sections will be consolidated into a new § 178.35. Proposed § 178.35, entitled ''General requirements for all DOT specification cylinders'' will prescribe these general requirements for all DOT specification cylinders. However, because some of the duties of the inspector and marking requirements are specific to the individual cylinder design, some specifications would have additional marking and inspector requirements remaining in their sections.

For the inspector's report, RSPA has proposed to adopt the inspector report formats in Compressed Gas Association (CGA) Pamphlet C–11, ''Recommended Practices for Inspection of Compressed Gas Cylinders at Time of Manufacture.'' The report formats can be modified to represent the inspection of specific cylinders. Additional information may be required as stated in each specification.

Those sections remaining in each specification will be consolidated into a single section. Presently, each specification is set forth in approximately 22 different sections. Under this proposal, there would be only one section for each specification. For example, Specification 3B is currently set forth in 24 sections, §§ 178.38 through 178.38–23. In this NPRM, Specification 3B is set forth in one section, § 178.38. Some of the requirements are relocated in § 178.35. Sixteen of the old sections are converted to paragraphs (a) through (o) of § 178.38. As an aid to the reader, the regulatory text in this notice includes all of the requirements for cylinders in the current Subpart C of part 178, even though not all of the requirements are changed.

The purpose of this rulemaking action is to reduce the size of the HMR and make it easier to use. It is not intended to make substantive changes to regulatory requirements and no adverse impacts are anticipated on the regulated community.

III. Regulatory Analyses and Notices

Executive Order 12866 and DOT Regulatory Policies and Procedures

This proposed rule is not considered a significant regulatory action under section 3(f) of Executive Order 12866 and was not reviewed by the Office of Management and Budget. The rule is not considered significant under the regulatory policies and procedures of the Department of Transportation (44 FR 11034). The economic impact of this rule is minimal to the extent that the preparation of a regulatory evaluation is not warranted.

Executive Order 12612

This proposed rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12612 (''Federalism''). The Federal hazardous materials transportation law (49 U.S.C. 5101–5127) contains an express preemption provision that preempts State, local, and Indian tribe requirements on certain covered subjects. Covered subjects are:

(i) the designation, description, and classification of hazardous material;

(ii) the packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(iii) the preparation, execution, and use of shipping documents pertaining to hazardous material and requirements respecting the number, content, and placement of such documents;

(iv) the written notification, recording, and reporting of the unintentional release in transportation of hazardous material; or

(v) the design, manufacturing, fabrication, marking, maintenance, reconditioning, repairing, or testing of a package or container which is represented, marked, certified, or sold as qualified for use in the transportation of hazardous material.

The Federal hazardous materials transportation law provides that if DOT issues a regulation concerning any of the covered subjects after November 16, 1990, DOT must determine and publish in the Federal Register the effective date of Federal preemption. 49 U.S.C. 5125(b)(2). That effective date may not be earlier than the 90th day following the date of issuance of the final rule and not later than two years after the date of issuance. This proposed rule deals with the packaging of compressed gases. Although this proposal does not contemplate substantive changes, RSPA solicits comments on whether the proposed rule would have any effect on State, local or Indian tribe requirements and, if so, the most appropriate effective date of Federal preemption. Because RSPA lacks discretion in this area, preparation of a federalism assessment is not warranted.

Regulatory Flexibility Act

I certify that this proposed rule will not have a significant economic impact on a substantial number of small entities. This proposed rule does not impose any new requirements on persons subject to the HMR.

Paperwork Reduction Act

This proposed rule does not propose any new information collection requirements.

Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements, Uranium.

49 CFR Part 178

Hazardous materials transportation, Packaging and containers, Reporting and recordkeeping requirements.

In consideration of the foregoing, 49 CFR parts 171, 173, and 178 would be amended to read as follows:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

1. The authority citation for Part 171 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR part 1.53.

2. In § 171.7(a)(3), in the table, under the entry ''Aluminum Standards and Data, Seventh Edition, June 1982'', the section reference ''178.65–5'' is revised to read ''178.65''; and under the entry *Compressed Gas Association, Inc.*, a new entry is added in alpha-numerical order to read as follows:

§ 171.7 Reference material.

* * * * *

(a) * * *

(3) * * *

Source and name of material	49 CFR reference
* * * * *	
Compressed Gas Association, Inc.,	
* * * * *	
CGA Pamphlet C–11, Recommended Practices for Inspection of Compressed Gas Cylinders at Time of Manufacture, 1993	178.35
* * * * *	

* * * * *

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

3. The authority citation for Part 173 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR part 1.53.

§ 173.34 [Amended]

4. In § 173.34, paragraph (h) would be amended by:

a. Removing, in the first sentence, the phrase ''§§ 178.36–9(a), 178.37–9(a), 178.38–9(a), and 178.40–9(a)'' and replacing it with the phrase ''§§ 178.36(e), 178.37(e), 178.38(e), and 178.40(e)''.

b. Removing, in the fourth sentence, the phrase ''§ 178.36–9(a), § 178.37–9(a), § 178.38–9(a), or § 178.40–9(a)'' and replacing it with the phrase ''§ 178.36(e), § 178.37(e), § 178.38(e), or § 178.40(e)''.

§ 173.316 [Amended]

5. In § 173.316, in paragraph (a)(8), the section reference ''178.57- 20(a)(4)'' would be revised to read ''178.35'' and in paragraph (c)(3)(ii) the section reference ''178.57–20'' would be revised to read ''178.35''.

PART 178—SPECIFICATIONS FOR PACKAGINGS

6. The authority citation for Part 178 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR 1.53.

7. Subpart C of Part 178 would be revised to read as follows:

Subpart C—Specifications for Cylinders

Sec.
178.35 General requirements for specification cylinders.
178.36 Specifications 3A and 3AX seamless steel cylinders.
178.37 Specification 3AA and 3AAX seamless steel cylinders.

178.38 Specification 3B seamless steel cylinders.
178.39 Specification 3BN seamless nickel cylinders.
178.42 Specification 3E seamless steel cylinders.
178.44 Specification 3HT seamless steel cylinders for aircraft use.
178.45 Specification 3T seamless steel cylinder.
178.46 Specification 3AL seamless aluminum cylinders.
178.47 Specification 4DS welded stainless steel cylinders for aircraft use.
178.50 Specification 4B welded or brazed steel cylinders.
178.51 Specification 4BA welded or brazed steel cylinders.
178.53 Specification 4D welded steel cylinders for aircraft use.
178.55 Specification 4B240ET welded or brazed cylinders.
178.56 Specification 4AA480 welded steel cylinders.
178.57 Specification 4L welded insulated cylinders.
178.58 Specification 4DA welded steel cylinders for aircraft use.
178.59 Specification 8 steel cylinders with porous fillings for acetylene.
178.60 Specification 8AL steel cylinders with porous fillings for acetylene.
178.61 Specification 4BW welded steel cylinders with electric-arc welded longitudinal seam.
178.65 Specification 39 non-reusable (non-refillable) cylinders.
178.68 Specification 4E welded aluminum cylinders.

Subpart C—Specifications for Cylinders

§ 178.35 General requirements for specification cylinders.

(a) Compliance with the requirements of this subpart is required in all details.

(b) *Inspections and analyses.* Chemical analyses and tests as specified must be made within the United States unless otherwise approved in writing by the Associate Administrator, in accordance with § 173.300b of this subchapter. Inspections and verifications must be performed by—

(1) An independent inspection agency approved in writing by the Associate Administrator, in accordance with § 173.300a of this subchapter; or

(2) For DOT Specifications 3B, 3BN, 4B, 4BA, 4D (water capacity less than 1,100 cubic inches), 4B240ET, 4AA480, 4L, 8, 8AL, 4BW, 39 (marked service pressure 900 p.s.i.g. or lower) and 4E manufactured in the United States, a competent inspector of the manufacturer.

(c) *Duties of inspector.* The inspector shall determine that each cylinder made is in conformance with the applicable specification. Except as otherwise specified in the applicable specification, the inspector shall perform the following:

(1) Inspect all material and reject any not meeting applicable requirements. For cylinders made by the billet-piercing process, billets must be inspected and shown to be free from pipe, cracks, excessive segregation and other injurious defects after parting or, when applicable, after nick and cold break.

(2) Verify the material of construction meets the requirements of the applicable specification by—

(i) Making a chemical analysis of each heat of material;

(ii) Obtaining a certified chemical analysis from the material manufacturer for each heat of material (a ladle analysis is acceptable); or

(iii) If an analysis is not provided for each heat of material by the material manufacturer, by making a check analysis of a sample from each coil, sheet, or tube.

(3) Verify compliance of cylinders with the applicable specification by—

(i) Verifying identification of material is proper;

(ii) Inspecting the inside of the cylinder before closing in ends;

(iii) Verifying that the heat treatment is proper;

(iv) Obtaining samples for all tests and check chemical analyses;

(v) Witnessing all tests;

(vi) Verify threads by gauge;

(vii) Reporting volumetric capacity and tare weight (see report form) and minimum thickness of wall noted; and

(viii) Verifying that each cylinder is marked in accordance with the applicable specification.

(4) Furnish complete test reports required by this subpart to the maker of the cylinder and, upon request, to the purchaser. The test report must be retained by the inspector for fifteen years from the original test date of the cylinder.

(d) *Defects.* A cylinder may not be constructed of material with seams, cracks, laminations, or other injurious defects.

(e) Safety devices and protection for valves, safety devices, and other connections, if applied, must be as required or authorized by the appropriate specification, and as required in §§ 173.34 and 173.301 of this subchapter.

(f) *Markings.* Markings on a DOT Specification cylinder must conform to applicable requirements.

(1) Each cylinder must be marked with the following information:

(i) The DOT specification marking must appear first, followed immediately by the service pressure. For example, DOT–3A1800.

(ii) The serial number must be placed just below or immediately following the DOT specification marking.

(iii) A symbol (letters) must be placed just below, immediately before or following the serial number. Other variations in sequence of markings are authorized only when necessitated by a lack of space. The symbol and numbers must be those of the manufacturer. The symbol must be registered with the Associate Administrator; duplications are not authorized.

(iv) The inspector's official mark and date of test (such as 5–95 for May 1995) must be placed near the serial number. This information must be placed so that dates of subsequent tests can be easily added. An example of the markings prescribed in this paragraph (f)(1) is as follows:

DOT–3A1800
1234
XY
AB 5–95

or;

DOT–3A1800–1234–XY
AB 5–95

where:

DOT–3A = specification number
1800 = service pressure
1234 = serial number
xy = symbol of manufacturer
AB = inspector's mark
5–95 = date of test

(2) Additional required marking must be applied to the cylinder as follows:

(i) The word ''spun'' or ''plug'' must be placed near the DOT specification marking when an end closure in the finished cylinder has been welded by the spinning process, or effected by plugging.

(ii) As prescribed in specification 3HT (§ 178.44) or 3T (§ 178.45), if applicable.

(3) Marking exceptions.

(i) A DOT 3E cylinder is not required to be marked with the inspector mark.

(ii) An identifying lot number may be marked on the cylinder in place of a serial number for cylinders not over 2 inches outside diameter or for cylinders with a volumetric capacity not exceeding 60 cubic inches. Each lot shall not have over 500 cylinders.

(4) Unless otherwise specified in the applicable specification, the markings on each cylinder must be stamped plainly and permanently on the shoulder, top head, or neck.

(5) The size of each marking must be least 0.25 inch or as space permits.

(6) Other markings are authorized provided they are made in low stress areas other than the side wall and are not of a size and depth that will create harmful stress concentrations. Such

marks may not conflict with any DOT required markings.

(g) *Inspector's report.* Each inspector shall prepare a report containing, at a minimum, the applicable information listed in CGA Pamphlet C–11. Any additional information or markings that are required by the applicable specification must be shown on the test report. The signature of the inspector on the reports certifies that the processes of manufacture and heat treatment of cylinders were observed and found satisfactory.

(h) *Report Retention.* The manufacturer of the cylinders shall retain the reports required by this subpart for 15 years from the original test date of the cylinder.

§ 178.36 Specification 3A and 3AX seamless steel cylinders.

(a) *Type size and service pressure.* In addition to the requirements of § 178.35, cylinders must conform to the following:

(1) A DOT–3A cylinder is a seamless steel cylinder with a water capacity (nominal) not over 1,000 pounds and a service pressure of at least 150 pounds per square inch.

(2) A DOT–3AX is a seamless stainless steel cylinder with a water capacity not less than 1,000 pounds and a service pressure of at least 500 pounds per square inch, conforming to the following requirements:

(i) Assuming the cylinder is to be supported horizontally at its two ends only and to be uniformly loaded over its entire length consisting of the weight per unit of length of the straight cylindrical portion filled with water and compressed to the specified test pressure; the sum of two times the maximum tensile stress in the bottom fibers due to bending, plus that in the same fibers (longitudinal stress), due to hydrostatic test may not exceed 80 percent of the minimum yield strength of the steel at such maximum stress. Wall thickness must be increased when necessary to meet the requirement.

(ii) To calculate the maximum longitudinal tensile stress due to bending, the following formula must be used:

$$S=Mc/I$$

(iii) To calculate the maximum longitudinal tensile stress due to hydrostatic test pressure, the following formula must be used:

$$S=A_1P/A_2$$

where:

S = tensile stress-p.s.i.;
M = bending moment-inch pounds $(wl^2)/8$;
w = weight per inch of cylinder filled with water;
l = length of cylinder-inches;
c = radius (D)/(2) of cylinder-inches;
I = moment of inertia-0.04909 $(D^4 - d^4)$ inches fourth;
D = outside diameter-inches;
d = inside diameter-inches;
A_1 = internal area in cross section of cylinder-square inches;
A_2 = area of metal in cross section of cylinder-square inches;
P = hydrostatic test pressure-p.s.i.

(b) *Steel.* Open-hearth or electric steel of uniform quality must be used. Content percent may not exceed the following: Carbon, 0.55; phosphorous, 0.045; sulphur, 0.050.

(c) *Identification of material.* Material must be identified by any suitable method, except that plates and billets for hot-drawn cylinders must be marked with the heat number.

(d) *Manufacture.* Cylinders must be manufactured using equipment and processes adequate to ensure that each cylinder produced conforms to the requirements of this subpart. No fissure or other defect is permitted that is likely to weaken the finished cylinder appreciably. A reasonably smooth and uniform surface finish is required. If not originally free from such defects, the surface may be machined or otherwise treated to eliminate these defects. The thickness of the bottoms of cylinders welded or formed by spinning is, under no condition, to be less than two times the minimum wall thickness of the cylindrical shell; such bottom thicknesses must be measured within an area bounded by a line representing the points of contact between the cylinder and floor when the cylinder is in a vertical position.

(e) *Welding or brazing.* Welding or brazing for any purpose whatsoever is prohibited except as follows:

(1) Welding or brazing is authorized for the attachment of neckrings and footrings which are non-pressure parts and only to the tops and bottoms of cylinders having a service pressure of 500 pounds per square inch or less. Cylinders, neckrings, and footrings must be made of weldable steel, the carbon content of which may not exceed 0.25 percent except in the case of 4130X steel which may be used with proper welding procedures.

(2) As permitted in paragraph (d) of this section.

(3) Cylinders used solely in anhydrous ammonia service may have a ½ inch diameter bar welded within their concave bottoms.

(f) *Wall thickness.* For cylinders with service pressure less than 900 pounds, the wall stress may not exceed 24,000 pounds per square inch. A minimum wall thickness of 0.100 inch is required for any cylinder over 5 inches outside diameter. Wall stress calculation must be made by using the following formula:

$$S=[P(1.3D^2+0.4d^2)]/(D^2 - d^2)$$

where:

S=wall stress in pounds per square inch;
P=minimum test pressure prescribed for water jacket test or 450 pounds per square inch whichever is the greater;
D=outside diameter in inches;
d=inside diameter in inches.

(g) *Heat treatment.* The completed cylinder must be uniformly and properly heat-treated prior to tests.

(h) *Openings in cylinders and connections (valves, fuse plugs, etc.) for those openings.* Threads are required on openings.

(1) Threads must be clean cut, even, without checks, and to gauge.

(2) Taper threads, when used, must be of length not less than as specified for American Standard taper pipe threads.

(3) Straight threads having at least 6 engaged threads are authorized. Straight threads must have a tight fit and calculated shear strength of at least 10 times the test pressure of the cylinder. Gaskets, adequate to prevent leakage, are required.

(i) *Hydrostatic test.* Each cylinder must successfully withstand a hydrostatic test, as follows:

(1) The test must be by water-jacket, or other suitable methods, operated so as to obtain accurate data. The pressure gauge must permit reading to an accuracy of 1 percent. The expansion gauge must permit reading of total expansion to an accuracy of either 1 percent or 0.1 cubic centimeter.

(2) Pressure must be maintained for at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and previous to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus the test pressure cannot be maintained the test may be repeated at a pressure increased by 10 percent or 100 pounds per square inch, whichever is the lower.

(3) Permanent, volumetric expansion may not exceed 10 percent of the total volumetric expansion at test pressure.

(4) Each cylinder must be tested to at least 5/3 times service pressure.

(j) *Flattening test.* A flattening test must be performed on one cylinder taken at random out or each lot of 200 or less, by placing the cylinder between wedge shaped knife edges having a 60° included angle, rounded to ½-inch radius. The longitudinal axis of the cylinder must be at a 90-degree angle to

knife edges during the test. For lots of 30 or less, flattening tests are authorized to be made on a ring at least 8 inches long cut from each cylinder and subjected to same heat treatment as the finished cylinder.

(k) *Physical test.* A physical test must be conducted to determine yield strength, tensile strength, elongation, and reduction of area of material as follows:

(1) The test is required on 2 specimens cut from 1 cylinder taken at random out of each lot of 200 or less. For lots of 30 or less, physical tests are authorized to be made on a ring at least 8 inches long cut from each cylinder and subjected to same heat treatment as the finished cylinder.

(2) Specimens must conform to the following:

(i) Gauge length of 8 inches with a width of not over 1½ inches, a gauge length of 2 inches with a width of not over 1½ inches, or a gauge length of at least 24 times thickness with width not over 6 times thickness is authorized when cylinder wall is not over 3⁄16 inch thick.

(ii) The specimen, exclusive of grip ends, may not be flattened. Grip ends may be flattened to within 1 inch of each end of the reduced section.

(iii) When size of cylinder does not permit securing straight specimens, the specimens may be taken in any location or direction and may be straightened or flattened cold, by pressure only, not by blows. When specimens are so taken and prepared, the inspector's report must show in connection with record of physical tests detailed information in regard to such specimens.

(iv) Heating of a specimen for any purpose is not authorized.

(3) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length. The following conditions apply:

(i) The yield strength must be determined by either the ''offset'' method or the ''extension under load'' method as prescribed in ASTM Standard E8–78.

(ii) In using the ''extension under load'' method, the total strain (or ''extension under load'') corresponding to the stress at which the 0.2-percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic extension of the gauge length under appropriate load and adding thereto 0.2 percent of the gauge length. Elastic extension calculations must be based on an elastic modulus of 30,000,000. In the event of controversy the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2 percent offset.

(iii) For the purpose of strain measurement, the initial strain must be set while the specimen is under a stress of 12,000 pounds per square inch and the strain indicator reading must be set at the calculated corresponding strain.

(iv) Cross-head speed of the testing machine may not exceed ⅛ inch per minute during yield strength determination.

(l) *Acceptable results for physical and flattening tests.* Either of the following is an acceptable result:

(1) An elongation at least 40 percent for a 2-inch gauge length or at least 20 percent in other cases and yield strength not over 73 percent of tensile strength. In this instance, the flattening test is not required.

(2) An elongation at least 20 percent for a 2-inch gauge length or 10 percent in other cases and a yield strength not over 73 percent of tensile strength. In this instance, the flattening test is required, without cracking, to 6 times the wall thickness.

(m) *Leakage test.* All spun cylinders and plugged cylinders must be tested for leakage by gas or air pressure after the bottom has been cleaned and is free from all moisture subject to the following conditions and limitations:

(1) Pressure, approximately the same as but no less than service pressure, must be applied to one side of the finished bottom over an area of at least 1⁄16 of the total area of the bottom but not less than ¾ inch in diameter, including the closure, for at least 1 minute, during which time the other side of the bottom exposed to pressure must be covered with water and closely examined for indications of leakage. Except as provided in paragraph (n) of this section, a cylinder that is leaking must be rejected.

(2) A spun cylinder is one in which an end closure in the finished cylinder has been welded by the spinning process.

(3) A plugged cylinder is one in which a permanent closure in the bottom of a finished cylinder has been effected by a plug.

(4) As a safety precaution, if the manufacturer elects to make this test before the hydrostatic test, the manufacturer should design the test apparatus so that the pressure is applied to the smallest area practicable, around the point of closure, and so as to use the smallest possible volume of air or gas.

(n) *Rejected cylinders.* Reheat treatment is authorized for rejected cylinders. Subsequent thereto, cylinders must pass all prescribed tests to be acceptable. Repair by welding or spinning is not authorized. Spun cylinders rejected under the provisions of paragraph (m) of this section may be removed from the spun cylinder category by drilling to remove defective material, tapping and plugging.

§ 178.37 Specification 3AA and 3AAX seamless steel cylinders.

(a) *Type, size and service pressure.* In addition to the requirements of § 178.35, cylinders must conform to the following:

(1) A DOT–3AA cylinder is a seamless steel cylinder with a water capacity (nominal) of not over 1,000 pounds and a service pressure of at least 150 pounds per square inch.

(2) A DOT–3AAX cylinder is a seamless steel cylinder with a water capacity of not less than 1,000 pounds and a service pressure of at least 500 pounds per square inch, conforming to the following requirements:

(i) Assuming the cylinder is to be supported horizontally at its two ends only and to be uniformly loaded over its entire length consisting of the weight per unit of length of the straight cylindrical portion filled with water and compressed to the specified test pressure; the sum of two times the maximum tensile stress in the bottom fibers due to bending, plus that in the same fibers (longitudinal stress), due to hydrostatic test pressure may not exceed 80 percent of the minimum yield strength of the steel at such maximum stress. Wall thickness must be increased when necessary to meet the requirement.

(ii) To calculate the maximum tensile stress due to bending, the following formula must be used:

$$S=Mc/I$$

(iii) To calculate the maximum longitudinal tensile stress due to hydrostatic test pressure, the following formula must be used:

$$S=A^1P/A^2$$

where:

S=tensile stress-p.s.i.;
M=bending moment-inch pounds $(wl^2)/8$;
w=weight per inch of cylinder filled with water;
l=length of cylinder-inches;
c=radius (D)/(2) of cylinder-inches;
I=moment of inertia-0.04909 $(D^4 - d^4)$ inches fourth;
D=outside diameter-inches;
d=inside diameter-inches;
A^1=internal area in cross section of cylinder-square inches;
A^2=area of metal in cross section of cylinder-square inches;
P=hydrostatic test pressure-p.s.i.

(b) *Authorized steel.* Open-hearth, basic oxygen, or electric steel of uniform

quality must be used. A heat of steel made under the specifications in Table 1 of this paragraph (b), check chemical analysis of which is slightly out of the specified range, is acceptable, if satisfactory in all other respects, provided the tolerance shown in Table 2 of this paragraph (b) are not exceeded. When a carbon-boron steel is used, a hardenability test must be performed on the first and last ingot of each heat of steel. The results of this test must be recorded on the Record of Chemical Analysis of Material for Cylinders required by § 178.35. This hardness test must be made 5/16-inch from the quenched end of the Jominy quench bar and the hardness must be at least Rc 33 and no more than Rc 53. The following chemical analyses are authorized:

TABLE 1.—AUTHORIZED MATERIALS

Designation	4130X (percent) (see Note 1)	NE–8630 (percent) (see Note 1)	9115 (percent) (see Note 1)	9125 (percent) (see Note 1)	Carbon-boron (percent)	Intermediate manganese (percent)
Carbon	0.25/0.35	0.28/0.33	0.10/0.20	0.20/0.30	0.27–0.37	0.40 max.
Manganese	0.40/0.90	0.70/0.90	0.50/0.75	0.50/0.75	0.80–1.40	1.35/1.65
Phosphorus	0.04 max	0.04 max	0.04 max	0.04 max	0.035 max	0.04 max.
Sulfur	0.05 max	0.04 max	0.04 max	0.04 max	0.045 max	0.05 max.
Silicon	0.15/0.35	0.20/0.35	0.60/0.90	0.60/0.90	0.3 max	0.10/0.30
Chromium	0.80/1.10	0.40/0.60	0.50/0.65	0.50/0.65		
Molybdenum	0.15/0.25	0.15/0.25				
Zirconium			0.05/0.15	0.05/0.15		
Nickel		0.40/0.70				
Boron					0.0005/0.003	

NOTE 1: This designation may not be restrictive and the commercial steel is limited in analysis as shown in this Table 1.

TABLE 2.—CHECK ANALYSIS TOLERANCES

Element	Limit or maximum specified (percent)	Tolerance (percent) over the maximum limit or under the minimum limit	
		Under minimum limit	Over maximum limit
Carbon	To 0.15 incl	0.02	0.03
	Over 0.15 to 0.40 incl	.03	.04
Manganese	To 0.60 incl	.03	.03
	Over 0.60 to 1.15 incl	.04	.04
	Over 1.15 to 2.50 incl	.05	.05
Phosphorus [1]	All ranges		.01
Sulphur	All ranges		.01
Silicon	To 0.30 incl	.02	.03
	Over 0.30 to 1.00 incl	.05	.05
Nickel	To 1.00 incl	.03	.03
Chromium	To 0.90 incl	.03	.03
	0.90 to 2.90 incl	.05	.05
Molybdenum	To 0.20 incl	.01	.01
	Over 0.20 to 0.40	.02	.02
Zirconium	All ranges	.01	.05

[1] Rephosphorized steels not subject to check analysis for phosphorus.

(c) *Identification of material.* Material must be identified by any suitable method except that plates and billets for hot-drawn cylinders must be marked with the heat number.

(d) *Manufacture.* Cylinders must be manufactured using equipment and processes adequate to ensure that each cylinder produced conforms to the requirements of this subpart. No fissure or other defects is permitted that is likely to weaken the finished cylinder appreciably. A reasonably smooth and uniform surface finish is required. If not originally free from such defects, the surface may be machined or otherwise treated to eliminate these defects. The thickness of the bottoms of cylinders welded or formed by spinning is, under no condition, to be less than two times the minimum wall thickness of the cylindrical shell; such bottom thicknesses must be measured within an area bounded by a line representing the points of contact between the cylinder and floor when the cylinder is in a vertical position.

(e) *Welding or brazing.* Welding or brazing for any purpose whatsoever is prohibited except as follows:

(1) Welding or brazing is authorized for the attachment of neckrings and footrings which are non-pressure parts, and only to the tops and bottoms of cylinders having a service pressure of 500 pounds per square inch or less. Cylinders, neckrings, and footrings must be made of weldable steel, the carbon content of which may not exceed 0.25 percent except in the case of 4130X steel which may be used with proper welding procedure.

(2) As permitted in paragraph (d) of this section.

(f) *Wall thickness.* The thickness of each cylinder must conform to the following:

(1) For cylinders with a service pressure of less than 900 pounds, the wall stress may not exceed 24,000 pounds per square inch. A minimum wall thickness of 0.100 inch is required for any cylinder with an outside diameter of over 5 inches.

(2) For cylinders with service pressure of 900 p.s.i. or more the minimum wall must be such that the wall stress at the

minimum specified test pressure may not exceed 67 percent of the minimum tensile strength of the steel as determined from the physical tests required in paragraphs (k) and (l) of this section and must be not over 70,000 p.s.i.

(3) Calculation must be made by the formula:

$$S=[P(1.3D^2+0.4d^2)]/(D^2-d^2)$$

where:

S=wall stress in pounds per square inch;
P=minimum test pressure prescribed for water jacket test or 450 pounds per square inch whichever is the greater;
D=outside diameter in inches;
d=inside diameter in inches.

(g) *Heat treatment.* The completed cylinders must be uniformly and properly heat treated prior to tests. Heat treatment of cylinders of the authorized analyses must be as follows:

(1) All cylinders must be quenched by oil, or other suitable medium except as provided in paragraph (g)(5) of this section.

(2) The steel temperature on quenching must be that recommended for the steel analysis, but may not exceed 1750 °F.

(3) All steels must be tempered at a temperature most suitable for that steel.

(4) The minimum tempering temperature may not be less than 1000 °F except as noted in paragraph (l)(vi) of this section.

(5) Steel 4130X may be normalized at a temperature of 1650 °F instead of being quenched and cylinders so normalized need not be tempered.

(6) Intermediate manganese steels may be tempered at temperatures not less than 1150 °F, and after heat treating each cylinder must be submitted to a magnetic test to detect the presence of quenching cracks. Cracked cylinders must be rejected and destroyed.

(7) Except as otherwise provided in paragraph (g)(6) of this section, all cylinders, if water quenched or quenched with a liquid producing a cooling rate in excess of 80 percent of the cooling rate of water, must be inspected by the magnetic particle, dye penetrant or ultrasonic method to detect the presence of quenching cracks. Any cylinder designed to the requirements for specification 3AA and found to have a quenching crack must be rejected and may not be requalified. Cylinders designed to the requirements for specification 3AAX and found to have cracks must have cracks removed to sound metal by mechanical means. Such specification 3AAX cylinders will be acceptable if the repaired area is subsequently examined to assure no defect, and it is determined that design thickness requirements are met.

(h) *Openings in cylinders and connections (valves, fuse plugs, etc.) for those openings.* Threads are required on openings.

(1) Threads must be clean cut, even, without checks, and to gauge.

(2) Taper threads, when used, must be of a length not less than as specified for American Standard taper pipe threads.

(3) Straight threads having at least 6 engaged threads are authorized. Straight threads must have a tight fit and a calculated shear strength of at least 10 times the test pressure of the cylinder. Gaskets, adequate to prevent leakage, are required.

(i) *Hydrostatic test.* Each cylinder must successfully withstand a hydrostatic test as follows:

(1) The test must be by water-jacket, or other suitable method, operated so as to obtain accurate data. The pressure gauge must permit reading to an accuracy of 1 percent. The expansion gauge must permit reading of total expansion to an accuracy of either 1 percent or 0.1 cubic centimeter.

(2) Pressure must be maintained for at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and previous to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus, the test pressure cannot be maintained, the test may be repeated at a pressure increased by 10 percent or 100 pounds per square inch, whichever is the lower.

(3) Permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

(4) Each cylinder must be tested to at least ⅔ times the service pressure.

(j) *Flattening test.* A flattening test must be performed on one cylinder taken at random out of each lot of 200 or less, by placing the cylinder between wedge shaped knife edges having a 60° included angle, rounded to ½-inch radius. The longitudinal axis of the cylinder must be at a 90-degree angle to knife edges during the test. For lots of 30 or less, flattening tests are authorized to be made on a ring at least 8 inches long cut from each cylinder and subjected to same heat treatment as the finished cylinder.

(k) *Physical test.* A physical test must be conducted to determine yield strength, tensile strength, elongation, and reduction of area of material as follows:

(1) The test is required on 2 specimens cut from 1 cylinder taken at random out of each lot of 200 or less. For lots of 30 or less, physical tests are authorized to be made on a ring at least 8 inches long cut from each cylinder and subjected to the same heat treatment as the finished cylinder.

(2) Specimens must conform to the following:

(i) Gauge length of 8 inches with a width of not over 1½ inches, a gauge length of 2 inches with a width of not over 1½ inches, or a gauge length of at least 24 times the thickness with width not over 6 times thickness when the thickness of the cylinder wall is not over 3⁄16 inch.

(ii) The specimen, exclusive of grip ends, may not be flattened. Grip ends may be flattened to within one inch of each end of the reduced section.

(iii) When size of cylinder does not permit securing straight specimens, the specimens may be taken in any location or direction and may be straightened or flattened cold, by pressure only, not by blows. When specimens are so taken and prepared, the inspector's report must show in connection with record of physical tests detailed information in regard to such specimens.

(iv) Heating of a specimen for any purpose is not authorized.

(3) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length. The following conditions apply:

(i) The yield strength must be determined by either the ''offset'' method or the ''extension under load'' method as prescribed in ASTM Standard E8–78.

(ii) In using the ''extension under load'' method, the total strain (or ''extension under load'') corresponding to the stress at which the 0.2 percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic extension of the gauge length under appropriate load and adding thereto 0.2 percent of the gauge length. Elastic extension calculations must be based on an elastic modulus of 30,000,000. In the event of controversy, the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2 percent offset.

(iii) For the purpose of strain measurement, the initial strain must be set while the specimen is under a stress of 12,000 pounds per square inch, the strain indicator reading being set at the calculated corresponding strain.

(iv) Cross-head speed of the testing machine may not exceed ⅛ inch per minute during yield strength determination.

(l) *Acceptable results for physical and flattening tests.* An acceptable result for physical and flattening tests is elongation at least 20 percent for 2

inches of gauge length or at least 10 percent in other cases. Flattening is required without cracking to 6 times the wall thickness of the cylinder.

(m) *Leakage test.* All spun cylinders and plugged cylinders must be tested for leakage by gas or air pressure after the bottom has been cleaned and is free from all moisture. Pressure, approximately the same as but no less than the service pressure, must be applied to one side of the finished bottom over an area of at least 1/16 of the total area of the bottom but not less than 3/4 inch in diameter, including the closure, for at least one minute, during which time the other side of the bottom exposed to pressure must be covered with water and closely examined for indications of leakage. Except as provided in paragraph (n) of this section, a cylinder must be rejected if there is any leaking.

(1) A spun cylinder is one in which an end closure in the finished cylinder has been welded by the spinning process.

(2) A plugged cylinder is one in which a permanent closure in the bottom of a finished cylinder has been effected by a plug.

(3) As a safety precaution, if the manufacturer elects to make this test before the hydrostatic test, the manufacturer should design the test apparatus so that the pressure is applied to the smallest area practicable, around the point of closure, and so as to use the smallest possible volume of air or gas.

(n) *Rejected cylinders.* Reheat treatment is authorized for rejected cylinders. Subsequent thereto, cylinders must pass all prescribed tests to be acceptable. Repair by welding or spinning is not authorized. Spun cylinders rejected under the provision of paragraph (m) of this section may be removed from the spun cylinder category by drilling to remove defective material, tapping and plugging.

§ 178.38 Specification 3B seamless steel cylinders.

(a) *Type, size, and service pressure.* A DOT 3B cylinder is a seamless steel cylinder with a water capacity (nominal) of not over 1,000 pounds and a service pressure of at least 150 to not over 500 pounds per square inch.

(b) *Steel.* Open-hearth or electric steel of uniform quality must be used. Content percent may not exceed the following: carbon, 0.55; phosphorus, 0.045; sulphur, 0.050.

(c) *Identification of material.* Material must be identified by any suitable method except that plates and billets for hot-drawn cylinders must be marked with the heat number.

(d) *Manufacture.* Cylinders must be manufactured using equipment and processes adequate to ensure that each cylinder produced conforms to the requirements of this subpart. No fissure or other defect is permitted that is likely to weaken the finished cylinder appreciably. A reasonably smooth and uniform surface finish is required. If not originally free from such defects, the surface may be machined or otherwise treated to eliminate these defects. The thickness of the bottoms of cylinders welded or formed by spinning is, under no condition, to be less than two times the minimum wall thickness of the cylindrical shell; such bottom thicknesses to be measured within an area bounded by a line representing the points of contact between the cylinder and floor when the cylinder is in a vertical position.

(e) *Welding or brazing.* Welding or brazing for any purpose whatsoever is prohibited except as follows:

(1) Welding or brazing is authorized for the attachment of neckrings and footrings which are non-pressure parts, and only to the tops and bottoms of cylinders having a service pressure of 500 pounds per square inch or less. Cylinders, neckrings, and footrings must be made of weldable steel, carbon content of which may not exceed 0.25 percent except in the case of 4130X steel which may be used with proper welding procedure.

(2) As permitted in paragraph (d) of this section.

(f) *Wall thickness.* The wall stress may not exceed 24,000 pounds per square inch. The minimum wall thickness is 0.090 inch for any cylinder with an outside diameter of 6 inches. Calculation must be made by the following formula:

$$S=[P(1.3D^2+0.4d^2)]/(D^2-d^2)$$

where:

S=wall stress in pounds per square inch;
P=at least two times service pressure or 450 pounds per square inch, whichever is the greater;
D=outside diameter in inches;
d=inside diameter in inches.

(g) *Heat treatment.* The completed cylinders must be uniformly and properly heat-treated prior to tests.

(h) *Openings in cylinders and connections (valves, fuse plugs, etc.) for those openings.* Threads, conforming to the following, are required on all openings.

(1) Threads must be clean cut, even, without checks, and to gauge.

(2) Taper threads when used, must be of a length not less than as specified for American Standard taper pipe threads.

(3) Straight threads having at least 4 engaged threads are authorized. Straight threads must have a tight fit, and calculated shear strength at least 10 times the test pressure of the cylinder. Gaskets, adequate to prevent leakage, are required.

(i) *Hydrostatic test.* Cylinders must successfully withstand a hydrostatic test, as follows:

(1) The test must be by water-jacket, or other suitable method, operated so as to obtain accurate data. The pressure gauge must permit reading to an accuracy of 1 percent. The expansion gauge must permit reading of total expansion to an accuracy either of 1 percent or 0.1 cubic centimeter.

(2) Pressure must be maintained for at least 30 seconds and sufficiently longer to insure complete expansion. Any internal pressure applied after heat-treatment and previous to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus, the test pressure cannot be maintained, the test may be repeated at a pressure increased by 10 percent or 100 pounds per square inch, whichever is the lower.

(3) Permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

(4) Cylinders must be tested as follows:

(i) Each cylinder; to at least 2 times service pressure; or

(ii) 1 cylinder out of each lot of 200 or less; to at least 3 times service pressure. Others must be examined under pressure of 2 times service pressure and show no defect.

(j) *Flattening test.* A flattening test must be performed on one cylinder taken at random out or each lot of 200 or less, by placing the cylinder between wedge shaped knife edges having a 60° included angle, rounded to ½-inch radius. The longitudinal axis of the cylinder must be at a 90-degree angle to knife edges during the test. For lots of 30 or less, flattening tests are authorized to be made on a ring at least 8 inches long cut from each cylinder and subjected to same heat treatment as the finished cylinder.

(k) *Physical test.* A physical test must be conducted to determine yield strength, tensile strength, elongation, and reduction of area of material, as follows:

(1) The test is required on 2 specimens cut from 1 cylinder taken at random out of each lot of 200 or less. For lots of 30 or less, physical tests are authorized to be made on a ring at least 8 inches long cut from each cylinder and subjected to same heat treatment as the finished cylinder.

(2) Specimens must conform to the following:

(i) Gauge length of 8 inches with a width of not over 1½ inches; or a gauge length of 2 inches with a width of not over 1½ inches; or a gauge length at least 24 times the thickness with a width not over 6 times thickness is authorized when a cylinder wall is not over 3/16 inch thick.

(ii) The specimen, exclusive of grip ends, may not be flattened. Grip ends may be flattened to within one inch of each end of the reduced section.

(iii) When size of cylinder does not permit securing straight specimens, the specimens may be taken in any location or direction and may be straightened or flattened cold, by pressure only, not by blows. When specimens are so taken and prepared, the inspector's report must show in connection with record of physical tests detailed information in regard to such specimens.

(iv) Heating of a specimen for any purpose is not authorized.

(3) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length. The following conditions apply:

(i) The yield strength must be determined by either the ''offset'' method or the ''extension under load'' method as prescribed in ASTM Standard E8–78.

(ii) In using the ''extension under load'' method, the total strain (or ''extension under load'') corresponding to the stress at which the 0.2 percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic extension of the gauge length under appropriate load and adding thereto 0.2 percent of the gauge length. Elastic extension calculations must be based on an elastic modulus of 30,000,000. In the event of controversy, the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2 percent offset.

(iii) For the purpose of strain measurement, the initial strain must be set while the specimen is under a stress of 12,000 pounds per square inch, and the strain indicator reading being set at the calculated corresponding strain.

(iv) Cross-head speed of the testing machine may not exceed ⅛ inch per minute during yield strength determination.

(l) *Acceptable results for physical and flattening tests.* Either of the following is an acceptable result:

(1) An elongation of at least 40 percent for a 2-inch gauge length or at least 20 percent in other cases and yield strength not over 73 percent of tensile strength. In this instance, the flattening test is not required.

(2) An elongation of at least 20 percent for a 2-inch gauge length or 10 percent in other cases and yield strength not over 73 percent of tensile strength. Flattening is required, without cracking, to 6 times the wall thickness.

(m) *Leakage test.* All spun cylinders and plugged cylinders must be tested for leakage by gas or air pressure after the bottom has been cleaned and is free from all moisture, subject to the following conditions and limitations:

(1) Pressure, approximately the same as but no less than service pressure, must be applied to one side of the finished bottom over an area of at least 1/16 of the total area of the bottom but not less than ¾ inch in diameter, including the closure, for at least one minute, during which time the other side of the bottom exposed to pressure must be covered with water and closely examined for indications of leakage. Except as provided in paragraph (n) of this section, a cylinder must be rejected if there is any leaking.

(2) A spun cylinder is one in which an end closure in the finished cylinder has been welded by the spinning process.

(3) A plugged cylinder is one in which a permanent closure in the bottom of a finished cylinder has been effected by a plug.

(4) As a safety precaution, if the manufacturer elects to make this test before the hydrostatic test, he should design his apparatus so that the pressure is applied to the smallest area practicable, around the point of closure, and so as to use the smallest possible volume of air or gas.

(n) *Rejected cylinders.* Reheat treatment of rejected cylinders is authorized. Subsequent thereto, cylinders must pass all prescribed tests to be acceptable. Repair by welding or spinning is not authorized. Spun cylinders rejected under the provisions of paragraph (m) of this section may be removed from the spun cylinder category by drilling to remove defective material, tapping and plugging.

(o) *Marking.* Markings may be stamped into the sidewalls of cylinders having a service pressure of 150 psi if all of the following conditions are met:

(1) Wall stress at test pressure may not exceed 24,000 psi.

(2) Minimum wall thickness must be not less than 0.090 inch.

(3) Depth of stamping must be no greater than 15 percent of the minimum wall thickness, but may not exceed 0.015 inch.

(4) Maximum outside diameter of cylinder may not exceed 5 inches.

(5) Carbon content of cylinder may not exceed 0.25 percent. If the carbon content exceeds 0.25 percent, the complete cylinder must be normalized after stamping.

(6) Stamping must be adjacent to the top head.

§ 178.39 Specification 3BN seamless nickel cylinders.

(a) *Type, size and service pressure.* A DOT 3BN cylinder is a seamless nickel cylinder with a water capacity (nominal) not over 125 pounds water capacity (nominal) and a service pressure at least 150 to not over 500 pounds per square inch.

(b) *Nickel.* The percentage of nickel plus cobalt must be at least 99.0 percent.

(c) *Identification of material.* The material must be identified by any suitable method except that plates and billets for hot-drawn cylinders must be marked with the heat number.

(d) *Manufacture.* Cylinders must be manufactured using equipment and processes adequate to ensure that each cylinder produced conforms to the requirements of this subpart. No defect is permitted that is likely to weaken the finished cylinder appreciably. A reasonably smooth and uniform surface finish is required. Cylinders closed in by spinning process are not authorized.

(e) *Welding or brazing.* Welding or brazing for any purpose whatsoever is prohibited except that welding is authorized for the attachment of neckrings and footrings which are nonpressure parts, and only to the tops and bottoms of cylinders. Neckrings and footrings must be of weldable material, the carbon content of which may not exceed 0.25 percent. Nickel welding rod must be used.

(f) *Wall thickness.* The wall stress may not exceed 15,000 pounds per square inch. A minimum wall thickness of 0.100 inch is required for any cylinder over 5 inches in outside diameter. Wall stress calculation must be made by using the following formula:

$$S=[P(1.3D^2+0.4d^2)]/(D^2-d^2)$$

where:

S=Wall stress in pounds per square inch;

P=Minimum test pressure prescribed for water jacket test or 450 pounds per square inch whichever is the greater;

D=Outside diameter in inches;

d=Inside diameter in inches.

(g) *Heat treatment.* The completed cylinders must be uniformly and properly heat-treated prior to tests.

(h) *Openings in cylinders and connections (valves, fuse plugs, etc.) for those openings.* Threads conforming to the following are required on openings.

(1) Threads must be clean cut, even, without checks, and to gauge.

(2) Taper threads, when used, to be of length not less than as specified for American Standard taper pipe threads.

(3) Straight threads having at least 6 engaged threads are authorized. Straight threads must have a tight fit and a calculated shear strength of at least 10 times the test pressure of the cylinder. Gaskets, adequate to prevent leakage, are required.

(i) *Hydrostatic test.* Each cylinder must successfully withstand a hydrostatic test, as follows:

(1) The test must be by water-jacket, or other suitable method, operated so as to obtain accurate data. The pressure gauge must permit reading to an accuracy of 1 percent. The expansion gauge must permit reading of total expansion to an accuracy either of 1 percent or 0.1 cubic centimeter.

(2) Pressure must be maintained for at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and previous to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus, the test pressure cannot be maintained, the test may be repeated at a pressure increased by 10 percent or 100 pounds per square inch, whichever is the lower.

(3) Permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

(4) Each cylinder must be tested to at least 2 times service pressure.

(j) *Flattening test.* A flattening test must be performed on one cylinder taken at random out or each lot of 200 or less, by placing the cylinder between wedge shaped knife edges having a 60° included angle, rounded to ½ inch radius. The longitudinal axis of the cylinder must be at a 90-degree angle to knife edges during the test. For lots of 30 or less, flattening tests are authorized to be made on a ring at least 8 inches long cut from each cylinder and subjected to same heat treatment as the finished cylinder.

(k) *Physical test.* A physical test must be conducted to determine yield strength, tensile strength, elongation, and reduction of area of material, as follows:

(1) The test is required on 2 specimens cut from 1 cylinder taken at random out of each lot of 200 or less. For lots of 30 or less, physical tests are authorized to be made on a ring at least 8 inches long cut from each cylinder and subjected to same heat treatment as the finished cylinder.

(2) Specimens must conform to the following:

(i) A gauge length of 8 inches with a width of not over 1½ inches, a gauge length of 2 inches with a width of not over 1½ inches, or a gauge length of at least 24 times the thickness with a width not over 6 times thickness is authorized when a cylinder wall is not over 3⁄16 inch thick.

(ii) The specimen, exclusive of grip ends, may not be flattened. Grip ends may be flattened to within one inch of each end of the reduced section.

(iii) When size of cylinder does not permit securing straight specimens, the specimens may be taken in any location or direction and may be straightened or flattened cold, by pressure only, not by blows. When specimens are so taken and prepared, the inspector's report must show in connection with record of physical tests detailed information in regard to such specimens.

(iv) Heating of a specimen for any purpose is not authorized.

(3) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length. The following conditions apply:

(i) The yield strength must be determined by either the ''offset'' method or the ''extension under load'' method as prescribed in ASTM Standard E8–78.

(ii) In using the ''extension under load'' method, the total strain (or ''extension under load'') corresponding to the stress at which the 0.2 percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic extension of the gauge length under appropriate load and adding thereto 0.2 percent of the gauge length. Elastic extension calculations must be based on an elastic modulus of 30,000,000. In the event of controversy, the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2 percent offset.

(iii) For the purpose of strain measurement, the initial strain must be set while the specimen is under a stress of 12,000 pounds per square inch, and the strain indicator reading must be set at the calculated corresponding strain.

(iv) Cross-head speed of the testing machine may not exceed ⅛ inch per minute during yield strength determination.

(l) *Acceptable results for physical and flattening tests.* Either of the following is an acceptable result:

(1) An elongation of at least 40 percent for a 2 inch gauge length or at least 20 percent in other cases and yield point not over 50 percent of tensile strength. In this instance, the flattening test is not required.

(2) An elongation of at least 20 percent for a 2 inch gauge length or 10 percent in other cases and a yield point not over 50 percent of tensile strength. Flattening is required, without cracking, to 6 times the wall thickness.

(m) *Rejected cylinders.* Reheat treatment is authorized for rejected cylinders. Subsequent thereto, cylinders must pass all prescribed tests to be acceptable. Repair by welding is not authorized.

§ 178.42 Specification 3E seamless steel cylinders.

(a) *Type, size, and service pressure.* A DOT 3E cylinder is a seamless steel cylinder with an outside diameter not greater than 2 inches nominal, a length less than 2 feet and a service pressure of 1,800 pounds per square inch.

(b) *Steel.* Open-hearth or electric steel of uniform quality must be used. Content percent may not exceed the following: Carbon, 0.55; phosphorus, 0.045; sulphur, 0.050.

(c) *Identification of steel.* Materials must be identified by any suitable method.

(d) *Manufacture.* Cylinders must be manufactured by best appliances and methods. No defect is permitted that is likely to weaken the finished cylinder appreciably. A reasonably smooth and uniform surface finish is required. The thickness of the spun bottom is, under no condition, to be less than two times the minimum wall thickness of the cylindrical shell; such bottom thickness must be measured within an area bounded by a line representing the points of contact between the cylinder and floor when the cylinder is in a vertical position.

(e) *Openings in cylinders and connections (valves, fuse plugs, etc.) for those openings.* Threads conforming to the following are required on openings.

(1) Threads must be clean cut, even, without checks, and to gauge.

(2) Taper threads, when used, must be of length not less than as specified for American Standard taper pipe threads.

(3) Straight threads having at least 4 engaged threads are authorized. Straight threads must have a tight fit and a calculated shear strength of at least 10 times the test pressure of the cylinder. Gaskets, adequate to prevent leakage, are required.

(f) *Hydrostatic test.* Cylinders must be tested as follows:

(1) One cylinder out of each lot of 500 or less must be subjected to a hydrostatic pressure of 6,000 pounds per square inch or higher.

(2) The cylinder referred to in paragraph (f)(1) of this section must burst at a pressure higher than 6,000 pounds per square inch without fragmenting or otherwise showing lack of ductility, or must hold a pressure of

12,000 pounds per square inch for 30 seconds without bursting. In which case, it must be subjected to a flattening test without cracking to six times wall thickness between knife edges, wedge shaped 60 degree angle, rounded out to a ½ inch radius. The inspector's report must be suitably changed to show results of latter alternate and flattening test.

(3) Other cylinders must be examined under pressure of at least 3,000 pounds per square inch and not to exceed 4,500 pounds per square inch and show no defect. Cylinders tested at a pressure in excess of 3,600 pounds per square inch must burst at a pressure higher than 7,500 pounds per square inch when tested as specified in paragraph (f)(2) of this section. The pressure must be maintained for at least 30 seconds and sufficiently longer to ensure complete examination.

(g) *Leakage test.* All spun cylinders and plugged cylinders must be tested for leakage by gas or air pressure after the bottom has been cleaned and is free from all moisture subject to the following conditions and limitations:

(1) A pressure, approximately the same as but not less than the service pressure, must be applied to one side of the finished bottom over an area of at least 1/16 of the total area of the bottom but not less than ¾ inch in diameter, including the closure, for at least one minute, during which time the other side of the bottom exposed to pressure must be covered with water and closely examined for indications of leakage. Accept as provided in paragraph (h) of this section, a cylinder must be rejected if there is any leakage.

(2) A spun cylinder is one in which an end closure in the finished cylinder has been welded by the spinning process.

(3) A plugged cylinder is one in which a permanent closure in the bottom of a finished cylinder has been effected by a plug.

(4) As a safety precaution, if the manufacturer elects to make this test before the hydrostatic test, the manufacturer shall design the test apparatus so that the pressure is applied to the smallest area practicable, around the point of closure, and so as to use the smallest possible volume of air or gas.

(h) *Rejected cylinders.* Reheat treatment is authorized for rejected cylinders. Subsequent thereto, cylinders must pass all prescribed tests to be acceptable. Repair by welding or spinning is not authorized. Spun cylinders rejected under the provisions of paragraph (g) of this section may be removed from the spun cylinder category by drilling to remove defective material, tapping and plugging.

(i) *Marking.* Markings required by § 178.35 must be stamped plainly and permanently on the shoulder, top head, neck or sidewall of each cylinder.

§ 178.44 Specification 3HT seamless steel cylinders for aircraft use.

(a) *Type, size and service pressure.* A DOT 3HT cylinder is a seamless steel cylinder with a water capacity (nominal) of not over 150 pounds and a service pressure of at least 900 pounds per square inch.

(b) *Authorized steel.* Open hearth or electric furnace steel of uniform quality must be used. A heat of steel made under the specifications listed in Table 1 of this paragraph (b), check chemical analysis of which is slightly out of the specified range, is acceptable, if satisfactory in all other respects, provided the tolerances shown in Table 2 of this paragraph (b) are not exceeded. Grain size 6 or finer according to ASTM Spec. E19–46. Steel of the following chemical analysis is authorized:

TABLE 1.—AUTHORIZED MATERIALS

Designation	AISI 4130 (percent)
Carbon	0.28/0.33
Manganese	0.40/0.60
Phosphorus	0.040 maximum
Sulfur	0.040 maximum
Silicon	0.15/0.35
Chromium	0.80/1.10
Molybdenum	0.18/0.25.

TABLE 2—CHECK ANALYSIS TOLERANCES

Element	Limit or maximum specified (percent)	Tolerance (percent) over the maximum limit or under the minimum limit	
		Under minimum limit	Over maximum limit
Carbon	Over 0.15 to 0.40 incl	.03	.04
Manganese	To 0.60 incl	.03	.03
Phosphorus [1]	All ranges		.01
Sulphur	All ranges		.01
Silicon	To 0.30 incl	.02	.03
	Over 0.30 to 1.00 incl	.05	.05
Chromium	To 0.90 incl	.03	.03
	Over 0.90 to 2.10 incl	.05	.05
Molybdenum	To 0.20 incl	.01	.01
	Over 0.20 to 0.40 incl	.02	.02

[1] Rephosphorized steels not subject to check analysis for phosphorus.

(c) *Identification of material.* Material must be identified by any suitable method. Steel stamping of heat identifications may not be made in any area which will eventually become the side wall of the cylinder. Depth of stamping may not encroach upon the minimum prescribed wall thickness of the cylinder.

(d) *Manufacture.* Cylinders must be manufactured using equipment and processes adequate to ensure that each cylinder produced conforms to the requirements of this subpart. No fissure or other defect is permitted that is likely to weaken the finished container appreciably. The general surface finish may not exceed a roughness of 250 RMS. Individual irregularities such as draw marks, scratches, pits, etc., should be held to a minimum consistent with good high stress pressure vessel manufacturing practices. If the cylinder is not originally free of such defects or does not meet the finish requirements, the surface may be machined or otherwise treated to eliminate these defects. The point of closure of cylinders closed by spinning may not be less than two times the prescribed wall thickness of the cylindrical shell. The cylinder end contour must be hemispherical or ellipsoidal with a ratio of major-to-minor axis not exceeding two to one and with the concave side to pressure.

(e) *Welding or brazing.* Welding or brazing for any purpose whatsoever is prohibited, except that welding by spinning is permitted to close the bottom of spun cylinders. Machining or grinding to produce proper surface finish at point of closure is required.

(f) *Wall thickness.* (1) Minimum wall thickness for any cylinder must be 0.050 inch. The minimum wall thickness must be such that the wall stress at the minimum specified test pressure may not exceed 75 percent of the minimum tensile strength of the steel as determined from the physical tests required in paragraph (m) of this section and may not be over 105,000 psi.

(2) Calculations must be made by the formula:

$$S=[P(1.3D^2+0.4d^2)]/(D^2-d^2)$$

where:

S=Wall stress in pounds per square inch;

P=Minimum test pressure prescribed for water jacket test;

D=Outside diameter in inches;

d=Inside diameter in inches.

(3) Wall thickness of hemispherical bottoms only permitted to 90 percent of minimum wall thickness of cylinder sidewall but may not be less than 0.050 inch. In all other cases, thickness to be no less than prescribed minimum wall.

(g) *Heat treatment.* The completed cylinders must be uniformly and properly heated prior to tests. Heat treatment of the cylinders of the authorized analysis must be as follows:

(1) All cylinders must be quenched by oil, or other suitable medium.

(2) The steel temperature on quenching must be that recommended for the steel analysis, but may not exceed 1750° F.

(3) The steel must be tempered at a temperature most suitable for the particular steel analysis but not less than 850° F.

(4) All cylinders must be inspected by the magnetic particle or dye penetrant method to detect the presence of quenching cracks. Any cylinder found to have a quenching crack must be rejected and may not be requalified.

(h) *Openings in cylinders and connections (valves, fuse plugs, etc.) for those openings.* Threads conforming to the following are required on openings:

(1) Threads must be clean cut, even, without cracks, and to gauge.

(2) Taper threads, when used, must be of length not less than as specified for National Gas Tapered Thread (NGT) as required by American Standard Compressed Gas Cylinder Valve Outlet and Inlet Connections.

(3) Straight threads having at least 6 engaged threads are authorized. Straight threads must have a tight fit and a calculated shear stress of at least 10 times the test pressure of the cylinder.

Gaskets, adequate to prevent leakage, are required.

(i) *Hydrostatic test.* Each cylinder must withstand a hydrostatic test, as follows:

(1) The test must be by water-jacket, or other suitable method, operated so as to obtain accurate data. Pressure gauge must permit reading to an accuracy of 1 percent. The expansion gauge must permit reading of total expansion to an accuracy either of 1 percent of 0.1 cubic centimeter.

(2) Pressure must be maintained for at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat treatment and previous to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus, the test pressure cannot be maintained, the test may be repeated at a pressure increased by 10 percent or 100 pounds per square inch, which ever is the lower.

(3) Permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

(4) Each cylinder must be tested to at least 5/3 times service pressure.

(j) *Cycling tests.* Prior to the initial shipment of any specific cylinder design, cyclic pressurization tests must have been performed on at least three representative samples without failure as follows:

(1) Pressurization must be performed hydrostatically between approximately zero psig and the service pressure at a rate not in excess of 10 cycles per minute. Adequate recording instrumentation must be provided if equipment is to be left unattended for periods of time.

(2) Tests prescribed in paragraph (j)(1) of this section must be repeated on one random sample out of each lot of cylinders. The cylinder may then be subjected to a burst test.

(3) A lot is defined as a group of cylinders fabricated from the same heat of steel, manufactured by the same process and heat treated in the same equipment under the same conditions of time, temperature, and atmosphere, and may not exceed a quantity of 200 cylinders.

(4) All cylinders used in cycling tests must be destroyed.

(k) *Burst test.* One cylinder taken at random out of each lot of cylinders must be hydrostatically tested to destruction.

(l) Flattening test. A flattening test must be performed on one cylinder taken at random out or each lot of 200 or less, by placing the cylinder between wedge shaped knife edges having a 60° included angle, rounded to ½-inch radius. The longitudinal axis of the cylinder must be at a 90-degree angle to knife edges during the test. For lots of 30 or less, flattening tests are authorized to be made on a ring at least 8 inches long cut from each cylinder and subjected to same heat treatment as the finished cylinder.

(m) *Physical tests.* A physical test must be conducted to determine yield strength, tensile strength, elongation, and reduction of area of material , as follows:

(1) Test is required on 2 specimens cut from 1 cylinder taken at random out of each lot of cylinders.

(2) Specimens must conform to the following:

(i) A gauge length of at least 24 times the thickness with a width not over six times the thickness. The specimen, exclusive of grip ends, may not be flattened. Grip ends may be flattened to within one inch of each end of the reduced section. When size of cylinder does not permit securing straight specimens, the specimens may be taken in any location or direction and may be straightened or flattened cold by pressure only, not by blows. When specimens are so taken and prepared, the inspector's report must show in connection with the record of physical tests detailed information in regard to such specimens.

(ii) Heating of a specimen for any purpose is not authorized.

(3) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length.

(i) The yield strength must be determined by either the ''offset'' method or the ''extension under load'' method as prescribed in ASTM Standard E8–78.

(ii) In using the ''extension under load'' method, the total strain (or ''extension under load'') corresponding to the stress at which the 0.2 percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic extension of the gauge length under appropriate load and adding thereto 0.2 percent of the gauge length. Elastic extension calculations must be based on an elastic modulus of 30,000,000. In the event of controversy, the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2 percent offset.

(iii) For the purpose of strain measurement, the initial strain must be set while the specimen is under a stress of 12,000 pounds per square inch, the strain indicator reading being set at the calculated corresponding strain.

(iv) Cross-head speed of the testing machine may not exceed ⅛ inch per minute during yield strength determination.

(n) *Magnetic particle inspection.* Inspection must be performed on the inside of each container before closing and externally on each finished container after heat treatment. Evidence of discontinuities, which in the opinion of a qualified inspector may appreciably weaken or decrease the durability of the cylinder, must be cause for rejection.

(o) *Leakage test.* All spun cylinders and plugged cylinders must be tested for leakage by dry gas or dry air pressure after the bottom has been cleaned and is free from all moisture, subject to the following conditions and limitations:

(1) Pressure, approximately the same as but not less than service pressure, must be applied to one side of the finished bottom over an area of at least 1/16 of the total area of the bottom but not less than ¾ inch in diameter, including the closure, for at least one minute, during which time the other side of the bottom exposed to pressure must be covered with water and closely examined for indications of leakage. Except as provided in paragraph (q) of this section, a cylinder must be rejected if there is leakage.

(2) A spun cylinder is one in which an end closure in the finished cylinder has been welded by the spinning process.

(3) A plugged cylinder is one in which a permanent closure in the bottom of a finished cylinder has been effected by a plug.

(4) As a safety precaution, if the manufacturer elects to make this test before the hydrostatic test, the manufacturer should design the test apparatus so that the pressure is applied to the smallest area practicable, around the point of closure, and so as to use the smallest possible volume of air or gas.

(p) *Acceptable results of tests.* Results of the flattening test, physical tests, burst test, and cycling test must conform to the following:

(1) Flattening required without cracking to ten times the wall thickness of the cylinder.

(2) Physical tests:

(i) An elongation of at least 6 percent for a gauge length of 24 times the wall thickness.

(ii) The tensile strength may not exceed 165,000 p.s.i.

(3) The burst pressure must be at least ¾ times the test pressure.

(4) Cycling-at least 10,000 pressurizations.

(q) *Rejected cylinders.* Reheat treatment is authorized for rejected cylinders. Subsequent thereto, cylinders must pass all prescribed tests to be acceptable. Repair by welding or spinning is not authorized. For each cylinder subjected to reheat treatment during original manufacture, sidewall measurements must be made to verify that the minimum sidewall thickness meets specification requirements after the final heat treatment.

(r) *Marking.* (1) Cylinders must be marked by low stress type steel stamping in an area and to a depth which will insure that the wall thickness measured from the root of the stamping to the interior surface is equal to or greater than the minimum prescribed wall thickness. Stamping must be permanent and legible. Stamping on side wall not authorized.

(2) The rejection elastic expansion (REE), in cubic centimeters (cc), must be marked on the cylinder near the date of test. The REE for a cylinder is 1.05 times its original elastic expansion.

(3) Name plates are authorized, provided that they can be permanently and securely attached to the cylinder. Attachment by either brazing or welding is not permitted. Attachment by soldering is permitted provided steel temperature does not exceed 500 °F.

(s) *Inspector's report.* In addition to the requirements of § 178.35, the inspector's report must indicate the rejection elastic expansion (REE), in cubic centimeters (cc).

§ 178.45 Specification 3T seamless steel cylinder.

(a) *Type, size, and service pressure.* A DOT 3T cylinder is a seamless steel cylinder with a minimum water capacity of 1,000 pounds and a minimum service pressure of 1,800 p.s.i. Each cylinder must have integrally formed heads concave to pressure at both ends. The inside head shape must be hemispherical, ellipsoidal in which the major axis is two times the minor axis, or a dished shape falling within these two limits. Permanent closures formed by spinning are prohibited.

(b) *Material, steel.* Only open hearth, basic oxygen, or electric furnace process steel of uniform quality is authorized. The steel analysis must conform to the following:

ANALYSIS TOLERANCES

Element	Ladle analysis	Check analysis	
		Under	Over
Carbon	0.35 to 0.50	0.03	0.04
Manganese	0.75 to 1.05	.04	.04
Phosphorus (max)	0.035		.01
Sulphur (max)	.04		.01
Silicon	0.15 to 0.35	.02	.03
Chromium	0.80 to 1.15	.05	.05
Molybdenum	0.15 to 0.25	.02	.02

(1) A heat of steel made under the specifications in the table in this paragraph (b), the ladle analysis of which is slightly out of the specified range, is acceptable if satisfactory in all other aspects. However, the check

analysis tolerances shown in the table in this paragraph (b) may not be exceeded except as approved by the Department.

(2) Material with seams, cracks, laminations, or other injurious defects is not permitted.

(3) Material used must be identified by any suitable method.

(c) *Manufacture.* General manufacturing requirements are as follows:

(1) Surface finish must be uniform and reasonably smooth.

(2) Inside surfaces must be clean, dry, and free of loose particles.

(3) No defect of any kind is permitted if it is likely to weaken a finished cylinder.

(4) If the cylinder surface is not originally free from the defects, the surface may be machined or otherwise treated to eliminate these defects provided the minimum wall thickness is maintained.

(5) Welding or brazing on a cylinder is not permitted.

(d) *Wall thickness.* The minimum wall thickness must be such that the wall stress at the minimum specified test pressure does not exceed 67 percent of the minimum tensile strength of the steel as determined by the physical tests required in paragraphs (j) and (k) of this section. A wall stress of more than 90,500 p.s.i. is not permitted. The minimum wall thickness for any cylinder may not be less than 0.225 inch.

(1) Calculation of the stress for cylinders must be made by the following formula:

$$S=[P(1.3D^2+0.4d^2)]/(D^2-d^2)$$

where:

S=Wall stress in pounds per square inch;

P=Minimum test pressure, at least 5/3 service pressure;

D=Outside diameter in inches;

d=Inside diameter in inches.

(2) Each cylinder must meet the following additional requirement which assumes a cylinder horizontally supported at its two ends and uniformly loaded over its entire length. This load consists of the weight per inch of length of the straight cylindrical portion filled with water compressed to the specified test pressure. The wall thickness must be increased when necessary to meet this additional requirement:

(i) The sum of two times the maximum tensile stress in the bottom fibers due to bending (see paragraph (d)(2)(ii) of this section), plus the maximum tensile stress in the same fibers due to hydrostatic testing (see paragraph (d)(2)(iii) of this section) may not exceed 80 percent of the minimum yield strength of the steel at this maximum stress.

(ii) The following formula must be used to calculate the maximum tensile stress due to bending:

$$S=Mc/I$$

where:

S=Tensile stress in pounds per square inch;

M=Bending moment in inch-pounds ($wl^2/8$);

I=Moment of inertia-0.04909 (D^4-d^4) in inches fourth;

c=Radius (D/2) of cylinder in inches;

w=Weight per inch of cylinder filled with water;

l=Length of cylinder in inches;

D=Outside diameter in inches;

d=Inside diameter in inches.

(iii) The following formula must be used to calculate the maximum longitudinal tensile stress due to hydrostatic test pressure:

$$S=A_1P/A_2$$

where:

S=Tensile stress in pounds per square inch;

A_1=Internal area in cross section of cylinder in square inches;

P=Hydrostatic test pressure in pounds per square, inch;

A_2=Area of metal in cross section of cylinder in square inches.

(e) *Heat treatment.* Each completed cylinder must be uniformly and properly heat treated prior to testing, as follows:

(1) Each cylinder must be heated and held at the proper temperature for at least one hour per inch of thickness based on the maximum thickness of the cylinder and then quenched in a suitable liquid medium having a cooling rate not in excess of 80 percent of water. The steel temperature on quenching must be that recommended for the steel analysis, but it must never exceed 1750 °F. (2) After quenching, each cylinder must be reheated to a temperature below the transformation range but not less than 1050 °F., and must be held at this temperature for at least one hour per inch of thickness based on the maximum thickness of the cylinder. Each cylinder must then be cooled under conditions recommended for the steel.

(f) *Openings.* Openings in cylinders must comply with the following:

(1) Openings are permitted on heads only.

(2) The size of any centered opening in a head may not exceed one half the outside diameter of the cylinder.

(3) Openings in a head must have ligaments between openings of at least three times the average of their hole diameter. No off-center opening may exceed 2.625 inches in diameter.

(4) All openings must be circular.

(5) All openings must be threaded. Threads must be in compliance with the following:

(i) Each thread must be clean cut, even, without any checks, and to gauge.

(ii) Taper threads, when used, must be the American Standard Pipe thread (NPT) type and must be in compliance with the requirements of NBS Handbook H–28, Part II, Section VII.

(iii) Taper threads conforming to National Gas Taper thread (NGT) standards must be in compliance with the requirements of NBS Handbook H–28, Part II, Sections VII and IX.

(iv) Straight threads conforming with National Gas Straight thread (NGS) standards are authorized. These threads must be in compliance with the requirements of NBS Handbook H–28, Part II, Sections VII and IX.

(g) *Hydrostatic test.* Each cylinder must be tested at an internal pressure by the water jacket method or other suitable method, conforming to the following requirements:

(1) The testing apparatus must be operated in a manner that will obtain accurate data. Any pressure gauge used must permit reading to an accuracy of one percent. Any expansion gauge used must permit reading of the total expansion to an accuracy of one percent.

(2) Any internal pressure applied to the cylinder after heat treatment and before the official test may not exceed 90 percent of the test pressure.

(3) The pressure must be maintained sufficiently long to assure complete expansion of the cylinder. In no case may the pressure be held less than 30 seconds.

(4) If, due to failure of the test apparatus, the required test pressure cannot be maintained, the test must be repeated at a pressure increased by 10 percent or 100 p.s.i., whichever is lower or, the cylinder must be reheat treated.

(5) Permanent volumetric expansion of the cylinder may not exceed 10 percent of its total volumetric expansion at the required test pressure.

(6) Each cylinder must be tested to at least 5/3 times its service pressure.

(h) *Ultrasonic examination.* After the hydrostatic test, the cylindrical section of each vessel must be examined in accordance with ASTM Standard A–388–67 using the angle beam technique. The equipment used must be calibrated to detect a notch equal to five percent of the design minimum wall thickness. Any discontinuity indication greater than that produced by the five percent notch must be cause for rejection of the

cylinder unless the discontinuity is repaired within the requirements of this specification.

(i) *Basic requirements for tension and Charpy impact tests.* Cylinders must be subjected to a tension and Charpy impact as follows:

(1) When the cylinders are heat treated in a batch furnace, two tension specimens and three Charpy impact specimens must be tested from one of the cylinders or a test ring from each batch. The lot size represented by these tests may not exceed 200 cylinders.

(2) When the cylinders are heat treated in a continuous furnace, two tension specimens and three Charpy impact specimens must be tested from one of the cylinders or a test ring from each four hours or less of production. However, in no case may a test lot based on this production period exceed 200 cylinders.

(3) Each specimen for the tension and Charpy impact tests must be taken from the side wall of a cylinder or from a ring which has been heat treated with the finished cylinders of which the specimens must be representative. The axis of the specimens must be parallel to the axis of the cylinder. Each cylinder or ring specimen for test must be of the same diameter, thickness, and metal as the finished cylinders they represent. A test ring must be at least 24 inches long with ends covered during the heat treatment process so as to simulate the heat treatment process of the finished cylinders it represents.

(4) A test cylinder or test ring need represent only one of the heats in a furnace batch provided the other heats in the batch have previously been tested and have passed the tests and that such tests do not represent more than 200 cylinders from any one heat.

(5) The test results must conform to the requirements specified in paragraphs (j) and (k) of this section.

(6) When the test results do not conform to the requirements specified, the cylinders represented by the tests may be reheat treated and the tests repeated. Paragraph (i)(5) of this section applies to any retesting.

(j) *Basic conditions for acceptable physical testing.* The following criteria must be followed to obtain acceptable physical test results:

(1) Each tension specimen must have a gauge length of two inches with a width not exceeding one and one-half inches. Except for the grip ends, the specimen may not be flattened. The grip ends may be flattened to within one inch of each end of the reduced section.

(2) A specimen may not be heated after heat treatment specified in paragraph (d) of this section.

(3) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gage length.

(i) This yield strength must be determined by the ''offset'' method or the ''extension under load'' method described in ASTM Standard E8–69.

(ii) For the ''extension under load'' method, the total strain (or extension under load) corresponding to the stress at which the 0.2 percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic extension of the gage length under appropriate load and adding thereto 0.2 percent of the gage length. Elastic extension calculations must be based on an elastic modulus of 30,000,000. However, when the degree of accuracy of this method is questionable the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2 percent offset.

(iii) For the purpose of strain measurement, the initial strain must be set with the specimen under a stress of 12,000 p.s.i. and the strain indicator reading set at the calculated corresponding strain.

(iv) The cross-head speed of the testing machine may not exceed ⅛ inch per minute during the determination of yield strength.

(4) Each impact specimen must be Charpy V-notch type size 10 mm × 10 mm taken in accordance with paragraph 11 of ASTM Standard A–333–67. When a reduced size specimen is used, it must be the largest size obtainable.

(k) *Acceptable physical test results.* Results of physical tests must conform to the following:

(1) The tensile strength may not exceed 155,000 p.s.i.

(2) The elongation must be at least 16 percent for a two-inch gage length.

(3) The Charpy V-notch impact properties for the three impact specimens which must be tested at 0° F may not be less than the values shown as follows:

Size of specimen (mm)	Average value for acceptance (3 specimens)	Minimum value (1 specimen only of the 3)
10.0 × 10.0 ...	25.0 ft. lbs	20.0 ft. lbs.
10.0 × 7.5	21.0 ft. lbs	17.0 ft. lbs.
10.0 × 5.0	17.0 ft. lbs	14.0 ft. lbs.

(4) After the final heat treatment, each vessel must be hardness tested on the cylindrical section. The tensile strength equivalent of the hardness number obtained may not be more than 165,000 p.s.i. (Rc 36). When the result of a hardness test exceeds the maximum permitted, two or more retests may be made; however, the hardness number obtained in each retest may not exceed the maximum permitted.

(l) *Rejected cylinders.* Reheat treatment is authorized for rejected cylinders. However, each reheat treated cylinder must subsequently pass all the prescribed tests. Repair by welding is not authorized.

(m) *Markings.* Marking must be done by stamping into the metal of the cylinder. All markings must be legible and located on a shoulder.

(n) *Inspector's report.* In addition to the requirements of § 178.35, the inspector's report for the physical test report, must indicate the average value for three specimens and the minimum value for one specimen for each lot number.

§ 178.46 Specification 3AL seamless aluminum cylinders.

(a) *Size and service pressure.* A DOT 3AL cylinder is a seamless aluminum cylinder with a maximum water capacity of 1000 pounds and minimum service pressure of 150 psig.

(b) *Authorized material and identification of material.* The material of construction must meet the following conditions:

(1) Starting stock must be cast stock or traceable to cast stock.

(2) Material with seams, cracks, laminations, or other defects likely to weaken the finished cylinder may not be used.

(3) Material must be identified by a suitable method that will identify the alloy, the aluminum producer's cast number, the solution heat treat batch number and the lot number.

(4) The material must be of uniform quality. Only the following heat treatable aluminum alloys in Tables 1 and 2 of this paragraph (b)(4) are permitted:

TABLE 1.—CHEMICAL COMPOSITION LIMITS[1]

[Chemical composition (in weight percent)]

Aluminum Assoc. alloy designation No.	Si	Fe	Cu	Mn	Mg	Cr	Zn	Ti	Pb	Bi	Other[2]		Al
											Each	Total	
6351	0.7–1.3	0.50	0.10	0.40–0.80	0.40–0.80	.....	0.20	0.20	0.01	0.01	0.05	0.15	Remainder.
6061	0.40–0.80	.70	0.15–0.40	0.15	0.80–1.20	0.04–0.35	.25	.15	.01	.01	.05	.15	Remainder.

[1] ASTM B 221–76 Standard Specification for Aluminum Alloy Extruded Bars, Rods, Shapes, and Tubes, Table 1 Chemical Composition Limits, Except for Pb and Bi. Limits are in percent maximum unless otherwise indicated.

[2] Analysis is regularly made only for the elements for which specific limits are shown, except for unalloyed aluminum. If however, the presence of other elements is suspected to be, or in the course of routine analysis is indicated to be in excess of specified limits, further analysis is made to determine that these other elements are not in excess of the amounts specified. (Aluminum Association Standards and Data/6th Edition, 1979).

TABLE 2—MECHANICAL PROPERTY LIMITS

Alloy and temper	Tensile strength—PSI		Elongation—percent minimum for 2″ or 4D[1] size specimen
	Ultimate—minimum	Yield-minimum	
6351–T6	42,000	37,000	[2] 14
6061–T6	38,000	35,000	[2] 14

[1] ''D'' represents specimen diameters. When the cylinder wall is greater than 3/16-inch thick, a retest without reheat treatment using the 4D size specimen is authorized if the test using the 2 inch size specimen fails to meet elongation requirements.

[2] When cylinder wall is not over 3/16-inch thick, 10 percent elongation is authorized when using a 24t x 6t size test specimen.

(5) All starting stock must be 100 percent ultrasonically inspected, along the length at right angles to the central axis from two positions at 90° to one another. The equipment and continuous scanning procedure must be capable of detecting and rejecting internal defects such as cracks which have an ultrasonic response greater than that of a calibration block with a 5/64-inch diameter flat bottomed hole.

(6) Cast stock must have uniform equiaxed grain structure not to exceed 500 microns maximum.

(7) Any starting stock not complying with the above must be rejected.

(c) *Manufacture.* Cylinders must be manufactured in accordance with the following requirements:

(1) Cylinder shells must be manufactured by the backward extrusion method and have a cleanliness level adequate to ensure proper inspection. No fissure or other defect is acceptable that is likely to weaken the finished cylinder below the design strength requirements. A reasonably smooth and uniform surface finish is required. If not originally free from such defects, the surface may be machined or otherwise conditioned to eliminate these defects.

(2) Thickness of the cylinder base may not be less than the prescribed minimum wall thickness of the cylindrical shell. The cylinder base must have a basic torispherical, hemispherical, or ellipsoidal interior base configuration where the dish radius is no greater than 1.2 times the inside diameter of the shell. The knuckle radius may not be less than 12 percent of the inside diameter of the shell. The interior base contour may deviate from the true torispherical, hemispherical or ellipsoidal configuration provided that—

(i) Any areas of deviation are accompanied by an increase in base thickness;

(ii) All radii of merging surfaces are equal to or greater than the knuckle radius;

(iii) Each design has been qualified by successfully passing the cycling tests in paragraph (c) of this section; and

(iv) Detailed specifications of the base design are available to the inspector.

(3) For free standing cylinders, the base thickness must be at least two times the minimum wall thickness along the line of contact between the cylinder base and the floor when the cylinders are in the vertical position.

(4) Welding or brazing is prohibited.

(5) Each new design and any significant change to any acceptable design must be qualified for production by testing prototype samples as follows:

(i) Three samples must be subjected to 100,000 pressure reversal cycles between zero and service pressure or 10,000 pressure reversal cycles between zero and test pressure, at a rate not in excess of 10 cycles per minute without failure.

(ii) Three samples must be pressurized to destruction and failure may not occur at less than 2.5 times the marked cylinder service pressure. Each cylinder must remain in one piece. Failure must initiate in the cylinder sidewall in a longitudinal direction. Rate of pressurization may not exceed 200 psi per second.

(6) In this specification ''significant change'' means a 10 percent or greater change in cylinder wall thickness, service pressure, or diameter; a 30 percent or greater change in water capacity or base thickness; any change in material; over 100 percent increase in size of openings; or any change in the number of openings.

(d) *Wall thickness.* The minimum wall thickness must be such that the wall stress at the minimum specified test pressure will not exceed 80 percent of the minimum yield strength nor exceed 67 percent of the minimum ultimate tensile strength as verified by physical tests in paragraph (i) of this section. The minimum wall thickness for any cylinder with an outside diameter greater than 5 inches must be 0.125 inch. Calculations must be made by the following formula:

$$S=[P(1.3D^2+0.4d^2)]/(D^2-d^2)$$

where:

S=Wall stress in pounds per square inch;

P=Prescribed minimum test pressure in pounds per square inch (see paragraph (g) of this section);

D=Outside diameter in inches; and

d=Inside diameter in inches.

(e) *Openings.* Openings must comply with the following requirements:

(1) Openings are permitted in heads only.

(2) The size of any centered opening in a head may not exceed one-half the outside diameter of the cylinder.

(3) Other openings are permitted in the head of a cylinder if:

(i) Each opening does not exceed 2.625 inches in diameter, or one-half the outside diameter of the cylinder; whichever is less;

(ii) Each opening is separated from each other by a ligament; and

(iii) Each ligament which separates two openings must be at least three times the average of the diameters of the two openings.

(4) All openings must be circular.

(5) All openings must be threaded. Threads must comply with the following:

(i) Each thread must be clean cut, even, without checks, and to gauge.

(ii) Taper threads, when used, must conform to one of the following:

(A) American Standard Pipe Thread (NPT) type, conforming to the requirements of Federal Standard H–28 (1978), Section 7;

(B) National Gas Taper Thread (NGT) type, conforming to the requirements of Federal Standard H–28 (1978), Sections 7 and 9; or

(C) Other taper threads conforming to other standards may be used provided the length is not less than that specified for NPT threads.

(iii) Straight threads, when used, must conform to one of the following:

(A) National Gas Straight Thread (NGS) type, conforming to the requirements of Federal Standard H–28, (1978), Sections 7 and 9;

(B) Unified Thread (UN) type, conforming to the requirements of Federal Standard H–28, (1978), Section 2;

(C) Controlled Radius Root Thread (UN) type, conforming to the requirements of Federal Standard H–28 (1978), Section 4; or

(D) Other straight threads conforming to other recognized standards may be used provided that the requirements in paragraph (e)(5)(iv) of this section are met.

(iv) All straight threads must have at least 6 engaged threads, a tight fit, and a factor of safety in shear of at least 10 at the test pressure of the cylinder. Shear stress must be calculated by using the appropriate thread shear area in accordance with Federal Standard H–28 (1978), Appendix A5, Section 3.

(f) *Heat treatment.* Prior to any test, all cylinders must be subjected to a solution heat treatment and aging treatment appropriate for the aluminum alloy used.

(g) *Hydrostatic test.* Each cylinder must be subjected to an internal test pressure using the water jacket equipment and method or other suitable equipment and method and comply with the following requirements:

(1) The testing apparatus must be operated in a manner so as to obtain accurate data. The pressure gauge used must permit reading to an accuracy of one percent. The expansion gauge must permit reading the total expansion to an accuracy of either one percent or 0.1 cubic centimeter.

(2) The test pressure must be maintained for a sufficient period of time to assure complete expansion of the cylinder. In no case may the pressure be held less than 30 seconds. If, due to failure of the test apparatus, the required test pressure cannot be maintained, the test may be repeated at a pressure increased by 10 percent or 100 psi, whichever is lower. If the test apparatus again fails to maintain the test pressure, the cylinder being tested must be rejected. Any internal pressure applied to the cylinder before any official test may not exceed 90 percent of the test pressure.

(3) The minimum test pressure is the greatest of the following:

(i) 450 psi regardless of service pressure;

(ii) Two times the service pressure for cylinders having service pressure less than 500 psi; or

(iii) Five-thirds times the service pressure for cylinders having a service pressure of at least 500 psi.

(4) Permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

(h) *Flattening test.* One cylinder taken at random out of each lot must be subjected to a flattening test as follows:

(1) The test must be between knife edges, wedge shaped, having a 60° included angle, and rounded in accordance with the following table. The longitudinal axis of the cylinder must be at an angle 90° to the knife edges during the test. The flattening test table is as follows:

TABLE 3.—FLATTENING TEST TABLE

Cylinder wall thickness in inches	Radius in inches
Under .150	.500
.150 to .249	.875
.250 to .349	1.500
.350 to .449	2.125
.450 to .549	2.750
.550 to .649	3.500
.650 to .749	4.125

(2) An alternate bend test in accordance with ASTM E 290–77 using a mandrel diameter not more than 6 times the wall thickness is authorized to qualify lots that fail the flattening test of this section without reheat treatment. If used, this test must be performed on two samples from one cylinder taken at random out of each lot of 200 cylinders or less.

(3) Each test cylinder must withstand flattening to nine times the wall thickness without cracking. When the alternate bend test is used, the test specimens must remain uncracked when bent inward around a mandrel in the direction of curvature of the cylinder wall until the interior edges are at a distance apart not greater than the diameter of the mandrel.

(i) *Mechanical properties test.* Two test specimens cut from one cylinder representing each lot of 200 cylinders or less must be subjected to the mechanical properties test, as follows:

(1) The results of the test must conform to at least the minimum acceptable mechanical property limits for aluminum alloys as specified in paragraph (b) of this section.

(2) Specimens must be 4D bar or gauge length 2 inches with width not over 1½ inch taken in the direction of extrusion approximately 180° from each other; provided that gauge length at least 24 times thickness with width not over 6 times thickness is authorized, when cylinder wall is not over 3⁄16 inch thick. The specimen, exclusive of grip ends, may not be flattened. Grip ends may be flattened to within one inch of each end of the reduced section. When the size of the cylinder does not permit securing straight specimens, the specimens may be taken in any location or direction and may be straightened or flattened cold by pressure only, not by blows. When such specimens are used, the inspector's report must show that the specimens were so taken and prepared. Heating of specimens for any purpose is forbidden.

(3) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length.

(i) The yield strength must be determined by either the ''offset'' method or the ''extension under load'' method as prescribed in ASTM Standard B–557–79.

(ii) In using the ''extension under load'' method, the total strain (or ''extension under load'') corresponding to the stress at which the 0.2 percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic extension of the gauge length under appropriate load and adding thereto 0.2 percent of the gauge length. Elastic extension calculations must be based on an elastic modulus of

10,000,000 psi. In the event of controversy, the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2 percent offset.

(iii) For the purpose of strain measurement, the initial strain must be set while the specimen is under a stress of 6,000 psi, the strain indicator reading being set at the calculated corresponding strain.

(iv) Cross-head speed of the testing machine may not exceed 1/8 inch per minute during yield strength determination.

(j) *Rejected cylinder.* Reheat treatment of rejected cylinders is authorized one time. Subsequent thereto, cylinders must pass all prescribed tests to be acceptable.

(k) *Duties of inspector.* In addition to the requirements of § 178.35, the inspector shall:

(1) Verify compliance with the provisions of paragraph (b) of this section by:

(i) Performing or witnessing the performance of the chemical analyses on each melt or cast lot or other unit of starting material; or

(ii) Obtaining a certified chemical analysis from the material or cylinder manufacturer for each melt, or cast of material; or

(iii) Obtaining a certified check analysis on one cylinder out of each lot of 200 cylinders or less, if a certificate containing data to indicate compliance with the material specification is obtained.

(2) The inspector shall verify ultrasonic inspection of all material by inspection or by obtaining the material producer's certificate of ultrasonic inspection. Ultrasonic inspection must be performed or verified as having been performed in accordance with paragraph (c) of this section.

(3) The inspector must also determine that each cylinder complies with this specification by:

(i) Selecting the samples for check analyses performed by other than the material producer;

(ii) Verifying that the prescribed minimum thickness was met by measuring or witnessing the measurement of the wall thickness; and

(iii) Verifying that the identification of material is proper.

(4) Prior to initial production of any design or design change, verify that the design qualification tests prescribed in paragraph (c)(6) of this section have been performed with acceptable results.

(l) *Definitions.* In this specification, a ''lot'' means of group of cylinders successively produced having the same:

(i) Size and configuration;

(ii) Specified material of construction;

(iii) Process of manufacture and heat treatment;

(iv) Equipment of manufacture and heat treatment; and

(v) Conditions of time, temperature and atmosphere during heat treatment. In no case may the lot size exceed 200 cylinders, but any cylinder processed for use in the required destructive physical testing need not be counted as being one of the 200.

(m) *Inspector's report.* In addition to the information required by § 178.35, the record of chemical analyses must also include the alloy designation, and applicable information on iron, titanium, zinc, magnesium and any other applicable element used in the construction of the cylinder.

§ 178.47 Specification 4DS welded stainless steel cylinders for aircraft use.

(a) *Type, size, and service pressure.* A DOT 4DS cylinder is either a welded stainless steel sphere (two seamless hemispheres) or circumferentially welded cylinder both with a water capacity of not over 100 pounds and a service pressure of at least 500 but not over 900 pounds per square inch.

(b) *Steel.* Types 304, 321 and 347 stainless steel are authorized with proper welding procedure. A heat of steel made under the specifications in Table 1 of this paragraph (b), check chemical analysis of which is slightly out of the specified range, is acceptable, if satisfactory in all other respects, provided the tolerances shown in Table 2 of this paragraph (b) are not exceeded, except as approved by Associate Administrator. The following chemical analyses are authorized:

TABLE 1.—AUTHORIZED MATERIALS

	Stainless steels		
	304 (percent)	321 (percent)	347 (percent)
Carbon (max)	0.08	0.08	0.08
Manganese (max)	2.00	2.00	2.00
Phosphorus[1] (max)	.030	.030	.030
Sulphur (max)	.030	.030	.030
Silicon (max)	.75	.75	.75
Nickel	8.0/11.0	9.0/13.0	9.0/13.0
Chromium	18.0/20.0	17.0/20.0	17.0/20.0
Molybdenum			
Titanium		(1)	
Columbium			(2)

[1] Titanium may not be than 5C and not more than 0.60%.
[2] Columbium may not be less than 10C and not more than 1.0%.

TABLE 2.—CHECK ANALYSIS TOLERANCES

Element	Limit or maximum specified (percent)	Tolerance (percent) over the maximum limit or under the minimum limit	
		Under minimum limit	Over maximum limit
Carbon	To 0.15 incl	0.01	0.01
Manganese	Over 1.15 to 2.50 incl	.05	.05
Phosphorus[1]	All ranges		.01
Sulphur	All ranges		.01

TABLE 2.—CHECK ANALYSIS TOLERANCES—Continued

Element	Limit or maximum specified (percent)	Tolerance (percent) over the maximum limit or under the minimum limit	
		Under minimum limit	Over maximum limit
Silicon	Over 0.30 to 1.00 incl	.05	.05
Nickel	Over 5.30 to 10.00 incl	.10	.10
	Over 10.00 to 14.00 incl	.15	.15
Chromium	Over 15.00 to 20.00 incl	.20	.20
Titanium	All ranges	.05	.05
Columbium	All ranges	.05	.05

[1] Rephosphorized steels not subject to check analysis for phosphorus.

(c) *Identification of material.* Materials must be identified by any suitable method.

(d) *Manufacture.* Cylinders must be manufactured using equipment and processes adequate to ensure that each cylinder produced conforms to the requirements of this subpart. No defect is permitted that is likely to weaken the finished cylinder appreciably; a reasonably smooth and uniform surface finish is required. No abrupt change in wall thickness is permitted. Welding procedures and operators must be qualified in accordance with CGA Pamphlet C–3. All seams of the sphere or cylinder must be fusion welded. Seams must be of the butt type and means must be provided for accomplishing complete penetration of the joint.

(e) *Attachments.* Attachments to the container are authorized by fusion welding provided that such attachments are made of weldable stainless steel in accordance with paragraph (b) of this section.

(f) *Wall thickness.* The minimum wall thickness must be such that the wall stress at the minimum specified test pressure may not be over 60,000 psi. A minimum wall thickness of 0.040 inch is required for any diameter container. Calculations must be made by the following formulas:

(1) Calculation for sphere must be made by the formula:

$$S=PD/4tE$$

where:

S=Wall stress in pounds per square inch;

P=Test pressure prescribed for water jacket test, i.e., at least two times service pressure, in pounds per square inch;

D=Outside diameter in inches;

t=Minimum wall thickness in inches;

E=0.85 (provides 85 percent weld efficiency factor which must be applied in the girth weld area and heat zones which zone must extend a distance of 6 times wall thickness from center of weld);

E=1.0 (for all other areas).

(2) Calculation for a cylinder must be made by the formula:

$$S=[P(1.3D^2+0.4d^2)]/(D^2-d^2)$$

where:

S=Wall stress in pounds per square inch;

P=Test pressure prescribed for water jacket test, i.e., at least two times service pressure, in pounds per square inch;

D=Outside diameter in inches;

d=Inside diameter in inches.

(g) *Heat treatment.* The seamless hemispheres and cylinders may be stress relieved or annealed for forming. Welded container must be stress relieved at a temperature of 775 °F ±25° after process treatment and before hydrostatic test.

(h) *Openings in container.* Openings must comply with the following:

(1) Each opening in the container must be provided with a fitting, boss or pad of weldable stainless steel securely attached to the container by fusion welding.

(2) Attachments to a fitting, boss, or pad must be adequate to prevent leakage. Threads must comply with the following:

(i) Threads must be clean cut, even, without checks, and tapped to gauge.

(ii) Taper threads to be of length not less than as specified for American Standard taper pipe threads.

(iii) Straight threads having at least 4 engaged threads, to have tight fit and calculated shear strength at least 10 times the test pressure of the container; gaskets required, adequate to prevent leakage.

(i) *Process treatment.* Each container must be hydraulically pressurized in a water jacket to at least 100 percent, but not more than 110 percent, of the test pressure and maintained at this pressure for a minimum of 3 minutes. Total and permanent expansion must be recorded and included in the inspector's report.

(j) *Hydrostatic test.* Each cylinder must successfully withstand a hydrostatic test as follows:

(1) The test must be by water-jacket, operated so as to obtain accurate data. The pressure gauge must permit reading to an accuracy of 1 percent. The expansion gauge must permit reading of total expansion to an accuracy either of 1 percent or 0.1 cubic centimeter.

(2) Pressure must be maintained for at least 30 seconds and sufficiently longer to ensure complete expansion. If, due to failure of the test apparatus, the test pressure cannot be maintained, the test may be repeated at a pressure increased by 10 percent or 100 pounds per square inch, whichever is the lower.

(3) Permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

(4) Each container must be tested to at least 2 times service pressure.

(5) Container must then be inspected. Any wall thickness lower than that required by paragraph (f) of this section must be cause for rejection. Bulges and cracks must be cause for rejection. Welded joint defects exceeding requirements of paragraph (k) of this section must be cause for rejection.

(k) *Radiographic inspection.* Radiographic inspection is required on all welded joints which are subjected to internal pressure, except that at the discretion of the disinterested inspector, openings less than 25 percent of the container diameter need not be subjected to radiographic inspection. Evidence of any defects likely to seriously weaken the container is cause for rejection. Radiographic inspection must be performed subsequent to the hydrostatic test.

(l) *Burst test.* One container taken at random out of 200 or less must be hydrostatically tested to destruction. Rupture pressure must be included as part of the inspector's report.

(m) *Flattening test.* A flattening test must be performed as follows:

(1) For spheres the test must be at the weld between parallel steel plates on a press with welded seam at right angles to the plates. Test one sphere taken at random out of each lot of 200 or less after the hydrostatic test. Any projecting appurtenances may be cut off (by mechanical means only) prior to crushing.

(2) For cylinders the test must be between knife edges, wedge shaped, 60° angle, rounded to ½-inch radius. Test one cylinder taken at random out of each lot of 200 or less, after the hydrostatic test.

(n) *Acceptable results for flattening and burst tests.* Acceptable results for flattening and burst tests are as follows:

(1) Flattening required to 50 percent of the original outside diameter without cracking.

(2) Burst pressure must be at least 3 times the service pressure.

(o) *Rejected containers.* Repair of welded seams by welding prior to process treatment is authorized. Subsequent thereto, containers must be heat treated and pass all prescribed tests.

(p) *Duties of inspector.* In addition to the requirements of § 178.35, the inspector must verify that all tests are conducted at temperatures between 60° F and 90° F.

(q) *Marking.* Markings must be stamped plainly and permanently on a permanent attachment or on a metal nameplate permanently secured to the container by means other than soft solder.

§ 178.50 Specification 4B welded or brazed steel cylinders.

(a) *Type, size, and service pressure.* A DOT 4B is a welded or brazed steel cylinder with longitudinal seams that are forged lap-welded or brazed and with water capacity (nominal) not over 1,000 pounds and a service pressure of at least 150 but not over 500 pounds per square inch. Cylinders closed in by spinning process are not authorized.

(b) *Steel.* Open-hearth, electric or basic oxygen process steel of uniform quality must be used. Content percent may not exceed the following: Carbon, 0.25; phosphorus, 0.045; sulphur, 0.050.

(c) *Identification of material.* Material must be identified by any suitable method except that plates and billets for hotdrawn cylinders must be marked with the heat number.

(d) *Manufacture.* Cylinders must be manufactured using equipment and processes adequate to ensure that each cylinder produced conforms to the requirements of this subpart. No defect is permitted that is likely to weaken the finished cylinder appreciably. A reasonably smooth and uniform surface finish is required. Exposed bottom welds on cylinders over 18 inch long must be protected by footrings. Welding procedures and operators must be qualified in accordance with CGA Pamphlet C–3. Seams must be made as follows:

(1) *Welded or brazed circumferential seams.* Heads attached by brazing must have a driving fit with the shell, unless the shell is crimped, swedged, or curled over the skirt or flange of the head, and be thoroughly brazed until complete penetration by the brazing material of the brazed joint is secured. Depth of brazing from end of shell must be at least four times the thickness of shell metal.

(2) *Longitudinal seams in shells.* Longitudinal seams must be forged lap welded, by copper brazing, by copper alloy brazing, or by silver alloy brazing. Copper alloy composition must be: Copper, 95 percent minimum; Silicon, 1.5 percent to 3.85 percent; Manganese, 0.25 percent to 1.10 percent. The melting point of the silver alloy brazing material must be in excess of 1000° F. When brazed, the plate edge must be lapped at least eight times the thickness of plate, laps being held in position, substantially metal to metal, by riveting or electric spot-welding; brazing must be done by using a suitable flux and by placing brazing material on one side of seam and applying heat until this material shows uniformly along the seam of the other side.

(e) *Welding or brazing.* Only the attachment of neckrings, footrings, handles, bosses, pads, and valve protection rings to the tops and bottoms of cylinders by welding or brazing is authorized. Such attachments and the portion of the container to which they are attached must be made of weldable steel, the carbon content of which may not exceed 0.25 percent except in the case of 4130X steel which may be used with proper welding procedure.

(f) *Wall thickness.* The wall thickness of the cylinder must comply with the following requirements:

(1) For cylinders with outside diameters over 6 inches the minimum wall thickness must be 0.090 inch. In any case, the minimum wall thickness must be such that calculated wall stress at minimum test pressure (paragraph (i)(4) of this section) may not exceed the following values:

(i) 24,000 pounds per square inch for cylinders without longitudinal seam.

(ii) 22,800 pounds per square inch for cylinders having copper brazed or silver alloy brazed longitudinal seam.

(iii) 18,000 pounds per square inch for cylinders having forged lapped welded longitudinal seam.

(2) Calculation must be made by the formula:

$$S=[P(1.3D^2+0.4d^2)]/(D^2-d^2)$$

where:

S=wall stress in pounds per square inch;
P=minimum test pressure prescribed for water jacket test or 450 pounds per square inch whichever is the greater;
D=outside diameter in inches;
d=inside diameter in inches.

(g) *Heat treatment.* Cylinder body and heads, formed by drawing or pressing, must be uniformly and properly heat treated prior to tests.

(h) *Opening in cylinders.* Openings in cylinders must conform to the following:

(1) Each opening in cylinders, except those for safety devices, must be provided with a fitting, boss, or pad, securely attached to cylinder by brazing or by welding or by threads. Fitting, boss, or pad must be of steel suitable for the method of attachment employed, and which need not be identified or verified as to analysis except that if attachment is by welding, carbon content may not exceed 0.25 percent. If threads are used, they must comply with the following:

(i) Threads must be clean cut, even without checks, and tapped to gauge.

(ii) Taper threads to be of length not less than as specified for American Standard taper pipe threads.

(iii) Straight threads, having at least 4 engaged threads, to have tight fit and calculated shear strength at least 10 times the test pressure of the cylinder; gaskets required, adequate to prevent leakage.

(iv) A brass fitting may be brazed to the steel boss or flange on cylinders used as component parts of hand fire extinguishers.

(2) The closure of a fitting, boss, or pad must be adequate to prevent leakage.

(i) *Hydrostatic test.* Each cylinder must withstand a hydrostatic test as follows:

(1) The test must be by water-jacket, or other suitable method, operated so as to obtain accurate data. The pressure gauge must permit reading to an accuracy of 1 percent. The expansion gauge must permit reading of total expansion to an accuracy either of 1 percent or 0.1 cubic centimeter.

(2) Pressure must be maintained for at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and previous to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus, the test pressure cannot be

maintained, the test may be repeated at a pressure increased by 10 percent or 100 pounds per square inch, whichever is the lower.

(3) Permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

(4) Cylinders must be tested as follows:

(i) At least one cylinder selected at random out of each lot of 200 or less must be tested as outlined in paragraphs (i)(1), (i)(2), and (i)(3) of this section to at least two times service pressure.

(ii) All cylinders not tested as outlined in paragraph (i)(4)(i) of this section must be examined under pressure of at least two times service pressure and show no defect.

(j) *Flattening test.* After the hydrostatic test, a flattening test must be performed on one cylinder taken at random out or each lot of 200 or less, by placing the cylinder between wedge shaped knife edges having a 60° included angle, rounded to ½-inch radius. The longitudinal axis of the cylinder must be at a 90-degree angle to knife edges during the test. For lots of 30 or less, flattening tests are authorized to be made on a ring at least 8 inches long cut from each cylinder and subjected to same heat treatment as the finished cylinder.

(k) *Physical test.* A physical test must be conducted to determine yield strength, tensile strength, elongation, and reduction of area of material as follows:

(1) The test is required on 2 specimens cut from 1 cylinder, or part thereof heat-treated as required, taken at random out of each lot of 200 or less. For lots of 30 or less, physical tests are authorized to be made on a ring at least 8 inches long cut from each cylinder and subjected to same heat treatment as the finished cylinder.

(2) Specimens must conform to the following:

(i) A gauge length of 8 inches with a width of not over 1½ inches, a gauge length of 2 inches with a width of not over 1½ inches, or a gauge length at least 24 times the thickness with a width not over 6 times the thickness is authorized when a cylinder wall is not over 3⁄16 inch thick.

(ii) The specimen, exclusive of grip ends, may not be flattened. Grip ends may be flattened to within one inch of each end of the reduced section.

(iii) When size of cylinder does not permit securing straight specimens, the specimens may be taken in any location or direction and may be straightened or flattened cold, by pressure only, not by blows. When specimens are so taken and prepared, the inspector's report must show in connection with record of physical tests detailed information in regard to such specimens.

(iv) Heating of a specimen for any purpose is not authorized.

(3) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length. The following conditions apply:

(i) The yield strength must be determined by either the ''offset'' method or the ''extension under load'' method as prescribed in ASTM Standard E8–78.

(ii) In using the ''extension under load'' method, the total strain (or ''extension under load'') corresponding to the stress at which the 0.2 percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic extension of the gauge length under appropriate load and adding thereto 0.2 percent of the gauge length. Elastic extension calculations must be based on an elastic modulus of 30,000,000. In the event of controversy, the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2 percent offset.

(iii) For the purpose of strain measurement, the initial strain must be set while the specimen is under a stress of 12,000 pounds per square inch, and strain indicator reading must be set at the calculated corresponding strain.

(iv) Cross-head speed of the testing machine may not exceed ⅛ inch per minute during yield strength determination.

(l) *Acceptable results for physical and flattening tests.* Either of the following is an acceptable result:

(1) An elongation of at least 40 percent for a 2 inch gauge length or at least 20 percent in other cases and yield strength not over 73 percent of tensile strength. In this instance, a flattening test is not required.

(2) When cylinders are constructed of lap welded pipe, flattening test is required, without cracking, to 6 times the wall thickness. In such case, the rings (crop ends) cut from each end of pipe, must be tested with the weld 45° or less from the point of greatest stress. If a ring fails, another from the same end of pipe may be tested.

(m) *Rejected cylinders.* Reheat treatment is authorized for rejected cylinder. Subsequent thereto, cylinders must pass all prescribed tests to be acceptable. Repair of brazed seams by brazing and welded seams by welding is authorized.

(n) *Markings.* Markings must be stamped plainly and permanently in any of the following locations on the cylinder:

(1) On shoulders and top heads when they are not less than 0.087-inch thick.

(2) On side wall adjacent to top head for side walls which are not less than 0.090 inch thick.

(3) On a cylindrical portion of the shell which extends beyond the recessed bottom of the cylinder, constituting an integral and non-pressure part of the cylinder.

(4) On a metal plate attached to the top of the cylinder or permanent part thereof; sufficient space must be left on the plate to provide for stamping at least six retest dates; the plate must be at least 1⁄16 inch thick and must be attached by welding, or by brazing. The brazing rod must melt at a temperature of 1100 °F. Welding or brazing must be along all the edges of the plate.

(5) On the neck, neckring, valve boss, valve protection sleeve, or similar part permanently attached to the top of the cylinder.

(6) On the footring permanently attached to the cylinder, provided the water capacity of the cylinder does not exceed 25 pounds.

§ 178.51 Specification 4BA welded or brazed steel cylinders.

(a) *Type, size, and service pressure.* A DOT 4BA cylinder is a cylinder, either spherical or cylindrical in shape, with a water capacity of 1,000 pounds or less and a service pressure of at least 225 and not over 500 pounds per square inch. Closures made by the spinning process are not authorized.

(1) Spherical type cylinders must be made from two seamless hemispheres joined by the welding of one circumferential seam.

(2) Cylindrical type cylinders must be of circumferentially welded or brazed construction.

(b) *Steel.* The steel used in the construction of the cylinder must be as specified in Table 1 of Appendix A to this part.

(c) *Identification of material.* Material must be identified by any suitable method except that plates and billets for hotdrawn cylinders must be marked with the heat number.

(d) *Manufacture.* Cylinders must be manufactured using equipment and processes adequate to ensure that each cylinder produced conforms to the requirements of this subpart. No defect is permitted that is likely to weaken the finished cylinder appreciably. A reasonably smooth and uniform surface finish is required. Exposed bottom welds on cylinders over 18 inches long must be protected by footrings.

(1) Seams must be made as follows:

(i) Minimum thickness of heads and bottoms must be not less than 90

percent of the required thickness of the side wall.

(ii) Circumferential seams must be made by welding or by brazing. Heads must be attached by brazing and must have a driving fit with the shell, unless the shell is crimped, swedged or curled over the skirt or flange of the head and must be thoroughly brazed until complete penetration by the brazing material of the brazed joint is secured. Depth of brazing from end of the shell must be at least four times the thickness of shell metal.

(iii) Longitudinal seams in shells must be made by copper brazing, copper alloy brazing, or by silver alloy brazing. Copper alloy composition must be: Copper 95 percent minimum, Silicon 1.5 percent to 3.85 percent, Manganese 0.25 percent to 1.10 percent. The melting point of the silver alloy brazing material must be in excess of 1,000 °F. The plate edge must be lapped at least eight times the thickness of plate, laps being held in position, substantially metal to metal, by riveting or by electric spot-welding. Brazing must be done by using a suitable flux and by placing brazing material on one side of seam and applying heat until this material shows uniformly along the seam of the other side. Strength of longitudinal seam: Copper brazed longitudinal seam must have strength at least ⅜ times the strength of the steel wall.

(2) Welding procedures and operators must be qualified in accordance with CGA Pamphlet C–3.

(e) *Welding and brazing.* Only the welding or brazing of neckrings, footrings, handles, bosses, pads, and valve protection rings to the tops and bottoms of cylinders is authorized. Provided that such attachments and the portion of the container to which they are attached are made of weldable steel, the carbon content of which may not exceed 0.25 percent except in the case of 4130X steel which may be used with proper welding procedures.

(f) *Wall thickness.* The minimum wall thickness of the cylinder must meet the following conditions:

(1) For any cylinder with an outside diameter of greater than 6 inches, the minimum wall thickness is 0.078 inch. In any case the minimum wall thickness must be such that the calculated wall stress at the minimum test pressure may not exceed the lesser value of any of the following:

(i) The value shown in Table I of Appendix A to this part, for the particular material under consideration;

(ii) One-half of the minimum tensile strength of the material determined as required in paragraph (j) of this section;

(iii) 35,000 pounds per square inch; or

(iv) Further provided that wall stress for cylinders having copper brazed longitudinal seams may not exceed 95 percent of any of the above values. Measured wall thickness may not include galvanizing or other protective coating.

(2) Cylinders that are cylindrical in shape must have the wall stress calculated by the formula:

$$S=[P(1.3D^2+0.4d^2)]/(D^2-d^2)$$

where:

S=wall stress in pounds per square inch;
P=minimum test pressure prescribed for water jacket test;
D=outside diameter in inches;
d=inside diameter in inches.

(3) Cylinders that are spherical in shape must have the wall stress calculated by the formula:

$$S=PD/4tE$$

where:

S=wall stress in pounds per square inch;
P=minimum test pressure prescribed for water jacket test;
D=outside diameter in inches;
t=minimum wall thickness in inches;
E=0.85 (provides 85 percent weld efficiency factor which must be applied in the girth weld area and heat affected zones which zone must extend a distance of 6 times wall thickness from center line of weld);
E=1.0 (for all other areas).

(4) For a cylinder with a wall thickness less than 0.100 inch, the ratio of tangential length to outside diameter may not exceed 4.1.

(g) *Heat treatment.* Cylinders must be heat treated in accordance with the following requirements:

(1) Each cylinder must be uniformly and properly heat treated prior to test by the applicable method shown in Table I of Appendix A to this Part. Heat treatment must be accomplished after all forming and welding operations, except that when brazed joints are used, heat treatment must follow any forming and welding operations, but may be done before, during or after the brazing operations.

(2) Heat treatment is not required after the welding or brazing of weldable low carbon parts to attachments of similar material which have been previously welded or brazed to the top or bottom of cylinders and properly heat treated, provided such subsequent welding or brazing does not produce a temperature in excess of 400 °F in any part of the top or bottom material.

(h) *Openings in cylinders.* Openings in cylinders must comply with the following requirements:

(1) Any opening must be placed on other than a cylindrical surface.

(2) Each opening in a spherical type cylinder must be provided with a fitting, boss, or pad of weldable steel securely attached to the container by fusion welding.

(3) Each opening in a cylindrical type cylinder must be provided with a fitting, boss, or pad, securely attached to container by brazing or by welding.

(4) If threads are used, they must comply with the following:

(i) Threads must be clean-cut, even, without checks and tapped to gauge.

(ii) Taper threads must be of a length not less than that specified for American Standard taper pipe threads.

(iii) Straight threads, having at least 4 engaged threads, must have a tight fit and a calculated shear strength of at least 10 times the test pressure of the cylinder. Gaskets, adequate to prevent leakage, are required.

(i) *Hydrostatic test.* Each cylinder must successfully withstand a hydrostatic test, as follows:

(1) The test must be by water jacket, or other suitable method, operated so as to obtain accurate data. A pressure gauge must permit reading to an accuracy of 1 percent. An expansion gauge must permit reading of total expansion to an accuracy of either 1 percent or 0.1 cubic centimeter.

(2) Pressure must be maintained for at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat treatment and previous to the official test may not exceed 90 percent of the test pressure.

(3) Permanent volumetric expansion may not exceed 10 percent of the total volumetric expansion at test pressure.

(4) Cylinders must be tested as follows:

(i) At least one cylinder selected at random out of each lot of 200 or less must be tested as outlined in paragraphs (i)(1), (i)(2), and (i)(3) of this section to at least two times service pressure.

(ii) All cylinders not tested as outlined in paragraph (i)(4)(i) of this section must be examined under pressure of at least two times service pressure and show no defect.

(j) *Physical test.* A physical test must be conducted to determine yield strength, tensile strength, elongation, and reduction of area of material, as follows:

(1) The test is required on 2 specimens cut from one cylinder or part thereof having passed the hydrostatic test and heat-treated as required, taken at random out of each lot of 200 or less. Physical tests for spheres are required on 2 specimens cut from flat representative sample plates of the same heat taken at random from the steel used

to produce the spheres. This flat steel from which 2 specimens are to be cut must receive the same heat treatment as the spheres themselves. Sample plates must be taken from each lot of 200 or less spheres.

(2) Specimens must conform to the following:

(i) A gauge length of 8 inches with a width not over 1½ inches, or a gauge length of 2 inches with a width not over 1½ inches, or a gauge length at least 24 times the thickness with a width not over 6 times the thickness is authorized when a cylinder wall is not over 3/16 inch thick.

(ii) The specimen, exclusive of grip ends, may not be flattened. Grip ends may be flattened to within one inch of each end of the reduced section.

(iii) When size of the cylinder does not permit securing straight specimens, the specimens may be taken in any location or direction and may be straightened or flattened cold, by pressure only, not by blows. When specimens are so taken and prepared, the inspector's report must show in connection with record of physical tests detailed information in regard to such specimens.

(iv) Heating of a specimen for any purpose is not authorized.

(3) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length. The following conditions apply:

(i) The yield strength must be determined by either the ''offset'' method or the ''extension under load'' method as prescribed in ASTM Standard E8–78.

(ii) In using the ''extension under load'' method, the total strain (or ''extension under load''), corresponding to the stress at which the 0.2 percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic extension of the gauge length under appropriate load and adding thereto 0.2 percent of the gauge length. Elastic extension calculations must be based on an elastic modulus of 30,000,000. In the event of controversy, the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2 percent offset.

(iii) For the purpose of strain measurement, the initial strain reference must be set while the specimen is under a stress of 12,000 pounds per square inch, and the strain indicator reading must be set at the calculated corresponding strain.

(iv) Cross-head speed of the testing machine may not exceed 1/8 inch per minute during yield strength determination.

(k) *Elongation.* Physical test specimens must show at least a 40 percent elongation for a 2-inch gauge length or at least 20 percent in other cases. Except that these elongation percentages may be reduced numerically by 2 for 2-inch specimens, and by 1 in other cases, for each 7,500 pounds per square inch increment of tensile strength above 50,000 pounds per square inch to a maximum of four such increments.

(l) *Tests of welds.* Except for brazed seams, welds must be tested as follows:

(1) *Tensile test.* A specimen must be cut from one cylinder of each lot of 200 or less, or welded test plate. The welded test plate must be of one of the heats in the lot of 200 or less which it represents, in the same condition and approximately the same thickness as the cylinder wall except that in no case must it be of a lesser thickness than that required for a quarter size Charpy impact specimen. The weld must be made by the same procedures and subjected to the same heat treatment as the major weld on the cylinder. The specimen must be taken from across the major seam and must be prepared and tested in accordance with and must meet the requirements of CGA Pamphlet C–3. Should this specimen fail to meet the requirements, specimens may be taken from two additional cylinders or welded test plates from the same lot and tested. If either of the latter specimens fail to meet the requirements, the entire lot represented must be rejected.

(2) *Guided bend test.* A root bend test specimen must be cut from the cylinder or welded test plate, used for the tensile test specified in paragraph (l)(1) of this section. Specimens must be taken from across the major seam and must be prepared and tested in accordance with and must meet the requirements of CGA Pamphlet C–3.

(3) *Alternate guided-bend test.* This test may be used and must be as required by CGA Pamphlet C–3. The specimen must be bent until the elongation at the outer surface, adjacent to the root of the weld, between the lightly scribed gage lines a to b, must be at least 20 percent, except that this percentage may be reduced for steels having a tensile strength in excess of 50,000 pounds per square inch, as provided in paragraph (k) of this section.

(m) *Rejected cylinders.* Reheat treatment is authorized for rejected cylinders. Subsequent thereto, cylinders must pass all prescribed tests to be acceptable. Repair of brazed seams by brazing and welded seams by welding is authorized.

(n) *Markings.* Markings must be stamped plainly and permanently in one of the following locations on the cylinder:

(1) On shoulders and top heads not less than 0.087 inch thick.

(2) On side wall adjacent to top head for side walls not less than 0.090 inch thick.

(3) On a cylindrical portion of the shell which extends beyond the recessed bottom of the cylinder constituting an integral and non-pressure part of the cylinder.

(4) On a plate attached to the top of the cylinder or permanent part thereof; sufficient space must be left on the plate to provide for stamping at least six retest dates; the plate must be at least 1/16 inch thick and must be attached by welding, or by brazing at a temperature of at least 1100° F., throughout all edges of the plate.

(5) On the neck, neckring, valve boss, valve protection sleeve, or similar part permanently attached to the top of the cylinder.

(6) On the footring permanently attached to the cylinder, provided the water capacity of the cylinder does not exceed 25 pounds.

§ 178.53 Specification 4D welded steel cylinders for aircraft use.

(a) *Type, size, and service pressure.* A DOT 4D cylinder is a welded steel sphere (two seamless hemispheres) or circumferentially welded cylinder (two seamless drawn shells) with a water capacity not over 100 pounds and a service pressure of at least 300 but not over 500 pounds per square inch. Cylinders closed in by spinning process are not authorized.

(b) *Steel.* Open-hearth or electric steel of uniform and weldable quality must be used. Content may not exceed the following: Carbon, 0.25; phosphorus, 0.045; sulphur, 0.050, except that the following steels commercially known as 4130X and Type 304, 316, 321, and 347 stainless steels may be used with proper welding procedure. A heat of steel made under Table 1 of this paragraph (b), check chemical analysis of which is slightly out of the specified range, is acceptable, if satisfactory in all other respects, provided the tolerances shown in Table 2 of this paragraph (b) are not exceeded, except as approved by the Associate Administrator. The following chemical analyses are authorized:

TABLE 1.—4130X STEEL

4130X	Percent
Carbon	0.25/0.35.
Manganese	0.40/0.60.
Phosphorus	0.04 max.
Sulphur	0.05 max.
Silicon	0.15/0.35.
Chromium	0.80/1.10.
Molybdenum	0.15/0.25.
Zirconium	None.
Nickel	None.

TABLE 2.—AUTHORIZED STAINLESS STEELS

	Stainless steels			
	304 (percent)	316 (percent)	321 (percent)	347 (percent)
Carbon (max)	0.08	0.08	0.08	0.08
Manganese (max)	2.00	2.00	2.00	2.00
Phosphorus1 (max)	.030	.045	.030	.030
Sulphur (max)	.030	.030	.030	.030
Silicon (max)	.75	1.00	.75	.75
Nickel	8.0/11.0	10.0/14.0	9.0/13.0	9.0/13.0
Chromium	18.0/20.0	16.0/18.0	17.0/20.0	17.0/20.0
Molybdenum		2.0/3.0		
Titanium			(1)	
Columbium				(2)

1 Titanium may not be less than 5C and not more than 0.60%.
2 Columbium may not be less than 10C and not more than 1.0%.

TABLE 3.—CHECK ANALYSIS TOLERANCES

Element	Limit or maximum specified (percent)	Tolerance (percent) over the maximum limit or under the minimum limit	
		Under minimum limit	Over maximum limit
Carbon	To 0.15 incl	0.01	0.01
	Over 0.15 to 0.40 incl	.03	.04
Manganese	To 0.60 incl	.03	.03
	Over 1.15 to 2.50 incl	.05	.05
Phosphorus1	All ranges		.01
Sulphur	All ranges		.01
Silicon	To 0.30 incl	.02	.03
	Over 0.30 to 1.00 incl	.05	.05
Nickel	Over 5.30 to 10.00 incl	.10	.10
	Over 10.00 to 14.00 incl	.15	.15
Chromium	To 0.90 incl	.03	.03
	Over 0.90 to 2.10 incl	.05	.05
	Over 15.00 to 20.00 incl	.20	.20
Molybdenum	To 0.20 incl	.01	.01
	Over 0.20 to 0.40 incl	.02	.02
	Over 1.75 to 3.0 incl	.10	.10
Titanium	All ranges	.05	.05
Columbium	All ranges	.05	.05

1 Rephosphorized steels not subject to check analysis for phosphorus.

(c) *Identification of material.* Material must be identified by any suitable method except that plates and billets for hotdrawn cylinders must be marked with the heat number.

(d) *Manufacture.* Cylinders must be manufactured using equipment and processes adequate to ensure that each cylinder produced conforms to the requirements of this subpart. No defect is permitted that is likely to weaken the finished container appreciably. A reasonably smooth and uniform surface finish is required. Welding procedures and operators must be qualified in accordance with CGA Pamphlet C–3.

(e) *Wall thickness.* The wall stress at the minimum test pressure may not exceed 24,000 pounds per square inch, except where steels commercially known as 4130X, types 304, 316, 321, and 347 stainless steels are used, stress at the test pressures may not exceed 37,000 pounds per square inch. The minimum wall thickness for any container having a capacity of 1,100 cubic inches or less is 0.04 inch. The

minimum wall thickness for any container having a capacity in excess of 1,100 cubic inches is 0.095 inch. Calculations must be done by the following:

(1) Calculation for a ''sphere'' must be made by the formula:

$S=PD/4tE$

Where:

S=wall stress in pounds per square inch;
P=test pressure prescribed for water jacket test, i.e., at least two times service pressure, in pounds per square inch;
D=outside diameter in inches;
t=minimum wall thickness in inches;
E=0.85 (provides 85 percent weld efficiency factor which must be applied in the girth weld area and heat affected zones which zone must extend a distance of 6 times wall thickness from center line of weld);
E=1.0 (for all other areas).

(2) Calculation for a cylinder must be made by the formula:

$S=[P(1.3D^2+0.4d^2)]/(D^2-d^2)$

Where:

S=wall stress in pounds per square inch;
P=test pressure prescribed for water jacket test, i.e., at least two times service pressure, in pounds per square inch;
D=outside diameter in inches;
d=inside diameter in inches.

(f) *Heat treatment.* The completed cylinders must be uniformly and properly heat-treated prior to tests.

(g) *Openings in container.* Openings in cylinders must comply with the following:

(1) Each opening in the container, except those for safety devices, must be provided with a fitting, boss, or pad, securely attached to the container by brazing or by welding or by threads. If threads are used, they must comply with the following:

(i) Threads must be clean cut, even, without checks, and tapped to gauge.

(ii) Taper threads must be of a length not less than that specified for American Standard taper pipe threads.

(iii) Straight threads, having at least 4 engaged threads, must have a tight fit and calculated shear strength of at least 10 times the test pressure of the container. Gaskets, adequate to prevent leakage, are required.

(2) Closure of a fitting, boss, or pad must be adequate to prevent leakage.

(h) *Hydrostatic test.* Each cylinder must successfully withstand a hydrostatic test, as follows:

(1) The test must be by water-jacket, or other suitable method, operated so as to obtain accurate data. A pressure gauge must permit a reading to an accuracy of 1 percent. An expansion gauge must permit reading of total expansion to an accuracy of either 1 percent or 0.1 cubic centimeter.

(2) Pressure must be maintained for at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and previous to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus, the test pressure cannot be maintained, the test may be repeated at a pressure increased by 10 percent or 100 pounds per square inch, whichever is the lower.

(3) Permanent volumetric expansion may not exceed 10 percent of the total volumetric expansion at test pressure.

(4) Containers must be tested as follows:

(i) Each container to at least 2 times service pressure; or

(ii) One container out of each lot of 200 or less to at least 3 times service pressure. Others must be examined under pressure of 2 times service pressure and show no defects.

(i) *Flattening test for spheres and cylinders.* Spheres and cylinders must be subjected to a flattening test as follows:

(1) One sphere taken at random out of each lot of 200 or less must be subjected to a flattening test as follows:

(i) The test must be performed after the hydrostatic test.

(ii) The test must be between parallel steel plates on a press with a welded seam at right angles to the plates. Any projecting appurtenances may be cut off (by mechanical means only) prior to crushing.

(2) One cylinder taken at random out of each lot of 200 or less must be subjected to a flattening test, as follows:

(i) The test must be performed after the hydrostatic test.

(ii) The test must be between knife edges, wedge shaped, 60° angle, rounded to ½ inch radius. For lots of 30 or less, physical tests are authorized to be made on a ring at least 8 inches long cut from each cylinder and subjected to the same heat treatment as the finished cylinder.

(j) *Physical test and specimens for spheres and cylinders.* Spheres and cylinders must be subjected to a physical test as follows:

(1) Physical test for spheres are required on 2 specimens cut from a flat representative sample plate of the same heat taken at random from the steel used to produce the sphere. This flat steel from which the 2 specimens are to be cut must receive the same heat-treatment as the spheres themselves. Sample plates must be taken for each lot of 200 or less spheres.

(2) Specimens for spheres must have a gauge length 2 inches with a width not over 1½ inches, or a gauge length at least 24 times the thickness with a width not over 6 times the thickness is authorized when a wall is not over 3/16 inch thick.

(3) Physical test for cylinders is required on 2 specimens cut from 1 cylinder taken at random out of each lot of 200 or less. For lots of 30 or less, physical tests are authorized to be made on a ring at least 8 inches long cut from each cylinder and subjected to the same heat treatment as the finished cylinder.

(4) Specimens for cylinders must conform to the following:

(i) A gauge length of 8 inches with a width not over 1½ inches, or a gauge length of 2 inches with a width not over 1½ inches, or a gauge length at least 24 times the thickness with a width not over 6 times the thickness is authorized when a cylinder wall is not over 3/16 inch thick.

(ii) The specimen, exclusive of grip ends, may not be flattened. Grip ends may be flattened to within 1 inch of each end of the reduced section. Heating of the specimen for any purpose is not authorized.

(5) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length. The following conditions apply:

(i) The yield strength must be determined by either the ''offset'' method or the ''extension under load'' method as prescribed in ASTM Standard E8–78.

(ii) In using the ''extension under load'' method, the total strain (or ''extension under load'') corresponding to the stress at which the 0.2 percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic extension of the gauge length under appropriate load and adding thereto 0.2 percent of the gauge length. Elastic extension calculations must be based on an elastic modulus of 30,000,000. In the event of controversy, the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2 percent offset.

(iii) For the purpose of strain measurement, the initial strain must be set while the specimen is under a stress of 12,000 pounds per square inch and the strain indicator reading being set at the calculated corresponding strain.

(iv) Cross-head speed of the testing machine may not exceed ⅛ inch per minute during yield strength determination.

(k) *Acceptable results for physical and flattening tests.* Either of the following is an acceptable result:

(1) An Elongation of at least 40 percent for a 2 inch gauge length or at least 20 percent in other cases and yield strength not over 73 percent of tensile strength. In this instance, the flattening test is not required.

(2) An elongation of at least 20 percent for a 2 inch gauge length or 10 percent in other cases. Flattening is required to 50 percent of the original outside diameter without cracking.

(l) *Rejected cylinders.* Reheat-treatment is authorized for rejected cylinders. Subsequent thereto, containers must pass all prescribed tests to be acceptable. Repair of welded seams by welding prior to reheat-treatment is authorized.

(m) *Marking.* Marking on each container by stamping plainly and permanently are only authorized where the metal is at least 0.09 inch thick, or on a metal nameplate permanently secured to the container by means other than soft solder, or by means that would not reduce the wall thickness.

§ 178.55 Specification 4B240ET welded or brazed cylinders.

(a) *Type, spinning process, size and service pressure.* A DOT 4B240ET cylinder is a brazed type cylinder made from electric resistance welded tubing. The maximum water capacity of this cylinder is 12 pounds or 333 cubic inches and the service must be 240 pounds per square inch. The maximum outside diameter of the shell must be five inches and maximum length of the shell is 21 inches. Cylinders closed in by a spinning process are authorized.

(b) *Steel.* Open-hearth, basic oxygen, or electric steel of uniform quality must be used. Plain carbon steel content may not exceed the following: Carbon, 0.25; phosphorus, 0.045; sulfur, 0.050. The addition of other elements for alloying effect is prohibited.

(c) *Identification of material.* Material must be identified by any suitable method.

(d) *Manufacture.* Cylinders must be manufactured using equipment and processes adequate to ensure that each cylinder produced conforms to the requirements of this subpart. No defect is permitted that is likely to weaken the finished cylinder appreciably. A reasonably smooth and uniform surface finish is required. Heads may be attached to shells by lap brazing or may be formed integrally. The thickness of the bottom of cylinders welded or formed by spinning is, under no condition, to be less than two times the minimum wall thickness of the cylindrical shell. Such bottom thicknesses must be measured within an area bounded by a line representing the points of contact between the cylinder and the floor when the cylinder is in a vertical position. Seams must conform to the following:

(1) Circumferential seams must be by brazing only. Heads must be attached to shells by the lap brazing method and must overlap not less than four times the wall thickness. Brazing material must have a melting point of not less than 1000° F. Heads must have a driving fit with the shell unless the shell is crimped, swedged, or curled over the skirt or flange of the head and be thoroughly brazed until complete penetration of the joint by the brazing material is secured. Brazed joints may be repaired by brazing.

(2) Longitudinal seams in shell must be by electric resistance welded joints only. No repairs to longitudinal joints is permitted.

(3) Welding procedures and operators must be qualified in accordance with CGA Pamphlet C–3.

(e) *Welding or brazing.* Only the attachment, by welding or brazing, to the tops and bottoms of cylinders of neckrings, footrings, handles, bosses, pads, and valve protection rings is authorized. Provided that such attachments and the portion of the container to which they are attached are made of weldable steel, the carbon content of which may not exceed 0.25 percent.

(f) *Wall thickness.* The wall stress must be at least two times the service pressure and may not exceed 18,000 pounds per square inch. The minimum wall thickness is 0.044 inch. Calculation must be made by the following formula:

$$S=[P(1.3D^2+0.4d^2)]/(D^2-d^2)$$

where:

S=wall stress in pounds per square inch;
P=2 times service pressure;
D=outside diameter in inches;
d=inside diameter in inches.

(g) *Heat treatment.* Heads formed by drawing or pressing must be uniformly and properly heat treated prior to tests. Cylinders with integral formed heads or bases must be subjected to a normalizing operation. Normalizing and brazing operations may be combined, provided the operation is carried out at a temperature in excess of the upper critical temperature of the steel.

(h) *Openings in cylinders.* Openings in cylinders must comply with the following:

(1) Each opening in cylinders, except those for safety devices, must be provided with a fitting, boss, or pad, securely attached to the cylinder by brazing or by welding or by threads. A fitting, boss, or pad must be of steel suitable for the method of attachment employed, and which need not be identified or verified as to analysis, except that if attachment is by welding, carbon content may not exceed 0.25 percent. If threads are used, they must comply with the following:

(i) Threads must be clean cut, even without checks, and tapped to gauge.

(ii) Taper threads to be of length not less than as specified for American Standard taper pipe threads.

(iii) Straight threads, having at least 4 engaged threads, to have tight fit and calculated shear strength at least 10 times the test pressure of the cylinder; gaskets required, adequate to prevent leakage.

(2) Closure of a fitting, boss, or pad must be adequate to prevent leakage.

(i) *Hydrostatic test.* Each cylinder must successfully withstand a hydrostatic test as follows:

(1) The test must be by water-jacket, or other suitable method, operated so as to obtain accurate data. The pressure gauge must permit reading to an accuracy of 1 percent. The expansion gauge must permit reading of total expansion to an accuracy of either 1 percent or 0.1 cubic centimeter.

(2) Pressure must be maintained for at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and previous to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus, the test pressure cannot be maintained, the test may be repeated at a pressure increased by 10 percent or 100 pounds per square inch, whichever is the lower.

(3) Permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

(4) Cylinders must be tested as follows:

(i) At least one cylinder selected at random out of each lot of 200 or less must be tested as outlined in paragraphs (i)(1), (i)(2), and (i)(3) of this section to at least two times service pressure.

(ii) All cylinders not tested as outlined in paragraph (i)(4)(i) of this section must be examined under pressure of at least two times service pressure and show no defect.

(5) Each 1000 cylinders or less successively produced each day must constitute a lot. One cylinder must be selected from each lot and hydrostatically tested to destruction. If this cylinder bursts below five times the service pressure, then two additional cylinders must be selected and subjected to this test. If either of these

cylinders fails by bursting below five times the service pressure then the entire lot must be rejected. All cylinders constituting a lot must be of identical size, construction heat-treatment, finish, and quality.

(j) *Flattening test.* Following the hydrostatic test, one cylinder taken at random out of each lot of 200 or less, must be subjected to a flattening test that is between knife edges, wedge shaped, 60° angle, rounded to ½ inch radius.

(k) *Physical test.* A physical test must be conducted to determine yield strength, tensile strength, elongation, and reduction of area of material, as follows:

(1) The test is required on 2 specimens cut from 1 cylinder, or part thereof heat-treated as required, taken at random out of each lot of 200 or less in the case of cylinders of capacity greater than 86 cubic inches and out of each lot of 500 or less for cylinders having a capacity of 86 cubic inches or less.

(2) Specimens must conform to the following:

(i) A gauge length of 8 inches with a width not over 1½ inches, a gauge length of 2 inches with a width not over 1½ inches, or a gauge length at least 24 times the thickness with a width not over 6 times the thickness is authorized when a cylinder wall is not over 3⁄16 inch thick.

(ii) The specimen, exclusive of grip ends, may not be flattened. Grip ends may be flattened to within one inch of each end of the reduced section.

(iii) When size of cylinder does not permit securing straight specimens, the specimens may be taken in any location or direction and may be straightened or flattened cold by pressure only, not by blows. When specimens are so taken and prepared, the inspector's report must show in connection with record of physical tests detailed information in regard to such specimens.

(iv) Heating of a specimen for any purpose is not authorized.

(3) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length. The following conditions apply:

(i) The yield strength must be determined by either the ''offset'' method or the ''extension under load'' method as prescribed in ASTM Standard E8–78.

(ii) In using the ''extension under load'' method, the total strain (or ''extension under load'') corresponding to the stress at which the 0.2 percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic extension of the gauge length under appropriate load and adding thereto 0.2 percent of the gauge length. Elastic extension calculations must be based on an elastic modulus of 30,000,000. In the event of controversy, the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2 percent offset.

(iii) For the purpose of strain measurement, the initial strain must be set while the specimen is under a stress of 12,000 pounds per square inch and the strain indicator reading being set at the calculated corresponding strain.

(iv) Cross-head speed of the testing machine may not exceed 1/8 inch per minute during yield strength determination.

(l) *Acceptable results for physical and flattening tests.* Acceptable results for the physical and flattening tests are an elongation of at least 40 percent for a 2 inch gauge length or at least 20 percent in other cases and a yield strength not over 73 percent of tensile strength. In this instance the flattening test is required, without cracking, to six times the wall thickness with a weld 90° from the direction of the applied load. Two rings cut from the ends of length of pipe used in production of a lot may be used for the flattening test provided the rings accompany the lot which they represent in all thermal processing operations. At least one of the rings must pass the flattening test.

(m) *Leakage test.* All spun cylinders and plugged cylinders must be tested for leakage by gas or air pressure after the bottom has been cleaned and is free from all moisture, subject to the following conditions:

(1) Pressure, approximately the same as but no less than service pressure, must be applied to one side of the finished bottom over an area of at least 1⁄16 of the total area of the bottom but not less than ¾ inch in diameter, including the closure, for at least 1 minute, during which time the other side of the bottom exposed to pressure must be covered with water and closely examined for indications of leakage. Except as provided in paragraph (n) of this section, cylinders which are leaking must be rejected.

(2) A spun cylinder is one in which an end closure in the finished cylinder has been welded by the spinning process.

(3) A plugged cylinder is one in which a permanent closure in the bottom of a finished cylinder has been effected by a plug.

(4) As a safety precaution, if the manufacturer elects to make this test before the hydrostatic test, he should design his apparatus so that the pressure is applied to the smallest area practicable, around the point of closure, and so as to use the smallest possible volume of air or gas.

(n) *Rejected cylinders.* Repairs of rejected cylinders is authorized. Cylinders that are leaking must be rejected, except that:

(1) Spun cylinders rejected under the provisions of paragraph (m) of this section may be removed from the spun cylinder category by drilling to remove defective material, tapping, and plugging.

(2) Brazed joints may be rebrazed.

(3) Subsequent to the operations noted in paragraphs (n)(1) and (n)(2) of this section, acceptable cylinders must pass all prescribed tests.

(o) *Marking.* Markings on each cylinder must be by stamping plainly and permanently on shoulder, top head, neck or valve protection collar which is permanently attached to the cylinders and forming an integral part thereof, provided that cylinders not less than 0.090 inch thick may be stamped on the side wall adjacent to top head.

§ 178.56 Specification 4AA480 welded steel cylinders.

(a) *Type, size, and service pressure.* A DOT 4AA480 cylinder is a welded steel cylinder having a water capacity (nominal) not over 1,000 pounds water capacity and a service pressure of 480 pounds per square inch. Closures welded by spinning process not permitted.

(b) *Steel.* The limiting chemical composition of steel authorized by this specification must be as shown in Table I of Appendix A to this part.

(c) *Identification of material.* Material must be identified by any suitable method except that plates and billets for hotdrawn cylinders must be marked with the heat number.

(d) *Manufacture.* Cylinders must be manufactured using equipment and processes adequate to ensure that each cylinder produced conforms to the requirements of this subpart. No defect is permitted that is likely to weaken the finished cylinder appreciably. A reasonably smooth and uniform surface finish is required. Exposed bottom welds on cylinders over 18 inches long must be protected by footrings. Minimum thickness of heads and bottoms may not be less than 90 percent of the required thickness of the side wall. Seams must be made as follows:

(1) Circumferential seams must be welded. Brazing is not authorized.

(2) Longitudinal seams are not permitted.

(3) Welding procedures and operators must be qualified in accordance with CGA Pamphlet C–3.

(e) *Welding.* Only the welding of neckrings, footrings, bosses, pads, and valve protection rings to the tops and bottoms of cylinders is authorized. Provided that such attachments are made of weldable steel, the carbon content of which does not exceed 0.25 percent.

(f) *Wall thickness.* The wall thickness of the cylinder must conform to the following:

(1) For cylinders with an outside diameter over 5 inches, the minimum wall thickness is 0.078 inch. In any case, the minimum wall thickness must be such that the calculated wall stress at the minimum test pressure (in paragraph (i) of this section) may not exceed the lesser value of either of the following:

(i) One-half of the minimum tensile strength of the material determined as required in paragraph (j) of this section; or

(ii) 35,000 pounds per square inch.

(2) Calculation must be made by the formula:

$$S=[P(1.3D^2+0.4d^2)]/(D^2-d^2)$$

Where:

S=wall stress in pounds per square inch;
P=minimum test pressure prescribed for water jacket test;
D=outside diameter in inches;
d=inside diameter in inches.

(3) The ratio of tangential length to outside diameter may not exceed 4.0 for cylinders with a wall thickness less than 0.100 inch.

(g) *Heat treatment.* Each cylinder must be uniformly and properly heat treated prior to tests. Any suitable heat treatment in excess of 1100° F is authorized except that liquid quenching is not permitted. Heat treatment must be accomplished after all forming and welding operations. Heat treatment is not required after welding weldable low carbon parts to attachments of similar material which have been previously welded to the top or bottom of cylinders and properly heat treated, provided such subsequent welding does not produce a temperature in excess of 400° F., in any part of the top or bottom material.

(h) *Openings in cylinders.* Openings in cylinders must conform to the following:

(1) All openings must be in the heads or bases.

(2) Each opening in the cylinder, except those for safety devices, must be provided with a fitting boss, or pad, securely attached to the cylinder by welding or by threads. If threads are used they must comply with the following:

(i) Threads must be clean-cut, even without checks and cut to gauge.

(ii) Taper threads to be of length not less than as specified for American Standard taper pipe threads.

(iii) Straight threads having at least 6 engaged threads, must have a tight fit and a calculated shear strength at least 10 times the test pressure of the cylinder. Gaskets, adequate to prevent leakage, are required.

(3) Closure of a fitting, boss or pad must be adequate to prevent leakage.

(i) *Hydrostatic test.* Each cylinder must successfully withstand a hydrostatic test as follows:

(1) The test must be by water jacket, or other suitable method, operated so as to obtain accurate data. The pressure gauge must permit reading to an accuracy of 1 percent. The expansion gauge must permit reading of total expansion to an accuracy of either 1 percent or 0.1 cubic centimeter.

(2) Pressure must be maintained for at least 30 seconds or sufficiently longer to assure complete expansion. Any internal pressure applied after heat-treatment and before the official test may not exceed 90 percent of the test pressure. If, due to failure of test apparatus, the test pressure cannot be maintained, the test may be repeated at a pressure increased by 10 percent or 100 pounds per square inch, whichever is lower.

(3) Permanent volumetric expansion may not exceed 10 percent of the total volumetric expansion at test pressure.

(4) Cylinders must be tested as follows:

(i) At least one cylinder selected at random out of each lot of 200 or less must be tested as described in paragraphs (i)(1), (i)(2), and (i)(3) of this section, to at least two times service pressure. If a selected cylinder fails, then two additional specimens must be selected at random from the same lot and subjected to the prescribed test. If either of these fails the test, then each cylinder in that lot must be so tested; and

(ii) Each cylinder not tested as prescribed in paragraph (i)(4)(i) of this section must be examined under pressure of at least two times service pressure and must show no defect. A cylinder showing a defect must be rejected unless it may be requalified under paragraph (m) of this section.

(j) *Physical test.* A physical test must be conducted to determine yield strength, tensile strength, elongation, and reduction of area of material, as follows:

(1) The test is required on 2 specimens cut from one cylinder having passed the hydrostatic test, or part thereof heat-treated as required, taken at random out of each lot of 200 or less.

(2) Specimens must conform to the following:

(i) A gauge length of 8 inches with a width not over 1½ inches, a gauge length of 2 inches with a width not over 1½ inches, or a gauge length at least 24 times the thickness with a width not over 6 times thickness is authorized when the cylinder wall is not over 3⁄16 inch thick.

(ii) The specimen, exclusive of grip ends, may not be flattened. Grip ends may be flattened to within one inch of each end of the reduced section.

(iii) When size of cylinder does not permit securing straight specimens, the specimens may be taken in any location or direction and may be straightened or flattened cold, by pressure only, not by blows. When specimens are so taken and prepared, the inspector's report must show in connection with record of physical tests detailed information in regard to such specimens.

(iv) Heating of a specimen for any purpose is not authorized.

(3) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length. The following conditions apply:

(i) The yield strength must be determined by either the ''offset'' method or the ''extension under load'' method as prescribed in ASTM Standard E8–78.

(ii) In using the ''extension under load'' method, the total strain (or ''extension under load''), corresponding to the stress at which the 0.2 percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic extension of the gauge length under appropriate load and adding thereto 0.2 percent of the gauge length. Elastic extension calculations must be based on an elastic modulus of 30,000,000. In the event of controversy, the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2 percent offset.

(iii) For the purpose of strain measurement, the initial strain reference must be set while the specimen is under a stress of 12,000 pounds per square inch and the strain indicator reading being set at the calculated corresponding strain.

(iv) Cross-head speed of the testing machine may not exceed ⅛ inch per minute during yield strength determination.

(k) *Elongation.* Physical test specimens must show at least a 40 percent elongation for 2-inch gauge lengths or at least a 20 percent elongation in other cases. Except that these elongation percentages may be reduced numerically by 2 for 2-inch

specimens and by 1 in other cases for each 7,500 pounds per square inch increment of tensile strength above 50,000 pounds per square inch to a maximum of four such increments.

(l) *Tests of welds.* Welds must be tested as follows:

(1) *Tensile test.* A specimen must be cut from one cylinder of each lot of 200 or less, or a welded test plate. The welded test plate must be of one of the heats in the lot of 200 or less which it represents, in the same condition and approximately the same thickness as the cylinder wall except that it may not be of a lesser thickness than that required for a quarter size Charpy impact specimen. The weld must be made by the same procedures and subjected to the same heat treatment as the major weld on the cylinder. The specimens must be taken across the major seam and must be prepared and tested in accordance with and must meet the requirements of CGA Pamphlet C–3. Should this specimen fail to meet the requirements, specimens may be taken from two additional cylinders or welded test plates from the same lot and tested. If either of the latter specimens fail to meet the requirements, the entire lot represented must be rejected.

(2) *Guided bend test.* A root bend test specimen must be cut from the cylinder or a welded test plate, used for the tensile test specified in paragraph (l)(1) of this section. Specimens must be taken from across the major seam and must be prepared and tested in accordance with and must meet the requirements of CGA Pamphlet C–3.

(3) *Alternate guided-bend test.* This test may be used and must be as required by CGA Pamphlet C–3. The specimen must be bent until the elongation at the outer surface, adjacent to the root of the weld, between the lightly scribed gage lines-a to b, is at least 20 percent, except that this percentage may be reduced for steels having a tensile strength in excess of 50,000 pounds per square inch, as provided in paragraph (k) of this section.

(m) *Rejected cylinders.* Reheat treatment of rejected cylinders is authorized. Subsequent thereto, cylinders must pass all prescribed tests to be acceptable. Repair of welded seams by welding is authorized.

(n) *Markings.* Markings must be stamped plainly and permanently in one of the following locations on the cylinder:

(1) On shoulders and top heads not less than 0.087 inch thick.

(2) On neck, valve boss, valve protection sleeve, or similar part permanently attached to top end of cylinder.

(3) On a plate attached to the top of the cylinder or permanent part thereof: sufficient space must be left on the plate to provide for stamping at least six retest dates: the plate must be at least 1/16 inch thick and must be attached by welding or by brazing at a temperature of at least 1100° F, throughout all edges of the plate.

(4) Variations in location of markings authorized only when necessitated by lack of space.

§ 178.57 Specification 4L welded insulated cylinders.

(a) *Type, size, service pressure, and design service temperature.* A DOT 4L cylinder is a fusion welded insulated cylinder with a water capacity (nominal) not over 1,000 pounds water capacity and a service pressure of at least 40 but not greater than 500 pounds per square inch conforming to the following requirements:

(1) For liquefied hydrogen service, the cylinders must be designed to stand on end, with the axis of the cylindrical portion vertical.

(2) The design service temperature is the coldest temperature for which a cylinder is suitable. The required design service temperatures for each cryogenic liquid is as follows:

Cryogenic liquid	Design service temperature
Argon	Minus 320° F or colder.
Helium	Minus 452° F or colder.
Hydrogen	Minus 423° F or colder.
Neon	Minus 411° F or colder.
Nitrogen	Minus 320° F or colder.
Oxygen	Minus 320° F or colder.

(b) *Material.* Material use in the construction of this specification must conform to the following:

(1) *Inner containment vessel (cylinder).* Designations and limiting chemical compositions of steel authorized by this specification must be as shown in Table 1 in paragraph (o) of this section.

(2) *Outer jacket.* Steel or aluminum may be used subject to the requirements of paragraph (o)(2) of this section.

(c) *Identification of material.* Material must be identified by any suitable method.

(d) *Manufacture.* Cylinders must be manufactured using equipment and processes adequate to ensure that each cylinder produced conforms to the requirements of this subpart and to the following requirements:

(1) No defect is permitted that is likely to weaken the finished cylinder appreciably. A reasonably smooth and uniform surface finish is required. The shell portion must be a reasonably true cylinder.

(2) The heads must be seamless, concave side to the pressure, hemispherical or ellipsoidal in shape with the major diameter not more than twice the minor diameter. Minimum thickness of heads may not be less than 90 percent of the required thickness of the sidewall. The heads must be reasonably true to shape, have no abrupt shape changes, and the skirts must be reasonably true to round.

(3) The surface of the cylinder must be insulated. The insulating material must be fire resistant. The insulation on non-evacuated jackets must be covered with a steel jacket not less than 0.060-inch thick or an aluminum jacket not less than 0.070 inch thick, so constructed that moisture cannot come in contact with the insulating material. If a vacuum is maintained in the insulation space, the evacuated jacket must be designed for a minimum collapsing pressure of 30 psi differential whether made of steel or aluminum. The construction must be such that the total heat transfer, from the atmosphere at ambient temperature to the contents of the cylinder, will not exceed 0.0005 Btu per hour, per Fahrenheit degree differential in temperature, per pound of water capacity of the cylinder. For hydrogen, cryogenic liquid service, the total heat transfer, with a temperature differential of 520 Fahrenheit degrees, may not exceed that required to vent 30 SCF of hydrogen gas per hour.

(4) For a cylinder having a design service temperature colder than minus 320° F, a calculation of the maximum weight of contents must be made and that weight must be marked on the cylinder as prescribed in § 178.35.

(5) Welding procedures and operators must be qualified in accordance with CGA Pamphlet C–3. In addition, an impact test of the weld must be performed in accordance with paragraph (l) of this section as part of the qualification of each welding procedure and operator.

(e) *Welding.* Welding of the cylinder must be as follows:

(1) All seams of the cylinder must be fusion welded. A means must be provided for accomplishing complete penetration of the joint. Only butt or joggle butt joints for the cylinder seams are authorized. All joints in the cylinder must have reasonably true alignment.

(2) All attachments to the sidewalls and heads of the cylinder must be by fusion welding and must be of a weldable material complying with the impact requirements of paragraph (l) of this section.

(3) For welding the cylinder, each procedure and operator must be qualified in accordance with the sections of CGA Pamphlet C–3 that apply. In addition, impact tests of the weld must be performed in accordance with paragraph (l) of this section as part of the qualification of each welding procedure and operator.

(4) Brazing, soldering and threading are permitted only for joints not made directly to the cylinder body. Threads must comply with the requirements of paragraph (h) of this section.

(f) *Wall thickness.* The minimum wall thickness of the cylinder must be such that the calculated wall stress at the minimum required test pressure may not exceed the least value of the following:

(1) 45,000 pounds per square inch.

(2) One-half of the minimum tensile strength across the welded seam determined in paragraph (l) of this section.

(3) One-half of the minimum tensile strength of the base metal determined as required in paragraph (j) of this section.

(4) The yield strength of the base metal determined as required in paragraph (l) of this section.

(5) Further provided that wall stress for cylinders having longitudinal seams may not exceed 85 percent of the value in paragraph (f)(4) of this section, whichever applies.

(6) Calculation must be made by the following formula:

$$S=[P(1.3D^2+0.4d^2)]/(D^2-d^2)$$

where:

S=Wall stress in pounds per square inch;

P=Minimum test pressure prescribed for pressure test in pounds per square inch;

D=Outside diameter in inches;

d=Inside diameter in inches.

(g) *Heat treatment.* Heat treatment is not permitted.

(h) *Openings in cylinder.* Openings in cylinders must conform to the following:

(1) Openings are permitted in heads only. They must be circular and may not exceed 3 inches in diameter or one third of the cylinder diameter, whichever is less. Each opening in the cylinder must be provided with a fitting, boss or pad, either integral with, or securely attached to, the cylinder body by fusion welding. Attachments to a fitting, boss or pad may be made by welding, brazing, mechanical attachment, or threading.

(2) Threads must comply with the following:

(i) Threads must be clean-cut, even, without checks and cut to gauge.

(ii) Taper threads to be of a length not less than that specified for NPT.

(iii) Straight threads must have at least 4 engaged threads, tight fit and calculated shear strength at least 10 times the test pressure of the cylinder. Gaskets, which prevent leakage and are inert to the hazardous material, are required.

(i) *Pressure test.* Each cylinder, before insulating and jacketing, must be examined under a pressure of at least 2 times the service pressure maintained for at least 30 seconds without evidence of leakage, visible distortion or other defect. The pressure gauge must permit reading to an accuracy of 1 percent.

(j) *Physical test.* A physical test must be conducted to determine yield strength, tensile strength, and elongation as follows:

(1) The test is required on 2 specimens selected from material of each heat and in the same condition as that in the completed cylinder.

(2) Specimens must conform to the following:

(i) A gauge length of 8 inches with a width not over 1½ inches, a gauge length of 2 inches with width not over 1½ inches, or a gauge length at least 24 times thickness with a width not over 6 times thickness (authorized when cylinder wall is not over 3⁄16 inch thick).

(ii) The specimen, exclusive of grip ends, may not be flattened. Grip ends may be flattened to within one inch of each end of the reduced section.

(iii) When size of the cylinder does not permit securing straight specimens, the specimens may be taken in any location or direction and may be straightened or flattened cold by pressure only, not by blows. When specimens are so taken and prepared, the inspector's report must show in connection with record of physical tests detailed information in regard to such specimens.

(iv) Heating of a specimen for any purpose is not authorized.

(3) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length. The following conditions apply:

(i) The yield strength must be determined by either the ''offset'' method or the ''extension under load'' method as prescribed in ASTM Standard E8–78.

(ii) In using the ''extension under load'' method, the total strain (or ''extension under load''), corresponding to the stress at which the 0.2 percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic expansion of the gauge length under appropriate load and adding thereto 0.2 percent of the gauge length. Elastic extension calculations must be based on the elastic modulus of the material used. In the event of controversy, the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2 percent offset.

(iii) For the purpose of strain measurement, the initial strain reference must be set while the specimen is under a stress of 12,000 pounds per square inch and the strain indicator reading being set at the calculated corresponding strain.

(iv) Cross-head speed of the testing machine may not exceed ⅛ inch per minute during yield strength determination.

(k) *Acceptable results for physical tests.* Physical properties must meet the limits specified in paragraph (o)(1), Table 1, for the particular steel in the annealed condition. The specimens must show at least a 20 percent elongation for a 2-inch gage length. Except that the percentage may be reduced numerically by 2 for each 7,500 pounds per square inch increment of tensile strength above 100,000 pounds per square inch to a maximum of 5 such increments. Yield strength and tensile strength must meet the requirements of paragraph (o)(1), Table 1, of this section.

(l) *Tests of welds.* Welds must be tested as follows:

(1) *Tensile test.* A specimen must be cut from one cylinder of each lot of 200 or less, or welded test plate. The welded test plate must be of one of the heats in the lot of 200 or less which it represents, in the same condition and approximately the same thickness as the cylinder wall except that it may not of a lesser thickness than that required for a quarter size Charpy impact specimen. The weld must be made by the same procedures and subjected to the same heat treatment as the major weld on the cylinder. The specimen must be taken across the major seam and must be prepared and tested in accordance with and must meet the requirements of CGA Pamphlet C–3. Should this specimen fail to meet the requirements, specimens may be taken from two additional cylinders or welded test plates from the same lot and tested. If either of the latter specimens fails to meet the requirements, the entire lot represented must be rejected.

(2) *Guided bend test.* A ''root'' bend test specimen must be cut from the cylinder or welded test plate, used for the tensile test specified in paragraph (l)(1) of this section and from any other seam or equivalent welded test plate if the seam is welded by a procedure different from that used for the major seam. Specimens must be taken across the particular seam being tested and

must be prepared and tested in accordance with and must meet the requirements of CGA Pamphlet C–3.

(3) *Alternate guided-bend test.* This test may be used and must be as specified in CGA Pamphlet C–3. The specimen must be bent until the elongation at the outer surface, adjacent to the root of the weld, between the lightly scribed gage lines-a to b, is at least 20 percent, except that this percentage may be reduced for steels having a tensile strength in excess of 100,000 pounds per square inch, as provided in paragraph (c) of this section.

(4) *Impact tests.* One set of three impact test specimens (for each test) must be prepared and tested for determining the impact properties of the deposited weld metal—

(i) As part of the qualification of the welding procedure.

(ii) As part of the qualification of the operators.

(iii) For each ''heat'' of welding rodor wire used.

(iv) For each 1,000 feet of weld made with the same heat of welding rod or wire.

(v) All impact test specimens must be of the Charpy type, keyhole or milled U-notch, and must conform in all respects to Figure 3 of ASTM E–23–60T. Each set of impact specimens must be taken across the weld and have the notch located in the weld metal. When the cylinder material thickness is 2.5 mm or thicker, impact specimens must be cut from a cylinder or welded test plate used for the tensile or bend test specimens. The dimension along the axis of the notch must be reduced to the largest possible of 10 mm, 7.5 mm, 5 mm or 2.5 mm, depending upon cylinder thickness. When the material in the cylinder or welded test plate is not of sufficient thickness to prepare 2.5 mm impact test specimens, 2.5 mm specimens must be prepared from a welded test plate made from ⅛ inch thick material meeting the requirements specified in paragraph (o)(1), Table 1, of this section and having a carbon analysis of .05 minimum, but not necessarily from one of the heats used in the lot of cylinders. The test piece must be welded by the same welding procedure as used on the particular cylinder seam being qualified and must be subjected to the same heat treatment.

(vi) Impact test specimens must be cooled to the design service temperature. The apparatus for testing the specimens must conform to the requirements of ASTM Standard E–23–60T. The test piece, as well as the handling tongs, must be cooled for a length of time sufficient to reach the service temperature. The temperature of the cooling device must be maintained within a range of plus or minus 3° F. The specimen must be quickly transferred from the cooling device to the anvil of the testing machine and broken within a time lapse of not more than six seconds.

(vii) The impact properties of each set of impact specimens may not be less than the values in the following table:

Size of specimen	Minimum impact value required for avg. of each set of three specimens (ft.-lb.)	Minimum impact value permitted on one only of a set of three (ft.- lb.)
10 mm×10 mm .	15	10
10 mm×7.5 mm	12.5	8.5
10 mm×5 mm ...	10	7.0
10 mm×2.5 mm	5	3.5

(viii) When the average value of the three specimens equals or exceeds the minimum value permitted for a single specimen and the value for more than one specimen is below the required average value, or when the value for one specimen is below the minimum value permitted for a single specimen, a retest of three additional specimens must be made. The value of each of these retest specimens must equal or exceed the required average value. When an erratic result is caused by a defective specimen, or there is uncertainty in test procedure, a retest is authorized.

(m) *Radiographic examination.* Cylinders must be subject to a radiographic examination as follows:

(1) The techniques and acceptability of radiographic inspection must conform to the standards set forth in CGA Pamphlet C–3.

(2) One finished longitudinal seam must be selected at random from each lot of 100 or less successively produced and be radiographed throughout its entire length. Should the radiographic examination fail to meet the requirements of paragraph (m)(1) of this section, two additional seams of the same lot must be examined, and if either of these fail to meet the requirements of (m)(1) of this section, only those passing are acceptable.

(n) *Rejected cylinders.* Reheat treatment of rejected cylinders is authorized. Subsequent thereto, cylinders must pass all prescribed tests to be acceptable. Welds may be repaired by suitable methods of fusion welding.

(o) *Authorized materials of construction.* Authorized materials of construction are as follows:

(1) *Inner containment vessel (cylinder).* Electric furnace steel of uniform quality must be used. Chemical analysis must conform to ASTM A240, Type 304 Stainless Steel. A heat of steel made under Table 1 and Table 2 of this paragraph (o)(1) is acceptable, even though its check chemical analysis is slightly out of the specified range, if it is satisfactory in all other respects, provided the tolerances shown in Table 3 of this paragraph (o)(1) are not exceeded. The following chemical analyses and physical properties are authorized:

TABLE 1.—AUTHORIZED MATERIALS

Designation	Chemical analysis, limits in percent
Carbon[1]	0.08 max.
Manganese	2.00 max.
Phosphorus	0.045 max.
Sulphur	0.030 max.
Silicon	1.00 max.
Nickel	8.00–10.50
Chromium	18.00–20.00
Molybdenum	None.
Titanium	None.
Columbium	None.

[1] The carbon analysis must be reported to the nearest hundredth of one percent.

TABLE 2.—PHYSICAL PROPERTIES

	Physical properties (annealed)
Tensile strength, p.s.i. (minimum)	75,000
Yield strength, p.s.i. (minimum)	30,000
Elongation in 2 inches (minimum) percent	30.0
Elongation other permissible gauge lengths (minimum) percent	15.0

TABLE 3.—CHECK ANALYSIS TOLERANCES

Elements	Limit or specified range (percent)	Tolerance over the maximum limit or under the minimum limit
Carbon	To 0.030, incl	0.005
	Over 0.30 to 0.20, incl	0.01
Manganese	To 1.00 incl	.03
	Over 1.00 to 3.00, incl	0.04
Phosphorus [1]	To 0.040, incl	0.005
	Over 0.040 to 0.020 incl	0.010
Sulphur	To .40 incl	0.005
Silicon	To 1.00, incl	0.05
Nickel	Over 5.00 to 10.00, incl	0.10
	Over 10.00 to 20.00, incl	0.15
Chromium	Over 15.00 to 20.00, incl	0.20

[1] Rephosphorized steels not subject to check analysis for phosphorus.

(2) *Outer jacket.* (i) Nonflammable cryogenic liquids. Cylinders intended for use in the transportation of nonflammable cryogenic liquid must have an outer jacket made of steel or aluminum.

(ii) Flammable cryogenic liquids. Cylinders intended for use in the transportation of flammable cryogenic liquid must have an outer jacket made of steel.

(p) *Markings.* (1) Markings must be stamped plainly and permanently on shoulder or top head of jacket or on a permanently attached plate or head protective ring.

(2) The letters ''ST'', followed by the design service temperature (for example, ST–423F), must be marked on cylinders having a design service temperature of colder than minus 320° F only. Location to be just below the DOT mark.

(3) The maximum weight of contents, in pounds (for example, ''Max. Content 51 #''), must be marked on cylinders having a design service temperature colder than minus 320° F only. Location to be near symbol.

(4) Special orientation instructions must be marked on the cylinder (for example, THIS END UP), if the cylinder is used in an orientation other than vertical with openings at the top of the cylinder.

(5) If the jacket of the cylinder is constructed of aluminum, the letters ''AL'' must be marked after the service pressure marking. Example: DOT–4L150 AL.

(6) Except for serial number and jacket material designation, each marking prescribed in this paragraph (p) must be duplicated on each cylinder by any suitable means.

(q) *Inspector's report.* In addition to the information required by § 178.35, the inspector's reports must contain information on:

(1) The jacket material and insulation type;

(2) The design service temperature (° F); and

(3) The impact test results, on a lot basis.

§ 178.58 Specification 4DA welded steel cylinders for aircraft use.

(a) *Type, size, and service pressure.* A DOT 4DA is a welded steel sphere (two seamless hemispheres) or a circumferentially welded cylinder (two seamless drawn shells) with a water capacity not over 100 pounds and a service pressure of at least 500 but not over 900 pounds per square inch.

(b) *Steel.* Open-hearth or electric steel of uniform quality must be used. A heat of steel made under Table 1 of this paragraph (b), check chemical analysis of which is slightly out of the specified range, is acceptable, if satisfactory in all other respects, provided the tolerances shown in Table 2 of this paragraph (b) are not exceeded except as approved by the Associate Administrator. The following chemical analyses are authorized:

TABLE 1.—AUTHORIZED MATERIALS

4130	Percent
Carbon	0.28/0.33.
Manganese	0.40/0.60.
Phosphorus	0.040 max.
Sulfur	0.040 max.
Silicon	0.15/0.35.
Chromium	0.80/1.10.
Molybdenum	0.15/0.25.

TABLE 2.—CHECK ANALYSIS TOLERANCES

Element	Limit or maximum specified (percent)	Tolerance (percent) over the maximum limit or under the minimum limit	
		Under minimum limit	Over maximum limit
Carbon	Over 0.15 to 0.40 incl	.03	.04
Manganese	To 0.60 incl	.03	.03
Phosphorus [1]	All ranges		.01
Sulphur	All ranges		.01
Silicon	To 0.30 incl	.02	.03
	Over 0.30 to 1.00 incl	.05	.05
Chromium	To 0.90 incl	.03	.03
	Over 0.90 to 2.10 incl	.05	.05
Molybdenum	To 0.20 incl	.01	.01
	Over 0.20 to 0.40, incl	.02	.02

[1] Rephosphorized steels not subject to check analysis for phosphorus.

(c) *Identification of material.* Materials must be identified by any suitable method except that plates and billets for hot-drawn containers must be marked with the heat number.

(d) *Manufacture.* Cylinders must be manufactured in accordance with the following requirements:

(1) By best appliances and methods. No defect is acceptable that is likely to weaken the finished container appreciably. A reasonably smooth and uniform surface finish is required. No abrupt change in wall thickness is permitted. Welding procedures and operators must be qualified in accordance with CGA Pamphlet C–3.

(2) All seams of the sphere or cylinders must be fusion welded. Seams must be of the butt or joggle butt type and means must be provided for accomplishing complete penetration of the joint.

(e) *Welding.* Attachments to the container are authorized by fusion welding provided that such attachments are made of weldable steel, the carbon content of which may not exceed 0.25 percent except in the case of 4130 steel.

(f) *Wall thickness.* The minimum wall thickness must be such that the wall stress at the minimum specified test pressure may not exceed 67 percent of the minimum tensile strength of the steel as determined from the physical and burst tests required and may not be over 70,000 p.s.i. For any diameter container, the minimum wall thickness is 0.040 inch. Calculations must be made by the formulas in paragraph (f)(1) or (f)(2) of this section:

(1) Calculation for a sphere must be made by the following formula:

$S=PD/4tE$

where:

S=Wall stress in pounds per square inch;
P=Test pressure prescribed for water jacket test, i.e., at least 2 times service pressure, in pounds per square inch;
D=Outside diameter in inches;
t=Minimum wall thickness in inches;
E=0.85 (provides 85 percent weld efficiency factor which must be applied in the girth weld area and heat affected zones which zone must extend a distance of 6 times wall thickness from center line of weld);
E=1.0 (for all other areas).

(2) Calculation for a cylinder must be made by the following formula:

$S=[P(1.3D^2+0.4d^2)]/(D^2-d^2)$

Where:

S=wall stress in pounds per square inch;
P=test pressure prescribed for water jacket test, i.e., at least 2 times service pressure, in pounds per square inch;
D=outside diameter in inches;
d=inside diameter in inches.

(g) *Heat treatment.* The completed containers must be uniformly and properly heat-treated prior to tests. Heat-treatment of containers of the authorized analysis must be as follows:

(1) All containers must be quenched by oil, or other suitable medium except as provided in paragraph (l)(iv) of this section.

(2) The steel temperature on quenching must be that recommended for the steel analysis, but may not exceed 1,750° F.

(3) The steel must be tempered at the temperature most suitable for the analysis except that in no case shall the tempering temperature be less than 1,000° F.

(4) The steel may be normalized at a temperature of 1,650° F instead of being quenched, and containers so normalized need not be tempered.

(5) All cylinders, if water quenched or quenched with a liquid producing a cooling rate in excess of 80 percent of the cooling rate of water, must be inspected by the magnetic particle or dye penetrant method to detect the presence of quenching cracks. Any cylinder found to have a quench crack must be rejected and may not be requalified.

(h) *Openings in container.* Openings in the container must comply with the following requirements:

(1) Each opening in the container must be provided with a fitting, boss, or pad of weldable steel securely attached to the container by fusion welding.

(2) Attachments to a fitting, boss, or pad must be adequate to prevent leakage. Threads must comply with the following:

(i) Threads must be clean cut, even, without checks, and tapped to gauge.

(ii) Taper threads to be of length not less than as specified for American Standard taper pipe threads.

(iii) Straight threads, having at least 4 engaged threads, to have tight fit and calculated shear strength at least 10 times the test pressure of the container; gaskets required, adequate to prevent leakage.

(i) *Hydrostatic test.* Each cylinder must successfully withstand a hydrostatic test as follows:

(1) The test must be by water-jacket, or other suitable method, operated so as to obtain accurate data. The pressure gauge must permit reading to an accuracy of 1 percent. The expansion gauge must permit reading of total expansion to accuracy either of 1 percent or 0.1 cubic centimeter.

(2) Pressure must be maintained for at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and previous to the official test may not exceed 90 percent of the

test pressure. If, due to failure of the test apparatus, the test pressure cannot be maintained, the test may be repeated at a pressure increased by 10 percent or 100 pounds per square inch, whichever is the lower.

(3) Permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

(4) Each container must be tested to at least 2 times service pressure.

(j) *Burst test.* One container taken at random out of 200 or less must be hydrostatically tested to destruction. The rupture pressure must be included as part of the inspector's report.

(k) *Flattening test.* Spheres and cylinders must be subjected to a flattening test as follows:

(1) *Flattening test for spheres.* One sphere taken at random out of each lot of 200 or less must be subjected to a flattening test as follows:

(i) The test must be performed after the hydrostatic test.

(ii) The test must be at the weld between the parallel steel plates on a press with a welded seam, at right angles to the plates. Any projecting appurtenances may be cut off (by mechanical means only) prior to crushing.

(2) *Flattening test for cylinders.* One cylinder taken at random out of each lot of 200 or less, must be subjected to a flattening test as follows:

(i) The test must be performed after the hydrostatic test.

(ii) The test must between knife edges, wedge shaped, 60° angle, rounded to ½ inch radius; test

(l) *Radiographic inspection.* Radiographic examination is required on all welded joints which are subjected to internal pressure, except that at the discretion of the disinterested inspector, openings less than 25 percent of the sphere diameter need not be subjected to radiographic inspection. Evidence of any defects likely to seriously weaken the container must be cause for rejection.

(m) *Physical test and specimens for spheres and cylinders.* Spheres and cylinders must be subjected to a physical test as follows:

(1) A physical test for a sphere is required on 2 specimens cut from a flat representative sample plate of the same heat taken at random from the steel used to produce the sphere. This flat steel from which the 2 specimens are to be cut must receive the same heat-treatment as the spheres themselves. Sample plates to be taken for each lot of 200 or less spheres.

(2) Specimens for spheres have a gauge length 2 inches with a width not over 1½ inches, or a gauge length at least 24 times thickness with a width not over 6 times thickness is authorized when wall of sphere is not over 3⁄16 inch thick.

(3) A physical test for cylinders is required on 2 specimens cut from 1 cylinder taken at random out of each lot of 200 or less.

(4) Specimens for cylinder must conform to the following:

(i) A gauge length of 8 inches with a width not over 1½ inches, a gauge length of 2 inches with a width not over 1½ inches, a gauge length at least 24 times thickness with a width not over 6 times thickness is authorized when a cylinder wall is not over 3⁄16 inch thick.

(ii) The specimen, exclusive of grip ends, may not be flattened. Grip ends may be flattened to within 1 inch of each end of the reduced section.

(iii) Heating of a specimen for any purpose is not authorized.

(5) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length. The following conditions apply:

(i) The yield strength must be determined by either the ''offset'' method or the ''extension under load'' method as prescribed in ASTM Standard E8–78.

(ii) In using the ''extension under load'' method, the total strain (or ''extension under load'') corresponding to the stress at which the 0.2 percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic extension of the gauge length under appropriate load and adding thereto 0.2 percent of the gauge length. Elastic extension calculations must be based on an elastic modulus of 30,000,000. In the event of controversy, the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2 percent offset.

(iii) For the purpose of strain measurement, the initial strain must be set while the specimen is under a stress of 12,000 pounds per square inch and the strain indicator reading being set at the calculated corresponding strain.

(iv) Cross-head speed of the testing machine may not exceed ⅛ inch per minute during yield strength determination.

(n) *Acceptable results for physical, flattening, and burst tests.* The following are acceptable results of the physical, flattening and burst test:

(1) Elongation must be at least 20 percent for a 2-inch gauge length or 10 percent in other cases.

(2) Flattening is required to 50 percent of the original outside diameter without cracking.

(3) Burst pressure must be at least 3 times service pressure.

(o) *Rejected containers.* Reheat-treatment of rejected cylinders is authorized. Subsequent thereto, containers must pass all prescribed tests to be acceptable. Repair of welded seams by welding prior to reheat-treatment is authorized.

(p) *Marking.* Markings on each container must be stamped plainly and permanently on a permanent attachment or on a metal nameplate permanently secured to the container by means other than soft solder.

§ 178.59 Specification 8 steel cylinders with porous fillings for acetylene.

(a) Type and service pressure. A DOT 8 cylinder is a seamless cylinder with a service pressure of 250 pounds per square inch. The following steel is authorized:

(1) A longitudinal seam if forge lap welded;

(2) Attachment of heads by welding or by brazing by dipping process; or

(3) A welded circumferential body seam if the cylinder has no longitudinal seam.

(b) *Steel.* Open-hearth, electric or basic oxygen process steel of uniform quality must be used. Content percent may not exceed the following: Carbon, 0.25; phosphorus, 0.045; sulphur, 0.050.

(c) *Identification of steel.* Materials must be identified by any suitable method except that plates and billets for hot-drawn cylinders must be marked with the heat number.

(d) *Manufacture.* Cylinders must be manufactured using equipment and processes adequate to ensure that each cylinder produced conforms to the requirements of this subpart. No defect is acceptable that is likely to weaken the finished cylinder appreciably. A reasonably smooth and uniform surface finish is required. Welding procedures and operators must be qualified in accordance with CGA Pamphlet C–3.

(e) *Exposed bottom welds.* Exposed bottom welds on cylinders over 18 inches long must be protected by footrings.

(f) *Heat treatment.* Body and heads formed by drawing or pressing must be uniformly and properly heat treated prior to tests.

(g) *Openings.* Openings in the cylinders must comply with the following:

(1) Standard taper pipe threads are required;

(2) Length may not be less than as specified for American Standard pipe threads; tapped to gauge; clean cut, even, and without checks.

(h) *Hydrostatic test.* Each cylinder must successfully withstand a hydrostatic test as follows:

(1) The test must be by water-jacket, or other suitable method, operated so as to obtain accurate data. The pressure gauge must permit reading to an accuracy of 1 percent. The expansion gauge must permit reading of total expansion to an accuracy of either 1 percent or 0.1 cubic centimeter.

(2) Pressure must be maintained for at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and previous to the official test may not exceed 90 percent of the test pressure.

(3) Permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

(4) One cylinder out of each lot of 200 or less must be hydrostatically tested to at least 750 pounds per square inch. Cylinders not so tested must be examined under pressure of between 500 and 600 pounds per square inch and show no defect. If hydrostatically tested cylinder fails, each cylinder in the lot may be hydrostatically tested and those passing are acceptable.

(i) *Leakage test.* Cylinders with bottoms closed in by spinning must be subjected to a leakage test by setting the interior air or gas pressure to not less than the service pressure. Cylinders which leak must be rejected.

(j) *Physical test.* A physical test must be conducted as follows:

(1) The test is required on 2 specimens cut longitudinally from 1 cylinder or part thereof taken at random out of each lot of 200 or less, after heat treatment.

(2) Specimens must conform to a gauge length of 8 inches with a width not over 1½ inches, a gauge length of 2 inches with width not over 1½, or a gauge length at least 24 times thickness with a width not over 6 times thickness is authorized when a cylinder wall is not over 3⁄16 inch thick.

(3) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length. The following conditions apply:

(i) The yield strength must be determined by either the ''offset'' method or the ''extension under load'' method as prescribed in ASTM Standard E8–78.

(ii) In using the ''extension under load'' method, the total strain (or ''extension under load'') corresponding to the stress at which the 0.2 percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic extension of the gauge length under appropriate load and adding thereto 0.2 percent of the gauge length. Elastic extension calculations must be based on an elastic modulus of 30,000,000. In the event of controversy, the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2 offset.

(iii) For the purpose of strain measurement, the initial strain must be set while the specimen is under a stress of 12,000 pounds per square inch and the strain indicator reading being set at the calculated corresponding strain.

(iv) Cross-head speed of the testing machine may not exceed ⅛ inch per-minute during yield strength determination.

(4) Yield strength may not exceed 73 percent of tensile strength. Elongation must be at least 40 percent in 2 inch or 20 percent in other cases.

(k) *Rejected cylinders.* Reheat treatment of rejected cylinder is authorized. Subsequent thereto, cylinders must pass all prescribed tests to be acceptable. Repair by welding is authorized.

(l) *Porous filling.* (1) Cylinders must be filled with a porous material in accordance with the following:

(i) The porous material may not disintegrate or sag when wet with solvent or when subjected to normal service;

(ii) The porous filling material must be uniform in quality and free of voids, except that a well drilled into the filling material beneath the valve is authorized if the well is filled with a material of such type that the functions of the filling material are not impaired;

(iii) Overall shrinkage of the filling material is authorized if the total clearance between the cylinder shell and filling material, after solvent has been added, does not exceed ½ of 1 percent of the respective diameter or length, but not to exceed ⅛ inch, measured diametrically and longitudinally;

(iv) The clearance may not impair the functions of the filling material;

(v) The installed filling material must meet the requirements of CGA Pamphlet C–12; and

(vi) Porosity of filling material may not exceed 80 percent except that filling material with a porosity of up to 92 percent may be used when tested with satisfactory results in accordance with CGA Pamphlet C–12.

(2) When the porosity of each cylinder is not known, a cylinder taken at random from a lot of 200 or less must be tested for porosity. If the test cylinder fails, each cylinder in the lot may be tested individually and those cylinders that pass the test are acceptable.

(3) For filling that is molded and dried before insertion in cylinders, porosity test may be made on a sample block taken at random from material to be used.

(4) The porosity of the filling material must be determined. The amount of solvent at 70° F for a cylinder:

(i) Having shell volumetric capacity above 20 pounds water capacity (nominal) may not exceed the following:

Percent porosity of filler	Maximum acetone solvent percent shell capacity by volume
90 to 92	43.4
87 to 90	42.0
83 to 87	40.0
80 to 83	38.6
75 to 80	36.2
70 to 75	33.8
65 to 70	31.4

(ii) Having volumetric capacity of 20 pounds or less water capacity (nominal), may not exceed the following:

Percent porosity of filler	Maximum acetone solvent percent shell capacity by volume
90 to 92	41.8
83 to 90	38.5
80 to 83	37.1
75 to 80	34.8
70 to 75	32.5
65 to 70	30.2

(m) *Tare weight.* The tare weight is the combined weight of the cylinder proper, porous filling, valve, and solvent, without removable cap.

(n) *Duties of inspector.* In addition to the requirements of § 178.35, the inspector is required to—

(1) Certify chemical analyses of steel used, signed by manufacturer thereof; also verify by, check analyses of samples taken from each heat or from 1 out of each lot of 200 or less, plates, shells, or tubes used.

(2) Verify compliance of cylinder shells with all shell requirements; inspect inside before closing in both ends; verify heat treatment as proper; obtain all samples for all tests and for check analyses; witness all tests; verify threads by gauge; report volumetric capacity and minimum thickness of wall noted.

(3) Prepare report on manufacture of steel shells in form prescribed in § 178.35. Furnish one copy to manufacturer and three copies to the company that is to complete the cylinders.

(4) Determine porosity of filling and tare weights; verify compliance of marking with prescribed requirements; obtain necessary copies of steel shell reports; and furnish complete reports required by this specification to the person who has completed the manufacture of the cylinders and, upon request, to the purchaser. The test reports must be retained by the inspector for fifteen years from the original test date of the cylinder.

(o) *Marking.* (1) Marking on each cylinder must be stamped plainly and permanently on or near the shoulder, top head, neck or valve protection collar which is permanently attached to the cylinder and forming integral part thereof.

(2) Tare weight of cylinder, in pounds and ounces, must be marked on the cylinder.

(3) Cylinders, not completed, when delivered must each be marked for identification of each lot of 200 or less.

§ 178.60 Specification 8AL steel cylinders with porous fillings for acetylene.

(a) *Type and service pressure.* A DOT 8AL cylinder is a seamless steel cylinder with a service pressure of 250 pounds per square inch. However, the attachment of heads by welding or by brazing by dipping process and a welded circumferential body seam is authorized. Longitudinal seams are not authorized.

(b) *Authorized steel.* The authorized steel is as specified in Table I of Appendix A to this part.

(c) *Identification of steel.* Material must be identified by any suitable method except that plates and billets for hot-drawn cylinders must be marked with heat number.

(d) *Manufacture.* Cylinders must be manufactured using equipment and processes adequate to ensure that each cylinder produced conforms to the requirements of this subpart. No defect is permitted that is likely to weaken the finished cylinder appreciably. A reasonably smooth and uniform surface finish is required. Welding procedures and operators must be qualified in accordance with CGA Pamphlet C–3.

(e) *Footrings.* Exposed bottom welds on cylinders over 18 inches long must be protected by footrings.

(f) *Welding or brazing.* Welding or brazing for any purpose whatsoever is prohibited except as follows:

(1) The attachment to the tops or bottoms of cylinders of neckrings, footrings, handlers, bosses, pads, and valve protecting rings is authorized provided that such attachments and the portion of the container to which they are attached are made of weldable steel, the carbon content of which may not exceed 0.25 percent.

(2) Heat treatment is not required after welding or brazing weldable low carbon parts to attachments, specified in paragraph (f)(1) of this section, of similar material which have been previously welded or brazed to the top or bottom of cylinders and properly heat treated, provided such subsequent welding or brazing does not produce a temperature in excess of 400° F in any part of the top or bottom material.

(g) *Wall thickness; wall stress.* The wall thickness/wall stress of the cylinder must conform to the following:

(1) The calculated wall stress at 750 pounds per square inch may not exceed 35,000 pounds per square inch, or one-half of the minimum ultimate strength of the steel as determined in paragraph (l) of this section, whichever value is the smaller. The measured wall thickness may not include galvanizing or other protective coating.

(i) Calculation of wall stress must be made by the following formula:

$$S=[P(1.3D^2+0.4d^2)]/(D^2-d^2)$$

Where:

S=Wall stress in pounds per square inch;

P=750 pounds per square inch (minimum test pressure);

D=Outside diameter in inches;

d=Inside diameter in inches.

(ii) Either D or d must be calculated from the relation D=d + 2t, where t=minimum wall thickness.

(2) Cylinders with a wall thickness less than 0.100 inch, the ratio of straight side wall length to outside diameter may not exceed 3.5.

(3) For cylinders having outside diameter over 5 inches, the minimum wall thickness must be 0.087 inch.

(h) *Heat treatment.* Each cylinder must be uniformly and properly heat treated, prior to tests, by any suitable method in excess of 1100° F. Heat treatment must be accomplished after all forming and welding operations, except that when brazed joints are used, heat treatment must follow any forming and welding operations but may be done before, during, or after the brazing operations. Liquid quenching is not authorized.

(i) *Openings.* Standard taper pipe threads required in all openings. The length of the opening may not be less than as specified for American Standard pipe threads; tapped to gauge; clean cut, even, and without checks.

(j) *Hydrostatic test.* Each cylinder must successfully withstand a hydrostatic test as follows;

(1) The test must be by water-jacket, or other suitable method, operated so as to obtain accurate data. The pressure gauge must permit reading to an accuracy of 1 percent. The expansion gauge must permit reading of total expansion to an accuracy of either 1 percent or 0.1 cubic centimeter.

(2) Pressure must be maintained for at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and previous to the official test may not exceed 90 percent of the test pressure.

(3) Permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

(4) One cylinder out of each lot of 200 or less must be hydrostatically tested to at least 750 pounds per square inch. Cylinders not so tested must be examined under pressure of between 500 and 600 pounds per square inch and show no defect. If a hydrostatically tested cylinder fails, each cylinder in the lot may be hydrostatically tested and those passing are acceptable.

(k) *Leakage test.* Cylinders with bottoms closed in by spinning must be leakage tested by setting the interior air or gas pressure at not less than the service pressure. Any cylinder that leaks must be rejected.

(l) *Physical test.* A physical test must be conducted as follows;

(1) The test is required on 2 specimens cut longitudinally from 1 cylinder or part thereof taken at random out of each lot of 200 or less, after heat treatment.

(2) Specimens must conform to a gauge length of 8 inches with a width not over 1½ inches, a gauge length 2 inches with a width not over 1½ inches, or a gauge length at least 24 times thickness with a width not over 6 times thickness is authorized when a cylinder wall is not over 3⁄16 inch thick.

(3) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length. The following conditions apply:

(i) The yield strength must be determined by either the ''offset'' method or the ''extension under load'' method as prescribed in ASTM Standard E8–78.

(ii) In using the ''extension under load'' method, the total strain (or ''extension under load'') corresponding to the stress at which the 0.2 percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic extension of the gauge length under appropriate load and adding thereto 0.2 percent of the gauge length. Elastic extension calculations must be based on an elastic modulus of 30,000,000. In the event of controversy,

the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2 offset.

(iii) For the purpose of strain measurement, the initial strain must be set while the specimen is under a stress of 12,000 pounds per square inch, the strain indicator reading being set at the calculated corresponding strain.

(iv) Cross-head speed of the testing machine may not exceed 1/8 inch per minute during yield strength determination.

(m) *Elongation.* Physical test specimens must show at least a 40 percent elongation for a 2 inch gauge length or at least a 20 percent elongation in other cases. Except that these elongation percentages may be reduced numerically by 2 for 2 inch specimens and 1 in other cases for each 7,500 pounds per square inch increment of tensile strength above 50,000 pounds per square inch to a maximum of four such increments.

(n) *Weld tests.* Specimens taken across the circumferentially welded seam must be cut from one cylinder taken at random from each lot of 200 or less cylinders after heat treatment and must pass satisfactorily the following tests:

(1) *Tensile test.* A specimen must be cut from one cylinder of each lot of 200 or less, or welded test plate. The specimen must be taken from across the major seam and must be prepared and tested in accordance with and must meet the requirements of CGA Pamphlet C–3. Should this specimen fail to meet the requirements, specimens may be taken from two additional cylinders or welded test plates from the same lot and tested. If either of the latter specimens fail to meet the requirements, the entire lot represented must be rejected.

(2) *Guided bend test.* A root bend test specimen must be cut from the cylinder or welded test plate, used for the tensile test specified in paragraph (n)(1) of this section. Specimens must be prepared and tested in accordance with and must meet the requirements of CGA Pamphlet C–3.

(3) *Alternate guided-bend test.* This test may be used and must be as required by CGA Pamphlet C–3. The specimen must be bent until the elongation at the outer surface, adjacent to the root of the weld, between the lightly scribed gage lines—a to b, must be at least 20 percent, except that this percentage may be reduced for steels having a tensile strength in excess of 50,000 pounds per square inch, as provided in paragraph (m) of this section.

(o) *Rejected cylinders.* Reheat treatment of rejected cylinders is authorized. Subsequent thereto, cylinders must pass all prescribed tests to be acceptable. Repair by welding is authorized.

(p) *Porous filling.* (1) Cylinders must be filled with a porous material in accordance with the following:

(i) The porous material may not disintegrate or sag when wet with solvent or when subjected to normal service;

(ii) The filling material must be uniform in quality and free of voids, except that a well drilled into the filling material beneath the valve is authorized if the well is filled with a material of such type that the functions of the filling material are not impaired;

(iii) Overall shrinkage of the filling material is authorized if the total clearance between the cylinder shell and filling material, after solvent has been added, does not exceed ½ of 1 percent of the respective diameter or length but not to exceed ⅛ inch, measured diametrically and longitudinally;

(iv) The clearance may not impair the functions of the filling material;

(v) The installed filling material must meet the requirements of CGA Pamphlet C–12; and

(vi) Porosity of filling material may not exceed 80 percent except that filling material with a porosity of up to 92 percent may be used when tested with satisfactory results in accordance with CGA Pamphlet C–12.

(2) When the porosity of each cylinder is not known, a cylinder taken at random from a lot of 200 or less must be tested for porosity. If the test cylinder fails, each cylinder in the lot may be tested individually and those cylinders that pass the test are acceptable.

(3) For filling that is molded and dried before insertion in cylinders, porosity test may be made on sample block taken at random from material to be used.

(4) The porosity of the filling material must be determined; the amount of solvent at 70° F for a cylinder:

(i) Having shell volumetric capacity above 20 pounds water capacity (nominal) may not exceed the following:

Percent porosity of filler	Maximum acetone solvent percent shell capacity by volume
90 to 92	43.4
87 to 90	42.0
83 to 87	40.0
80 to 83	38.6
75 to 80	36.2
70 to 75	33.8
65 to 70	31.4

(ii) Having volumetric capacity of 20 pounds or less water capacity (nominal), may not exceed the following:

Percent porosity of filler	Maximum acetone solvent percent shell capacity by volume
90 to 92	41.8
83 to 90	38.5
80 to 83	37.1
75 to 80	34.8
70 to 75	32.5
65 to 70	30.2

(q) *Tare weight.* The tare weight is the combined weight of the cylinder proper, porous filling, valve, and solvent, but without removable cap.

(r) *Duties of inspector.* In addition to the requirements of § 178.35, the inspector shall—

(1) Certify chemical analyses of steel used, signed by manufacturer thereof; also verify by check analyses, of samples taken from each heat or from 1 out of each lot of 200 or less plates, shells, or tubes used.

(2) Verify compliance of cylinder shells with all shell requirements, inspect inside before closing in both ends, verify heat treatment as proper; obtain all samples for all tests and for check analyses, witness all tests; verify threads by gauge, report volumetric capacity and minimum thickness of wall noted.

(3) Report percentage of each specified alloying element in the steel. Prepare report on manufacture of steel shells in form prescribed in § 178.35. Furnish one copy to manufacturer and three copies to the company that is to complete the cylinders.

(4) Determine porosity of filling and tare weights; verify compliance of marking with prescribed requirements; obtain necessary copies of steel shell reports prescribed in paragraph (b) of this section; and furnish complete test reports required by this specification to the person who has completed the manufacture of the cylinders and, upon request, to the purchaser. The test reports must be retained by the inspector for fifteen years from the original test date of the cylinder.

(s) *Marking.* (1) Tare weight of cylinder, in pounds and ounces, must be marked on the cylinder.

(2) Cylinders, not completed, when delivered must each be marked for identification of each lot of 200 or less.

(3) Markings must be stamped plainly and permanently in locations in accordance with the following:

(i) On shoulders and top heads not less than 0.087 inch thick; or

(ii) On neck, valve boss, valve protection sleeve, or similar part permanently attached to the top end of cylinder; or

(iii) On a plate of ferrous material attached to the top of the cylinder or permanent part thereof; the plate must be at least 1/16 inch thick, and must be attached by welding, or by brazing at a temperature of at least 1,100 °F throughout all edges of the plate. Sufficient space must be left on the plate to provide for stamping at least four (4) retest dates.

§ 178.61 Specification 4BW welded steel cylinders with electric-arc welded longitudinal seam.

(a) *Type, size and service pressure.* A DOT 4BW cylinder is a welded type steel cylinder with a longitudinal electric-arc welded seam, a water capacity (nominal) not over 1,000 pounds and a service pressure at least 225 and not over 500 pounds per square inch gauge. Cylinders closed in by spinning process are not authorized.

(b) *Authorized steel.* Steel used in the construction of the cylinder must conform to the following:

(1) The body of the cylinder must be constructed of steel conforming to the limits specified in Table I of Appendix A to this part.

(2) Material for heads must meet the requirements of paragraph (a) of this section or be open hearth, electric or basic oxygen carbon steel of uniform quality. Content percent may not exceed the following: Carbon 0.25, Manganese 0.60, Phosphorus 0.045, Sulfur 0.050. Heads must be hemispherical or ellipsoidal in shape with a maximum ratio of 2.1. If low carbon steel is used, the thickness of such heads must be determined by using a maximum wall stress of 24,000 p.s.i. in the formula described in paragraph (f)(1) of this section.

(c) *Identification of material.* Material must be identified by any suitable method.

(d) *Manufacture.* Cylinders must be manufactured using equipment and processes adequate to ensure that each cylinder produced conforms to the requirements of this subpart and the following:

(1) No defect is permitted that is likely to weaken the finished cylinder appreciably. A reasonably smooth and uniform surface is required. Exposed bottom welds on cylinders over 18 inches long must be protected by footrings. Minimum thickness of heads may not be less than 90 percent of the required thickness of the sidewall. Heads must be concave to pressure.

(2) Circumferential seams must be by electric-arc welding. Joints must be butt with one member offset (joggle butt) or lap with minimum overlap of at least four times nominal sheet thickness.

(3) Longitudinal seams in shells must conform to the following:

(i) Longitudinal electric-arc welded seams must be of the butt welded type. Welds must be made by a machine process including automatic feed and welding guidance mechanisms. Longitudinal seams must have complete joint penetration, and must be free from undercuts, overlaps or abrupt ridges or valleys. Misalignment of mating butt edges may not exceed 1/6 of nominal sheet thickness or 1/32 inch whichever is less. All joints with nominal sheet thickness up to and including 1/8 inch must be tightly butted. When nominal sheet thickness is greater than 1/8 inch, the joint must be gapped with maximum distance equal to one-half the nominal sheet thickness or 1/32 inch whichever is less. Joint design, preparation and fit-up must be such that requirements of this paragraph (d) are satisfied.

(ii) Maximum joint efficiency must be 1.0 when each seam is radiographed completely. Maximum joint efficiency must be 0.90 when one cylinder from each lot of 50 consecutively welded cylinders is spot radiographed. In addition, one out of the first five cylinders welded following a shut down of welding operations exceeding four hours must be spot radiographed. Spot radiographs, when required, must be made of a finished welded cylinder and must include the girth weld for 2 inches in both directions from the intersection of the longitudinal and girth welds and include at least 6 inches of the longitudinal weld. Maximum joint efficacy of 0.75 must be permissible without radiography.

(4) Welding procedures and operators must be qualified in accordance with CGA Pamphlet C–3.

(e) *Welding of attachments.* The attachment to the tops and bottoms only of cylinders by welding of neckrings, footrings, handles, bosses, pads and valve protection rings is authorized provided that such attachments and the portion of the container to which they are attached are made of weldable steel, the carbon content of which may not exceed 0.25 percent.

(f) *Wall thickness.* For outside diameters over 6 inches the minimum wall thickness must be 0.078 inch. For a cylinder with a wall thickness less than 0.100 inch, the ratio of tangential length to outside diameter may not exceed 4 to 1 (4:1). In any case the minimum wall thickness must be such that the wall stress calculated by the formula listed in paragraph (f)(4) of this section may not exceed the lesser value of any of the following:

(1) The value referenced in paragraph (b) of this section for the particular material under consideration.

(2) One-half of the minimum tensile strength of the material determined as required in paragraph (m) of this section.

(3) 35,000 pounds per square inch.

(4) Stress must be calculated by the following formula:

$$S=[2P(1.3D^2+0.4d^2)]/[E(D^2-d^2)]$$

where:

S=wall stress, p.s.i.;
P=service pressure, p.s.i.;
D=outside diameter, inches;
d=inside diameter, inches;
E=joint efficiency of the longitudinal seam (from paragraph (d) of this section).

(g) *Heat treatment.* Each cylinder must be uniformly and properly heat treated prior to test by the applicable method referenced in paragraph (b) of this section. Heat treatment must be accomplished after all forming and welding operations. Heat treatment is not required after welding or brazing of weldable low carbon parts to attachments of similar material which have been previously welded to the top or bottom of cylinders and properly heat treated, provided such subsequent welding or brazing does not produce a temperature in excess of 400° F in any part of the top or bottom material.

(h) *Openings in cylinders.* Openings in the cylinder must conform to the following:

(1) All openings must be in the heads or bases.

(2) Openings in cylinders must be provided with adequate fittings, bosses, or pads, integral with or securely attached to the cylinder by welding.

(3) Threads must comply with the following:

(i) Threads must be clean cut and to gauge.

(ii) Taper threads must be of length not less than as specified for American Standard Taper Pipe threads.

(iii) Straight threads, having at least 4 engaged threads, to have tight fit and calculated shear strength at least 10 times the test pressure of the cylinder; gaskets required, adequate to prevent leakage.

(4) Closure of fittings, boss or pads must be adequate to prevent leakage.

(i) *Hydrostatic test.* Cylinders must withstand a hydrostatic test, as follows:

(1) The test must be by water-jacket, or other suitable method, operated so as to obtain accurate data. The pressure gauge must permit readings to an

accuracy of 1 percent. The expansion gauge must permit readings of total volumetric expansion to an accuracy either of 1 percent or 0.1 cubic centimeter.

(2) Pressure must be maintained for at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat treatment and previous to the official test may not exceed 90 percent of the test pressure.

(3) Permanent volumetric expansion may not exceed 10 percent of the total volumetric expansion at test pressure.

(4) Cylinders must be tested as follows:

(i) At least 1 cylinder selected at random out of each lot of 200 or less must be tested as outlined in paragraphs (i)(1), (i)(2), and (i)(3) of this section to at least two times service pressure.

(ii) All cylinders not tested as outlined in paragraph (i)(4)(i) of this section must be examined under pressure of at least two times service pressure and show no defect.

(5) One finished cylinder selected at random out of each lot of 500 or less successively produced must be hydrostatically tested to 4 times service pressure without bursting.

(j) *Physical tests.* Cylinders must be subjected to a physical test as follows:

(1) Specimens must be taken from one cylinder after heat treatment and chosen at random from each lot of 200 or less, as follows:

(i) Body specimen. One specimen must be taken longitudinally from the body section at least 90 degrees away from the weld.

(ii) Head specimen. One specimen must be taken from either head on a cylinder when both heads are made of the same material. However, if the two heads are made of differing materials, a specimen must be taken from each head.

(iii) If due to welded attachments on the top head there is insufficient surface from which to take a specimen, it may be taken from a representative head of the same heat treatment as the test cylinder.

(2) Specimens must conform to the following:

(i) A gauge length of 8 inches with a width not over 1½ inches, a gauge length of 2 inches with a width not over 1½ inches, or a gauge length at least 24 times thickness with a width not over 6 times thickness is authorized when a cylinder wall is not over 3⁄16 inch thick.

(ii) The specimen, exclusive of grip ends, may not be flattened. Grip ends may be flattened to within 1 inch of each end of the reduced section.

(iii) When size of the cylinder does not permit securing straight specimens, the specimens may be taken in any location or direction and may be straightened or flattened cold, by pressure only, not by blows when specimens are so taken and prepared, the inspector's report must show in connection with record of physical tests detailed information in regard to such specimens.

(iv) Heating of a specimen for any purpose is not authorized.

(3) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length. The following conditions apply:

(i) The yield strength must be determined by either the ''off-set'' method or the ''extension under load'' method as prescribed in ASTM Standard E8–78.

(ii) In using the ''extension under load'' method, the total strain (or ''extension under load''), corresponding to the stress at which the 0.2-percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic extension of the gauge length under appropriate load and adding thereto 0.2 percent of the gauge length. Elastic extension calculations must be based on an elastic modulus of 30,000,000. In the event of controversy, the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2-percent offset.

(iii) For the purpose of strain measurement, the initial strain reference must be set while the specimen is under a stress of 12,000 pounds per square inch and the strain indicator reading being set at the calculated corresponding strain.

(iv) Cross-head speed of the testing machine may not exceed ⅛ inch per minute during yield strength determination.

(k) *Elongation.* Physical test specimens must show at least a 40 percent elongation for a 2-inch gauge length or at least a 20 percent elongation in other cases. Except that these elongation percentages may be reduced numerically by 2 for 2-inch specimens and by 1 in other cases for each 7,500 pounds per square inch increment of tensile strength above 50,000 pounds per square inch to a maximum of four increments.

(l) *Tests of welds.* Welds must be subjected to the following tests:

(1) *Tensile test.* A specimen must be cut from one cylinder of each lot of 200 or less. The specimen must be taken from across the longitudinal seam and must be prepared and tested in accordance with and must meet the requirements of CGA Pamphlet C–3.

(2) *Guided bend test.* A root test specimen must be cut from the cylinder used for the tensile test specified in paragraph (l)(1) of this section. Specimens must be taken from across the longitudinal seam and must be prepared and tested in accordance with and must meet the requirements of CGA Pamphlet C–3.

(3) *Alternate guided bend test.* This test may be used and must be as required by CGA Pamphlet C–3. The specimen must be bent until the elongation at the outer surface, adjacent to the root of the weld, between the lightly scribed gauge lines a to b, must be at least 20 percent, except that this percentage may be reduced for steels having a tensile strength in excess of 50,000 pounds per square inch, as provided in paragraph (k) of this section.

(m) *Radiographic examination.* Welds of the cylinders must be subjected to a radiographic examination as follows:

(1) Radiographic inspection must conform to the techniques and acceptability criteria set forth in CGA Pamphlet C–3. When fluoroscopic inspection is used, permanent film records need not be retained.

(2) Should spot radiographic examination fail to meet the requirements of paragraph (m)(1) of this section, two additional welds from the same lot of 50 cylinders or less must be examined, and if either of these fail to meet the requirements, each cylinder must be examined as previously outlined; only those passing are acceptable.

(n) *Rejected cylinders.* (1) Unless otherwise stated, if a sample cylinder or specimen taken from a lot of cylinders fails the prescribed test, then two additional specimens must be selected from the same lot and subjected to the prescribed test. If either of these fails the test, then the entire lot must be rejected.

(2) Reheat treatment of rejected cylinders is authorized. Subsequent thereto, cylinders must pass all prescribed tests to be acceptable. Repair of welded seams by welding is authorized provided that all defective metal is cut away and the joint is rewelded as prescribed for original welded joints.

(o) *Markings.* Markings must be stamped plainly and permanently in any of the following locations on the cylinder:

(1) On shoulders and top heads when they are not less than 0.087-inch thick.

(2) On a metal plate attached to the top of the cylinder or permanent part thereof; sufficient space must be left on the plate to provide for stamping at least six retest dates; the plate must be at

least 1/16-inch thick and must be attached by welding, or by brazing. The brazing rod is to melt at a temperature of 1100° F. Welding or brazing must be along all the edges of the plate.

(3) On the neck, valve boss, valve protection sleeve, or similar part permanently attached to the top of the cylinder.

(4) On the footring permanently attached to the cylinder, provided the water capacity of the cylinder does not exceed 25 pounds.

(p) *Inspector's report.* In addition to the information required by § 178.35, the inspector's report must indicate the type and amount of radiography.

§ 178.65 Specification 39 non-reusable (non-refillable) cylinders.

(a) *Type, size, service pressure, and test pressure.* A DOT 39 cylinder is a seamless, welded, or brazed cylinder with a service pressure not to exceed 80 percent of the test pressure. Spherical pressure vessels are authorized and covered by references to cylinders in this specification.

(1) *Size limitation.* Maximum water capacity may not exceed:

(i) 55 pounds (1,526 cubic inches) for a service pressure of 500 p.s.i.g. or less, and

(ii) 10 pounds (277 cubic inches) for a service pressure in excess of 500 p.s.i.g.

(2) *Test pressure.* The minimum test pressure is the maximum pressure of contents at 130° F or 180 p.s.i.g. whichever is greater.

(3) *Pressure of contents.* The term ''pressure of contents'' as used in this specification means the total pressure of all the materials to be shipped in the cylinder.

(b) *Material; steel or aluminum.* The cylinder must be constructed of either steel or aluminum conforming to the following requirements:

(1) *Steel.* (i) The steel analysis must conform to the following:

	Ladle analysis	Check analysis
Carbon, maximum percent	0.12	0.15
Phosphorus, maximum percent	0.04	0.05
Sulfur, maximum percent	0.05	0.06

(ii) For a cylinder made of seamless steel tubing with integrally formed ends, hot drawn, and finished, content percent for the following may not exceed: Carbon, 0.55; phosphorous, 0.045; sulfur, 0.050.

(iii) For non-heat treated welded steel cylinders, adequately killed deep drawing quality steel is required.

(iv) Longitudinal or helical welded cylinders are not authorized for service pressures in excess of 500 p.s.i.g.

(2) *Aluminum.* Aluminum is not authorized for service pressures in excess of 500 p.s.i.g. The analysis of the aluminum must conform to the Aluminum Association standard for alloys 1060, 1100, 1170, 3003, 5052, 5086, 5154, 6061, and 6063 as specified in its publication entitled ''Aluminum Standards and Data'' (7th edition dated June 1982).

(3) *Unauthorized material.* Material with seams, cracks, laminations, or other injurious defects not permitted.

(4) *Identification.* Material used must be identified by any suitable method.

(c) *Manufacture.* (1) General manufacturing requirements are as follows:

(i) The surface finish must be uniform and reasonably smooth.

(ii) Inside surfaces must be clean, dry, and free of loose particles.

(iii) No defect of any kind is permitted if it is likely to weaken a finished cylinder.

(2) Requirements for seams:

(i) Brazing is not authorized on aluminum cylinders.

(ii) Brazing material must have a melting point of not lower than 1,000° F.

(iii) Brazed seams must be assembled with proper fit to ensure complete penetration of the brazing material throughout the brazed joint.

(iv) Minimum width of brazed joints must be at least four times the thickness of the shell wall.

(v) Brazed seams must have design strength equal to or greater than 1.5 times the minimum strength of the shell wall.

(vi) Welded seams must be properly aligned and welded by a method that provides clean, uniform joints with adequate penetration.

(vii) Welded joints must have a strength equal to or greater than the minimum strength of the shell material in the finished cylinder.

(3) Attachments to the cylinder are permitted by any means which will not be detrimental to the integrity of the cylinder. Welding or brazing of attachments to the cylinder must be completed prior to all pressure tests.

(4) Welding procedures and operators must be qualified in accordance with CGA Pamphlet C–3.

(d) *Wall thickness.* The minimum wall thickness must be such that the wall stress at test pressure does not exceed the yield strength of the material of the finished cylinder wall. Calculations must be made by the following formulas:

(1) Calculation of the stress for cylinders must be made by the following formula:

$$S=[P(1.3D^2+0.4d^2)]/(D^2-d^2)$$

where:

S=Wall stress, in p.s.i.;
P=Test pressure;
D=Outside diameter, in inches;
d=Inside diameter, in inches.

(2) Calculation of the stress for spheres must be made by the following formula:

$$S=PD/4t$$

Where:
S=Wall stress, in p.s.i.;
P=Test pressure;
D=Outside diameter, in inches;
t=Minimum wall thickness, in inches.

(e) *Openings and attachments.* Openings and attachments must conform to the following:

(1) Openings and attachments are permitted on heads only.

(2) All openings and their reinforcements must be within an imaginary circle, concentric to the axis of the cylinder. The diameter of the circle may not exceed 80 percent of the outside diameter of the cylinder. The plane of the circle must be parallel to the plane of a circumferential weld and normal to the long axis of the cylinder.

(3) Unless a head has adequate thickness, each opening must be reinforced by a securely attached fitting, boss, pad, collar, or other suitable means.

(4) Material used for welded openings and attachments must be of weldable quality and compatible with the material of the cylinder.

(f) *Pressure tests.* (1) Each cylinder must be tested at an internal pressure of at least the test pressure and must be held at that pressure for at least 30 seconds.

(i) The leakage test must be conducted by submersion under water or by some

other method that will be equally sensitive.

(ii) If the cylinder leaks, evidences visible distortion, or any other defect, while under test, it must be rejected (see paragraph (h) of this section).

(2) One cylinder taken from the beginning of each lot, and one from each 1,000 or less successively produced within the lot thereafter, must be hydrostatically tested to destruction. The entire lot must be rejected (see paragraph (h) of this section) if:

(i) A failure occurs at a gage pressure less than 2.0 times the test pressure;

(ii) A failure initiates in a braze or a weld or the heat affected zone thereof;

(iii) A failure is other than in the sidewall of a cylinder longitudinal with its long axis; or

(iv) In a sphere, a failure occurs in any opening, reinforcement, or at a point of attachment.

(3) A ''lot'' is defined as the quantity of cylinders successively produced per production shift (not exceeding 10 hours) having identical size, design, construction, material, heat treatment, finish, and quality.

(g) *Flattening test.* One cylinder must be taken from the beginning of production of each lot (as defined above) and subjected to a flattening test as follows:

(1) The flattening test must be made on a cylinder that has been tested at test pressure.

(2) A ring taken from a cylinder may be flattened as an alternative to a test on a complete cylinder. The test ring may not include the heat affected zone or any weld. However, for a sphere, the test ring may include the circumferential weld if it is located at a 45 degree angle to the ring, +/−5 degrees.

(3) The flattening must be between 60 degrees included-angle, wedge shaped knife edges, rounded to a 0.5 inch radius.

(4) Cylinders and test rings may not crack when flattened so that their outer surfaces are not more than six times wall thickness apart when made of steel or not more than ten times wall thickness apart when made of aluminum.

(5) If any cylinder or ring cracks when subjected to the specified flattening test, the lot of cylinders represented by the test must be rejected (see paragraph (h) of this section).

(h) *Rejected cylinders.* Rejected cylinders must conform to the following requirements:

(1) If the cause for rejection of a lot is determinable, and if by test or inspection defective cylinders are eliminated from the lot, the remaining cylinders must be qualified as a new lot under paragraphs (f) and (g) of this section.

(2) Repairs to welds are permitted. Following repair, a cylinder must pass the pressure test specified in paragraph (f) of this section.

(3) If a cylinder made from seamless steel tubing fails the flattening test described in paragraph (g) of this section, suitable uniform heat treatment must be used on each cylinder in the lot. All prescribed tests must be performed subsequent to this heat treatment.

(i) *Markings.* (1) The markings required by this section must be durable and waterproof. The requirements of § 173.24 (c)(1) (ii) and (iv) of this subchapter and § 178.35(h) do not apply to this section.

(2) Required markings are as follow:

(i) DOT–39.

(ii) NRC.

(iii) The service pressure.

(iv) The test pressure.

(v) The registration number (M****) of the manufacturer.

(vi) The lot number.

(vii) The date of manufacture if the lot number does not establish the date of manufacture.

(viii) The following statement: Federal law forbids transportation if refilled-penalty up to $500,000 fine and 5 years imprisonment (49 U.S.C. 5124).

(3) The markings required by paragraphs (i)(2)(i) through (i)(2)(v) of this section must be in numbers and letters at least ⅛ inch high and displayed sequentially. For example:

DOT–39 NRC 250/500 M1001.

(4) No person may mark any cylinder with the specification identification ''DOT–39'' unless it was manufactured in compliance with the requirements of this section and its manufacturer has a registration number (M****) from the Associate Administrator.

§ 178.68 Specification 4E welded aluminum cylinders.

(a) *Type, size and service pressure.* A DOT 4E cylinder is a welded aluminum cylinder with a water capacity (nominal) of not over 1,000 pounds and a service pressure of at least 250 to not over 500 pounds per square inch. The cylinder must be constructed of not more than two seamless drawn shells with no more than one circumferential weld. The circumferential weld may not be closer to the point of tangency of the cylindrical portion with the shoulder than 20 times the cylinder wall thickness. Cylinders or shells closed in by spinning process and cylinders with longitudinal seams are not authorized.

(b) *Authorized material.* The cylinder must be constructed of aluminum of uniform quality. The following chemical analyses are authorized:

TABLE 1.—AUTHORIZED MATERIALS

Designation	Chemical analysis—limits in percent 5154 [1]
Iron plus silicon	0.45 maximum.
Copper	0.10 maximum.
Manganese	0.10 maximum.
Magnesium	3.10/3.90.
Chromium	0.15/0.35.
Zinc	0.20 maximum.
Titanium	0.20 maximum.
Others, each	0.05 maximum.
Others, total	0.15 maximum.
Aluminum	Remainder.

[1] Analysis must regularly be made only for the elements specifically mentioned in this table. If, however, the presence of other elements is indicated in the course of routine analysis, further analysis should be made to determine conformance with the limits specified for other elements.

(c) *Identification.* Material must be identified by any suitable method that will identify the alloy and manufacturer's lot number.

(d) *Manufacture.* Cylinders must be manufactured using equipment and processes adequate to ensure that each cylinder produced conforms to the requirements of this subpart. No defect is permitted that is likely to weaken the finished cylinder appreciably. A reasonably smooth and uniform surface finish is required. All welding must be by the gas shielded arc process.

(e) *Welding.* The attachment to the tops and bottoms only of cylinders by welding of neckrings or flanges, footrings, handles, bosses and pads and valve protection rings is authorized. However, such attachments and the portion of the cylinder to which it is attached must be made of weldable aluminum alloys.

(f) *Wall thickness.* The wall thickness of the cylinder must conform to the following:

(1) The minimum wall thickness of the cylinder must be 0.140 inch. In any case, the minimum wall thickness must be such that calculated wall stress at twice service pressure may not exceed the lesser value of either of the following:

(i) 20,000 pounds per square inch.

(ii) One-half of the minimum tensile strength of the material as required in paragraph (m) of this section.

(2) Calculation must be made by the following formula:

$$S=[P(1.3D^2+0.4d^2)]/(D^2-d^2)$$

where:

S=Wall stress in pounds per square inch;

P=Minimum test pressure prescribed for water jacket test;

D=Outside diameter in inches;

d=Inside diameter in inches.

(3) Minimum thickness of heads and bottoms may not be less than the minimum required thickness of the side wall.

(g) *Opening in cylinder.* Openings in cylinders must conform to the following:

(1) All openings must be in the heads or bases.

(2) Each opening in cylinders, except those for safety devices, must be provided with a fitting, boss, or pad, securely attached to cylinder by welding by inert gas shielded arc process or by threads. If threads are used, they must comply with the following:

(i) Threads must be clean-cut, even, without checks and cut to gauge.

(ii) Taper threads to be of length not less than as specified for American Standard taper pipe threads.

(iii) Straight threads, having at least 4 engaged threads, to have tight fit and calculated shear strength at least 10 times the test pressure of the cylinder; gaskets required, adequate to prevent leakage.

(3) Closure of a fitting, boss, or pad must be adequate to prevent leakage.

(h) *Hydrostatic test.* Each cylinder must successfully withstand a hydrostatic test, as follows:

(1) The test must be by water jacket, or other suitable method, operated so as to obtain accurate data. The pressure gauge must permit reading to an accuracy of 1 percent. The expansion gauge must permit a reading of the total expansion to an accuracy either of 1 percent or 0.1 cubic centimeter.

(2) Pressure of 2 times service pressure must be maintained for at least 30 seconds and sufficiently longer to insure complete expansion. Any internal pressure applied previous to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus, the test pressure cannot be maintained, the test may be repeated at a pressure increased by 10 percent over the pressure otherwise specified.

(3) Permanent volumetric expansion may not exceed 12 percent of total volumetric expansion at test pressure.

(4) Cylinders having a calculated wall stress of 18,000 pounds per square inch or less at test pressure may be tested as follows:

(i) At least one cylinder selected at random out of each lot of 200 or less must be tested in accordance with paragraphs (h)(1), (h)(2), and (h)(3) of this section.

(ii) All cylinders not tested as provided in paragraph (h)(4)(i) of this section must be examined under pressure of at least 2 times service pressure and show no defect.

(5) One finished cylinder selected at random out of each lot of 1,000 or less must be hydrostatically tested to 4 times the service pressure without bursting. Inability to meet this requirement must result in rejection of the lot.

(i) *Flattening test.* After hydrostatic testing, a flattening test is required on one section of a cylinder, taken at random out of each lot of 200 or less as follows:

(1) If the weld is not at midlength of the cylinder, the test section must be no less in width than 30 times the cylinder wall thickness. The weld must be in the center of the section. Weld reinforcement must be removed by machining or grinding so that the weld is flush with the exterior of the parent metal. There must be no evidence of cracking in the sample when it is flattened between flat plates to no more than 6 times the wall thickness.

(2) If the weld is at midlength of the cylinder, the test may be made as specified in paragraph (i)(1)(i) of this section or must be made between wedge shaped knife edges (60° angle) rounded to a ½-inch radius. There must be no evidence of cracking in the sample when it is flattened to no more than 6 times the wall thickness.

(j) *Physical test.* A physical test must be conducted to determine yield strength, tensile strength, elongation, and reduction of area of material as follows:

(1) The test is required on 2 specimens cut from one cylinder or part thereof taken at random out of each lot of 200 or less.

(2) Specimens must conform to the following:

(i) A gauge length of 8 inches with a width not over 1½ inches, a gauge length of 2 inches with a width not over 1½ inches.

(ii) The specimen, exclusive of grip ends, may not be flattened. Grip ends may be flattened to within 1 inch of each end of the reduced section.

(iii) When size of cylinder does not permit securing straight specimens, the specimens may be taken in any location or direction and may be straightened or flattened cold, by pressure only, not by blows; when specimens are so taken and prepared, the inspector's report must show in connection with record of physical test detailed information in regard to such specimens.

(iv) Heating of a specimen for any purpose is not authorized.

(3) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length. The following conditions apply:

(i) The yield strength must be determined by the ''offset'' method as prescribed in ASTM Standard E8–78.

(ii) Cross-head speed of the testing machine may not exceed ⅛ inch per minute during yield strength determination.

(k) *Acceptable results for physical tests.* An acceptable result of the physical test requires an elongation to at least 7 percent and yield strength not over 80 percent of tensile strength.

(l) *Weld tests.* Welds of the cylinder are required to successfully pass the following tests:

(1) *Reduced section tensile test.* A specimen must be cut from the cylinder used for the physical tests specified in paragraph (j) of this section. The specimen must be taken from across the seam, edges must be parallel for a distance of approximately 2 inches on

either side of the weld. The specimen must be fractured in tension. The apparent breaking stress calculated on the minimum wall thickness must be at least equal to 2 times the stress calculated under paragraph (f)(2) of this section, and in addition must have an actual breaking stress of at least 30,000 pounds per square inch. Should this specimen fail to meet the requirements, specimens may be taken from 2 additional cylinders from the same lot and tested. If either of the latter specimens fails to meet requirements, the entire lot represented must be rejected.

(2) *Guided bend test.* A bend test specimen must be cut from the cylinder used for the physical tests specified in paragraph (j) of this section. Specimen must be taken across the seam, must be 1½ inches wide, edges must be parallel and rounded with a file, and back-up strip, if used, must be removed by machining. The specimen must be bent to refusal in the guided bend test jig illustrated in paragraph 6.10 of CGA Pamphlet C–3. The root of the weld (inside surface of the cylinder) must be located away from the ram of the jig. No specimen must show a crack or other open defect exceeding ⅛ inch in any direction upon completion of the test. Should this specimen fail to meet the requirements, specimens may be taken from each of 2 additional cylinders from the same lot and tested. If either of the latter specimens fail to meet requirements, the entire lot represented must be rejected.

(m) *Rejected cylinders.* Repair of welded seams is authorized. Acceptable cylinders must pass all prescribed tests.

(n) *Inspector's report.* In addition to the information required by § 178.35, the record of chemical analyses must also include applicable information on iron, titanium, zinc, and magnesium used in the construction of the cylinder.

Issued in Washington, DC on February 12, 1996, under authority delegated in 49 CFR Part 106.

Alan I. Roberts,

Associate Administrator for Hazardous Materials Safety.

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Monday
March 4, 1996

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 70, et al.
Permanent Listing of Color Additive Lakes; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 70, 73, 74, 80, 81, 82, 101, 178, 201, and 701

[Docket Nos. 79N–0043 and 92N–0334]

Permanent Listing of Color Additive Lakes

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to list certain color additive lakes permanently as suitable and safe for use in food, drugs, and cosmetics. The agency is proposing to permit the use of more than one straight color in the preparation of a lake, to modify the nomenclature for lakes, and to simplify the batch certification procedure for lakes. As part of these actions, the agency is proposing to amend its regulations to require the preparation of lakes from certified batches of straight color; to provide simplified nomenclature for declaring color additives, including lakes, on cosmetic products; to require declaration of FD&C Yellow No. 5 and FD&C Yellow No. 6 on all foods and some drug products containing lakes of these straight colors; and to terminate the listing of certain straight colors as components of lakes for drug and cosmetic use and the listing of calcium salts as components of lakes for food use.

This proposed rule is intended to complete the agency's disposition of the provisional list of color additives that was established under the transitional provisions of the Color Additive Amendments of 1960 (the 1960 amendments) and to establish regulations prescribing conditions under which lakes may be prepared, labeled, and safely used in food, drugs, and cosmetics.

DATES: Written comments by June 3, 1996, except that comments regarding information collection should be submitted by April 3, 1996, but not later than May 3, 1996.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments regarding information collection to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, rm. 10235, Washington, DC 20503, ATTN: Desk Officer for FDA. Process descriptions, identity information for anions in precipitants, and ingredient specifications for substrata (including rosin), and rosin samples to the Colors Technology Branch (HFS–126), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

FOR FURTHER INFORMATION CONTACT:

Regarding proposed certification procedures, including proposed paperwork requirements, and for proposed product ingredient declarations:

Julie N. Barrows, Center for Food Safety and Applied Nutrition (HFS–126), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4662.

Regarding other issues:

Arthur L. Lipman, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3073.

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I. Identity, Manufacture, and Properties of Lakes

Color additives may be added to food, drugs, cosmetics, and certain medical devices for the purpose of imparting color. The three categories of color additives are: (1) ''Straight colors'' (color additives that have not been mixed or chemically reacted with any other substance); (2) lakes (color additives formed by chemically reacting a straight color with water-insoluble substances); and (3) mixtures (color additives formed by mixing a color additive with one or more other color additives or noncolored substances, without chemical reaction.)

A lake is a water-insoluble pigment composed of a water-soluble straight color strongly adsorbed onto an insoluble substratum through use of a precipitant. The regulations in part 82 (21 CFR part 82), where lakes are provisionally listed, use the term ''basic radical'' to denote a precipitant. As more fully described in section III.A.6. of this document, the agency is proposing to replace the term ''basic radical'' with the more scientifically accurate term ''precipitant.'' The proposed terminology will be used throughout the rest of this document.

The first step in manufacturing a lake is the preparation of an aqueous slurry of the substratum (e.g., alumina). This aqueous slurry is mixed with an aqueous solution of a straight color to produce a partially precipitated (or laked) product. The laking process is completed by the addition of a precipitant (e.g., aluminum chloride), which results in the production of the salt (e.g., aluminum salt) of the straight color and the adsorption of the salt onto the substratum. The resulting lake is washed, dried, and finely ground before marketing.

The literature reports several variations of the basic laking process (Refs. 1 through 5). Some substrata are synthesized in situ; i.e., the components used to prepare the substratum, rather than the preformed substratum, are added during the laking procedure. For example, alumina slurries may be prepared by precipitation of hydrated alumina from an aluminum sulfate solution with a sodium carbonate or sodium hydroxide solution. These slurries are used directly in the synthesis of lakes, without isolation of the precipitated substratum.

Some lakes are themselves prepared in situ. In this process, the chemical precursors for the straight color are mixed directly with the substratum and the precipitant during the laking procedure. The lake is produced as the

straight color is synthesized, without isolation of the straight color as a discrete batch.

The chemical association between the components of a lake may involve various types of interactions, including ionic bonds, hydrogen bonds, and van der Waals forces (Refs. 4 through 9). Lakes generally contain 10 to 40 percent by weight of the straight color. They also contain approximately 1 to 4 percent of the weight of the lake as the cationic precipitant. The remaining 56 to 89 percent, by weight, of lakes consists primarily of substrata. The color content of a lake depends on the desired color intensity and shade of the lake.

Lakes offer many technical advantages over water-soluble straight colors. The chemical bonding of the color with substrata generally promotes light and heat stability. Furthermore, because lakes are not water-soluble, the use of lakes in aqueous foods reduces color migration.

The agency's current regulations for lakes in part 82 were issued under section 203 of the Color Additive Amendments of 1960 (Pub. L. 86–618), which provided for the temporary, provisional listing of commercially established colors. The regulations provide that before a lake may be used in a food, drug, or cosmetic product, each batch of the lake must be certified by FDA. When requesting certification of a batch of a lake, the requester submits a sample from the batch to the agency for analysis. If the agency finds that the concentrations of impurities in the sample are within the levels specified, and the batch otherwise appears to comply with the applicable regulations, the agency certifies the batch by issuing the requester a certificate showing the certification lot number assigned to that batch of lake.

Lakes represent approximately 25 percent of the total poundage of color additives certified by FDA. Approximately 80 percent of the lakes certified are FD&C (food, drugs, and cosmetics) lakes and the remaining 20 percent are D&C (drugs and cosmetics) lakes. (See section II.A. of this document for an explanation of the terms ''FD&C'' and ''D&C''.)

II. Regulatory History and Current Listings of Lakes

A. Regulatory History of Lakes

Section 7 of the Food and Drugs Act of 1906 (Pub. L. 59–384) prohibited the use of poisonous or deleterious colors in confectionery and the coloring or staining of food to conceal damage or inferiority. In 1907, the agency, then part of the Department of Agriculture, issued Food Inspection Decision 76 (Ref. 10), which contains a list of seven straight colors approved for use in food. Between 1907 and 1939, the agency expanded the list of straight colors approved for use in food from 7 to 15. These colors were known as ''coal tar colors'' because they were synthesized mainly from substances obtained from coal tar. However, prior to 1939, the agency's list of acceptable colors did not include lakes of coal tar colors because such lakes were not used in food. Also, prior to 1938, the government program for batch analysis and certification of colors was voluntary.

The Federal Food, Drug, and Cosmetic Act of 1938 (21 U.S.C. 301 *et seq.* (the act)) (Pub. L. 75–717) required FDA to list coal tar colors ''harmless and suitable'' for use in foods, drugs, and cosmetics, and to certify all batches of listed colors, including lakes. The agency issued regulations under the act listing lakes for food use, as well as for drug and cosmetic use, and establishing conditions for certification of batches of lakes (4 FR 1922, May 9, 1939; 4 FR 3931, September 16, 1939; and 5 FR 1138, March 23, 1940). The agency issued the first certificate for a lake under the act on May 11, 1939 (Ref. 11).

The initial listing of lakes for food use under the act restricted their use to coloring shell eggs (egg dyeing) (5 FR 1138). In 1959, at the request of industry, the agency expanded the uses of lakes prepared from FD&C straight colors to encompass general use in foods (24 FR 3818, May 13, 1959; and 24 FR 5302, June 30, 1959).

The 1960 amendments amended the act by defining the term ''color additive'' (section 201(t) (21 U.S.C. 321(t))) for the first time and restricting the use of color additives in or on food, drugs, cosmetics, or the human body to those listed in FDA regulations. (The Medical Device Amendments of 1976 (Pub. L. 94–295) extended these restrictions to the use of color additives in certain medical devices.) As amended, the act provides that a food (section 402(c) (21 U.S.C. 342(c))), drug or device (section 501(a)(4) (21 U.S.C. 351(a)(4))), or cosmetic, other than a coal tar hair dye (section 601(e) (21 U.S.C. 361(e))), is adulterated if it is, bears, or contains an unsafe color additive. Section 721 (formerly section 706) of the amended act (21 U.S.C. 379e) provides for the listing of safe and suitable color additives for use in foods, drugs, cosmetics, and medical devices; it prohibits the listing of a color additive for a proposed use unless data establish that such use will be safe. Section 721 of the act also continues the requirement for certification of batches of color additives, with or without diluents, to determine whether each batch conforms to the purity and identity specifications in the applicable listing regulation. However, the amendments allow FDA to exempt color additives from batch certification if certification is unnecessary to protect the public health.

Section 203 of the 1960 amendments also provided for the provisional listing of color additives that were commercially established when the 1960 amendments were enacted, pending completion of scientific investigations necessary to determine their safety under the new standard established by the 1960 amendments. The purpose of section 203 was to allow the use of such color additives on an interim basis, to the extent consistent with the public health. Section 203 directed the agency to recognize as provisionally listed the following color additives: (1) Any color additive which, on the day preceding the enactment date, was listed and certifiable for any use or uses and for which a batch or batches had been certified for such use or uses prior to the enactment date; (2) any color additive which was commercially used or sold prior to the enactment date for any use or uses on any food, drug, or cosmetic, but was not required to be listed under the act; (3) synthetic beta carotene. The provisional listing was to apply only to the use or uses to which the certification applied, or for which the color additive had been commercially used or sold.

Under the authority of the 1960 amendments, in the Federal Register of October 12, 1960 (25 FR 9759), the agency provisionally listed those color additives, including lakes, covered by section 203. This listing, originally codified as 21 CFR 8.501 and later recodified as § 81.1 (21 CFR 81.1) (42 FR 15665, March 22, 1977) included many of the coal tar colors (including lakes) that had been previously listed.

In the Federal Register of December 27, 1963 (28 FR 14311), the agency determined that batch certification was unnecessary to ensure the safety of most color additives derived from plant, animal, or mineral sources, and designated these color additives as exempt from certification. However, the agency determined that batch certification was necessary to ensure the safety of most color additives, including lakes, derived principally from coal and petroleum sources, and designated those colors as subject to certification. Currently, the color additives exempt from batch certification and the permanently listed color additives

subject to batch certification are listed in parts 73 and 74 (21 CFR parts 73 and 74), respectively.

Since the establishment of the provisional list in 1960, the agency has gradually removed color additives from the list either by permanent listing or by termination of listing due to lack of interest by industry or due to safety concerns prompted by the agency's reviews. At this time, only lakes remain provisionally listed in parts 81 and 82.

After the enactment of the act in 1938, FDA established the designation ''FD&C'' to identify color additives listed for use in foods, drugs, and cosmetics; the designation ''D&C'' to identify color additives listed for general use in drugs and cosmetics, but not foods; and the designation ''Ext. D&C'' to identify color additives listed for use only in externally applied drugs and cosmetics (4 FR 1922 at 1923). These designations are still part of the names of certified color additives. However, the uses of some straight colors (and consequently also of their lakes) were restricted when they were permanently listed, based on the safety reviews conducted by the agency under the 1960 amendments. Consequently, the designations ''FD&C'' or ''D&C'' in the name of a certified color additive can no longer be relied upon to accurately describe the approved uses of the color additive.

B. Current Listings of Lakes

1. Provisional Listing and General Provisions for Lakes

Section 81.1 identifies the provisionally listed color additives. The only color additives remaining on the provisional list are lakes (§ 81.1(a), (b), and (c)).

Part 82, subpart A, prescribes the general provisions applicable to provisionally listed color additives. Section 82.3 contains definitions of terms such as ''alumina'' and ''blanc fixe.'' Section 82.5 prescribes general specifications, including specifications for levels of lead, arsenic, and heavy metals other than lead and arsenic, that are applicable to lakes listed in the other subparts of part 82. It also provides a specification for the level of soluble barium applicable to lakes listed in subpart C or D of part 82 that contain a barium salt.

2. Provisional Listing of Lakes for Use in Foods, Drugs, and Cosmetics

Part 82, subpart B, identifies the lakes that are provisionally listed for use in foods, drugs, and cosmetics. Section 82.50 prescribes the certification requirements for these lakes.

Section 82.51 specifies that lakes for use in foods, drugs, and cosmetics are made by extending, on a substratum of alumina, a salt of one of the following certified water-soluble straight colors with the cation precipitant aluminum or calcium: FD&C Blue No. 1 (§ 82.101); FD&C Blue No. 2 (§ 82.102); FD&C Green No. 3 (§ 82.203); FD&C Yellow No. 5 (§ 82.705); and FD&C Yellow No. 6 (§ 82.706). Only previously certified batches of the straight color may be used. Section 82.51 also provides specifications for soluble chlorides and sulfates and for inorganic matter insoluble in hydrochloric acid (HCl) and prescribes rules for naming the lakes that are listed for use in foods, drugs, and cosmetics.

3. Provisional Listing of Lakes for Use in Drugs and Cosmetics

Part 82, subpart C, identifies the lakes that are provisionally listed for general use in drugs and cosmetics. Section 82.1051 prescribes the certification requirements for these lakes, which may be used both in ingested and externally applied drugs and cosmetics. Externally applied drugs and cosmetics are those that are applied to the external parts of the body and not to the lips or any body surface covered by mucous membrane (§ 70.3(v) (21 CFR 70.3(v))).

Section 82.1051 specifies that lakes for use in drugs and cosmetics are made by extending, on one or more listed substrata, one of the listed straight colors with one or more of the listed precipitants. The precipitant may be added either as a component of the listed straight color, or alone to form the salt of the listed straight color. The following substrata, alone or in any combination, are authorized for use in lakes for drug and cosmetic use: Alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, and calcium carbonate. The regulation also lists the following cation precipitants for use in lakes for drug and cosmetic use: Sodium, potassium, aluminum, barium, calcium, strontium, and zirconium.

The regulation provides for the use of the following straight colors in producing lakes for drug and cosmetic use: FD&C Blue No. 1 (§ 82.101); FD&C Blue No. 2 (§ 82.102); FD&C Green No. 3 (§ 82.203), FD&C Red No. 4 (§ 82.304); FD&C Yellow No. 5 (§ 82.705); FD&C Yellow No. 6 (§ 82.706); D&C Blue No. 4 (§ 82.1104), D&C Green No. 5 (§ 82.1205), D&C Orange No. 5 (§ 82.1255), D&C Red No. 6 (§ 82.1306), D&C Red No. 7 (§ 82.1307), D&C Red No. 21 (§ 82.1321), D&C Red No. 22 (§ 82.1322), D&C Red No. 27 (§ 82.1327), D&C Red No. 28 (§ 82.1328), D&C Red No. 30 (§ 82.1330), D&C Red No. 33 (§ 82.1333), D&C Red No. 34 (§ 82.1334), D&C Red No. 36 (§ 82.1336), D&C Violet No. 2 (§ 82.1602), and D&C Yellow No. 10 (§ 82.1710).

The regulations for lakes of D&C Red No. 33 (§ 82.1333), D&C Red No. 36 (§ 82.1336) and FD&C Yellow No. 6 (§ 82.706) further require that lakes of these straight colors for drug and cosmetic use be prepared from previously certified batches of the straight colors. Uncertified batches of the remaining straight colors may be used to prepare lakes for drug and cosmetic use. Section 82.1051 also provides specifications for ether extracts, soluble chlorides and sulfates, and intermediates, and prescribes rules for naming lakes that are listed for drug and cosmetic use.

4. Provisional Listing of Lakes for Use in Externally Applied Drugs and Cosmetics

Part 82, subpart D, identifies the lakes that are provisionally listed for use in externally applied drugs and cosmetics. Section 82.2050 prescribes the certification requirements for these lakes.

Section 82.2051 specifies that lakes for use in externally applied drugs and cosmetics are made by extending, on one or more listed substrata, one or more of the listed precipitants, and the straight color Ext. D&C Yellow No. 7 listed in § 82.2707a. The precipitant may be added either as a component of the listed straight color, or alone to form the salt of the listed straight color.

Although Ext. D&C Yellow No. 7 is the only straight color referred to in subpart D, its lakes are not the only lakes limited to use in externally applied drugs and cosmetics. As noted above, certain straight colors that were provisionally listed for general drug and cosmetic use were restricted to use in externally applied drugs and cosmetics as part of their permanent listing. The agency also amended the provisional listings for the lakes of these straight colors to impose the same restrictions. The provisional listings of the following color additives in subparts B and C of part 82 limit the use of their lakes to externally applied drugs and cosmetics: FD&C Red No. 4 (§ 82.304); D&C Blue No. 4 (§ 82.1104), D&C Green No. 6 (§ 82.1206), D&C Orange No. 4 (§ 82.1254), D&C Orange No. 10 (§ 82.1260), D&C Orange No. 11 (§ 82.1261), D&C Red No. 17 (§ 82.1317), D&C Red No. 31 (§ 82.1331), D&C Yellow No. 7 (§ 82.1707) and D&C Yellow No. 8 (§ 82.1708).

The substrata, precipitants, and additional specifications listed in

§ 82.2051 for lakes used in externally applied drugs and cosmetics are the same as those listed in § 82.1051 for D&C lakes. Section 82.2051 also specifies that the listed names of Ext. D&C lakes are derived in the same manner as for D&C lakes.

5. Permanently Listed Lakes of FD&C Red No. 40

The color additive FD&C Red No. 40 was not included in the provisional list because FD&C Red No. 40 was not in use in 1960. In the Federal Register of April 10, 1971 (36 FR 6892), the agency published a final rule, in response to a color additive petition, permanently listing FD&C Red No. 40 for use in food and drugs. The agency later amended these regulations in response to another petition to provide for use of the lakes of FD&C Red No. 40 in food and drugs (36 FR 23553, December 10, 1971). Subsequently, in response to further petitions, the agency published final rules expanding the listing of FD&C Red No. 40 to cosmetic uses. First, in the Federal Register of August 6, 1974 (39 FR 28278), the agency published a final rule permanently listing FD&C Red No. 40 for use in dentifrices that are cosmetics. Subsequently, the agency amended these regulations to expand the use of FD&C Red No. 40 and its lakes to cosmetics generally (39 FR 44198, December 23, 1974).

The permanent listings of FD&C Red No. 40 for food, drug, and cosmetic use in §§ 74.340, 74.1340, and 74.2340, respectively, include its lakes. However, the permanent listings of these lakes cite the provisional listings for lakes in part 82 for the preparation, specifications, and labeling requirements applicable to FD&C Red No. 40 lakes. As a result, any agency action on the provisional listings for lakes will affect the permanent listings for the lakes of FD&C Red No. 40. Therefore, this proposal includes consideration of the lakes of FD&C Red No. 40.

C. The 1965 Proposal for Permanent Listing of Lakes and the 1979 Notice of Intent

In the Federal Register of May 11, 1965 (30 FR 6490), the agency proposed to list permanently certain lakes for use in foods, drugs, and cosmetics under conditions similar to their current provisional listing. However, because many straight colors were still provisionally listed and because of the need for more information on lakes, the agency, in 1979, terminated the rulemaking initiated by this proposal without taking final action (44 FR 36411, June 22, 1979).

In the same issue of the Federal Register (44 FR 36411), the agency published a notice that announced the agency's intent to repropose regulations concerning lakes (the 1979 notice of intent (NOI)). The agency also addressed the comments it had received in response to the 1965 proposal regarding the permanent listing of lakes. Three of the five comments on the 1965 proposal recommended revising the regulations to provide for the use of more than one previously certified batch of color additive in the preparation of lakes for coloring drugs and cosmetics. In the 1979 NOI, the agency stated its intention to consider this recommendation in developing a new proposal for the permanent listing of lakes. The agency also identified the following issues for the scientific review of lakes: (1) The definition and nomenclature of lakes; (2) the safety of lakes; and (3) the specifications for lakes (stability and certification methodology). The agency requested information and comments pertaining to these issues.

The agency received four comments on the 1979 NOI. These included two brief responses from manufacturers and two extensive comments from trade associations, the International Association of Color Manufacturers (IACM) (formerly the Certified Color Manufacturers' Association (CCMA)) and the Cosmetic, Toiletry, and Fragrance Association, Inc. (CTFA). The issues raised by the agency in the 1979 NOI, along with the four comments received on that notice, and the agency's responses to the comments, are discussed in the following sections. This proposal does not, however, address comments related to the straight colors that were provisionally listed in 1979 but have been denied permanent listing in subsequent rulemakings (FD&C Red No. 3 (externally applied drug and all cosmetic uses), D&C Red Nos. 8, 9, and 19, and D&C Orange No. 17).

III. Development of Proposed Actions for Lakes

A. Terminology of Lakes

The agency is proposing the following changes to the existing definitions relating to lakes.

1. Straight Color

Currently, § 70.3(j) defines the term ''straight color'' as ''a color additive listed in parts 73, 74, and 81 of this chapter, and includes lakes * * *.'' Thus, the term encompasses all listed color additives, including lakes. Current § 70.3(l) defines the term ''lake'' as ''a straight color extended on a substratum by adsorption, coprecipitation, or chemical combination that does not include any combination of ingredients made by simple mixing process.'' These two regulations, when read together, suggest that a lake may be used as a color component of another lake. This implication is inconsistent with current regulations for lakes (§§ 82.51, 82.1051, and 82.2051) and with the proposed regulations for lakes in this document, which do not allow the synthesis of a lake using another lake as a color component.

There are other instances in which the existing definition of straight color creates confusion. For example, the procedures for requesting certification of a batch of a color additive treat straight colors (§ 80.21(j)(1) (21 CFR 80.21(j)(1)) and lakes (§ 80.21(j)(2)) separately. Federal Register publications relating to color additives also commonly use the term ''straight color'' to refer to a color additive other than a lake. For example, the 1979 NOI referred to straight colors as distinct from lakes; the agency's request for information concerning the usage of FD&C Red No. 3 requested data on straight colors, lakes, and mixtures (52 FR 44485; November 19, 1987). Communications between the agency and industry also indicate that the common usage of the term ''straight color'' does not ordinarily include the term ''lake.'' To eliminate the confusion resulting from the existing definition, the agency is proposing to revise the definition for ''straight color.'' As revised, the definition would read ''The term 'straight color' means a color additive that is listed in part 73 or 74 of this chapter, but does not include color additive mixtures or lakes.''

2. Listed Color

As discussed in section III.A.1., the proposed definition of ''straight color'' would exclude lakes. Therefore, the agency is proposing a new term ''listed color'' to refer to any color additive (including a lake) listed in part 73 or 74 for any use. By definition, the term would not include mixtures, which are not themselves listed colors but rather combinations of listed colors. The agency is proposing to add the following definition at § 70.3(w): ''The term 'listed color' means a color additive listed in part 73 or 74 of this chapter and includes lakes.''

3. Mixture

Currently, § 70.3(k) defines the term ''mixture'' as ''a color additive made by mixing two or more straight colors, or one or more straight colors and one or

more diluents.'' The agency is proposing to modify this definition to replace the current reference to ''straight color'' with ''listed color'' and to clarify that a mixture does not involve a chemical reaction between its components. Proposed § 70.3(k) would read ''The term 'mixture' means a color additive made by mixing two or more listed colors, or one or more listed colors and one or more diluents, without an accompanying chemical reaction.''

4. Lake

Currently, § 70.3(l) defines the term ''lake'' as ''a straight color extended on a substratum by adsorption, coprecipitation, or chemical combination that does not include any combination of ingredients made by simple mixing process.'' As discussed in sections IV. and V. of this document, the agency is proposing to permit the preparation of a lake using more than one straight color. Proposed § 70.3(l) would read ''The term 'lake' means a color additive made by extending one or more straight colors on one or more substrata by adsorption, coprecipitation, or chemical combination, but does not include mixtures.''

5. Substratum

Currently, § 70.3(n) defines ''substratum'' as ''the substance on which the pure color in a lake is extended.'' This definition implies that it is only the pure color that is extended on the substratum. However, the data reviewed by the agency on the stability of straight colors after laking clearly demonstrate that intermediates and subsidiary colors are also extended on the substratum during the laking process. Therefore, the agency is proposing to amend the definition of substratum to read ''The term 'substratum' means the substance on which the straight color in a lake is extended.''

6. Precipitant (Basic Radical)

Although the term ''basic radical'' is not defined in the color additive regulations, §§ 82.51 and 82.1051 use ''basic radical'' to denote a substance that may be used to precipitate a lake during its manufacture. The agency believes that ''precipitant'' is a more descriptive and scientifically accurate term for such a substance. ''Precipitant'' is the term normally used in technical publications. For example, the Condensed Chemical Dictionary (12th ed., 1993) defines a lake as a pigment produced by the interaction of an ''organic dye, a precipitant, and an absorptive inorganic substrate.'' However, the same source contains no definition of ''basic radical.'' The publications of trade organizations also use the term ''precipitant'' rather than ''basic radical'' in discussions of lakes (Ref. 12). Therefore, the agency is proposing to use the term ''precipitant'' rather than the term ''basic radical'' in new §§ 74.50 and 74.1050. However, the agency is not proposing any formal definition of ''precipitant'' in § 70.3.

7. Repack

Currently, § 70.3 does not define the term ''repack.'' However, repacks are one of the four forms of color additive (in addition to straight colors, lakes, and mixtures) that are certified under the procedures in part 80. The other three forms of color additive are defined in § 70.3. Therefore, the agency tentatively concludes that a definition of repack should be added to § 70.3. Proposed § 70.3(x) would read ''The term 'repack' means all or a portion of a batch of certified color additive that has been sealed in accordance with § 70.20 and labeled in accordance with § 70.25, but has been either opened for repackaging without further processing, or relabeled for shipment or delivery, by a person other than the person to whom the certificate or acceptance of a notice claiming certification for the batch was issued.'' Under § 80.32(d), such repackaging or relabeling results in the expiration of the certificate, and the batch therefore ceases to be a certified batch. A repack may be certified under the procedures in part 80 at a lower fee than for the original batch (§ 80.10(b)). The agency notes that if a batch or portion of a batch is processed in any way, including heating, then it is not a repack and must be recertified as a new batch of color additive.

B. Nomenclature of Lakes

The current nomenclature system for lakes is described in §§ 82.51(b), 82.1051(b) and 82.2051(b). These regulations specify that the listed name of a lake is formed from: (1) The listed name of the color from which the lake is prepared; (2) the name of the cation precipitant combined in such color; and (3) the word ''lake.'' This system of nomenclature identifies the color additive as a lake and specifies the straight-color component of the lake and the cation precipitant used to prepare the lake. However, the name of a lake does not identify the substrata used to prepare the lake. Because only one substratum (alumina) is permitted in lakes for food use, this system presents no identity problems for these lakes. However, under the current nomenclature system, lakes listed for drug and cosmetic use are not fully identified, because such lakes may contain a variety of substrata. Thus, lakes produced from a common straight color and cation, but different substrata, are identified with the same name. For example, two lakes of D&C Red No. 21, one prepared with the cation aluminum and the substratum alumina, the other with the cation aluminum and the substrata alumina and titanium dioxide, are both named ''D&C Red No. 21 Aluminum Lake.''

In the 1979 NOI, the agency described this problem with the current nomenclature system and stated its intention to modify the nomenclature system to include the substrata in the name of the lake. The agency received comments from the IACM and CTFA supporting inclusion of substrata in the name of a lake for the purpose of more accurately identifying the listed color additive. As explained above, although omitting the substratum from the name of a lake for food use presents no problems, omitting the substratum from the name of a lake restricted to drug or cosmetic use could cause confusion as to the identity of the lake. However, as the same batch of lake may be used for a food, a drug, or a cosmetic (if the lake is listed for all three uses), the agency tentatively finds that use of a single nomenclature system to identify all lakes would present the least overall confusion to users of these color additives. Use of a uniform nomenclature system for all lakes is also desirable because it avoids the necessity for manufacturers of lakes to provide different labels for packages of the same lake. Therefore, the agency is proposing that the same nomenclature system be used for all lakes.

Therefore, the agency is proposing to modify the nomenclature of lakes by requiring the inclusion of the identity of substrata in the name of a lake. The proposed nomenclature system would construct the name of a lake from the name(s) of the straight colors present in the lake (in descending order of predominance), followed by the names of the cations of the precipitants, and followed by the words ''Lake on _____ and _____'' (inserting the listed names of the substrata in descending order of predominance). For example, the name of a lake prepared by the extension of D&C Red No. 27 and D&C Orange No. 5 on alumina and titanium dioxide using aluminum chloride and calcium chloride as precipitants would be ''D&C Red No. 27 and D&C Orange No. 5 Aluminum Calcium Lake on Alumina and Titanium Dioxide.''

Currently, § 82.1051(b)(1) provides that the name of a D&C lake prepared

from an FD&C color shall be formed from the ''listed name of the color from which the lake is prepared, except that if such name contains the symbol 'FD&C' such symbol shall be changed to 'D&C'.'' For example, the name of the lake formed from FD&C Yellow No. 5, rosin, and zirconium cation is D&C Yellow No. 5 zirconium lake. The agency notes that the use of the FD&C, D&C, and Ext. D&C prefixes to designate the approved uses of colors originated in the 1939 listings of coal tar colors, including lakes (4 FR 1922) and was carried over into the provisional listing of these color additives in 1960 (25 FR 9759). The permanently listed straight colors retained the names under which they were provisionally listed, although the prefixes no longer accurately reflected the approved uses in some cases. For example, FD&C Red No. 4 is permitted for use only in externally applied drug and cosmetic products.

The agency is not proposing any action in this rulemaking to change the names of the color additives whose food, drug, or cosmetic use is no longer correctly designated by their FD&C or D&C prefix. However, the agency has tentatively decided not to continue the current system described in § 82.1051(b)(1), in which the prefix 'FD&C' is changed to 'D&C' when naming lakes for drug or cosmetic use that have been prepared from straight colors that contain the 'FD&C' prefix in their name. The agency tentatively concludes that continuation of this nomenclature provision is unnecessary to identify the approved uses of the lake and could be confusing to users of lakes. As discussed above, the designation 'D&C' does not always accurately describe the uses of the lake. Furthermore, under § 70.25, the label of the color additive must contain a declaration of the permitted uses of the lake. Finally, because the proposed procedure for certification of lakes (see section VI.B. of this document) would rely on the certificate for the straight color used to prepare the lake, the agency believes that the name of the lake should accurately identify the certified straight color on which the certification of the lake is based. For example, under the proposed certification procedure for lakes, the certificate for the straight color in the lake cited above would be for ''FD&C Yellow No. 5,'' not ''D&C Yellow No. 5.''

In the 1979 NOI, the agency also requested comments to address an inconsistency in the current system of nomenclature; namely, that certain lakes of identical composition may have different names. For example, FD&C Blue No. 1 and D&C Blue No. 4 are two separately listed straight colors that are different salt forms of the same dye. (FD&C Blue No. 1 is the disodium salt and D&C Blue No. 4 is the diammonium salt of a triphenylmethane derivative.) During the laking process the accompanying cation in the straight color is replaced by the precipitant cation. Thus, the lakes of these two straight colors, prepared from the same substrata and precipitants, are chemically identical. However, they have different names. For example, under the current nomenclature system, the aluminum lakes on alumina of these two straight colors are named ''FD&C Blue No. 1 Aluminum Lake'' and ''D&C Blue No. 4 Aluminum Lake.'' (Under the proposed system, they would be named ''FD&C Blue No. 1 Aluminum Lake on Alumina'' and ''D&C Blue No. 4 Aluminum Lake on Alumina,'' respectively.)

In its comment on the 1979 NOI, CTFA agreed with the agency's assessment of this nomenclature problem. However, the comment suggested that this and other problematic aspects of the current system of nomenclature are better viewed as problems with the general nomenclature of listed colors, not problems specific to lakes.

The agency agrees with CTFA's comment that these issues concerning the nomenclature of lakes are really issues related to the general nomenclature of listed colors. Therefore, the agency is not proposing any modifications in the nomenclature of lakes to address these issues, which are outside the scope of this rulemaking.

Under this proposal, the nomenclature proposed in this section would be used for two purposes: (1) To prescribe the listed name of the lake, because the agency is proposing to issue umbrella regulations for lakes rather than an individual regulation for each listed lake; (2) to identify the color additive on the labels of lakes that are packaged for sale to manufacturers of foods, drugs, and cosmetics to be used in coloring those products. The agency notes that lakes are also required to be declared as ingredients on the label of foods and cosmetics. Section VI.C.3. of this document describes the simplified nomenclature system that FDA is proposing for ingredient labeling of lakes on food and cosmetic labels.

TABLE 1.—CURRENT AND PROPOSED REGULATORY STATUS OF STRAIGHT COLORS USED IN LAKES

Current listings		Proposed listings	
Current regulatory status	Straight color	Proposed regulatory status	Straight color
Permanently listed: Part 74 (Subpart A—Foods, Subpart B—Drugs and Subpart C—Cosmetics).	FD&C Red No. 40	Permanently listed: Part 74 (Subpart A—Foods (§ 74.50)).	FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, FD&C Red No. 40, FD&C Yellow No. 5, FD&C Yellow No. 6.
Provisionally listed: Part 82 (Subpart B—Foods, Drugs, and Cosmetics).	FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Red No. 4.	(Subpart B—Drugs (§ 74.1050) and Subpart C—Cosmetics (§ 74.2050))..	FD&C Blue No.1, FD&C Blue No. 2 (drugs only), FD&C Green No. 3, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Red No. 4, FD&C Red No. 40, D&C Blue No. 4, D&C Orange No. 4, D&C Orange No. 5, D&C Orange No. 10, D&C Red No. 6, D&C Red No. 7, D&C Red No. 21, D&C Red No. 22, D&C Red No. 27, D&C Red No. 28, D&C Red No. 31, D&C Red No. 33, D&C Red No. 34, D&C Yellow No. 10.

TABLE 1.—CURRENT AND PROPOSED REGULATORY STATUS OF STRAIGHT COLORS USED IN LAKES—Continued

Current listings		Proposed listings	
Current regulatory status	Straight color	Proposed regulatory status	Straight color
(Subpart C—Drugs and Cosmetics).	FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Red No. 4, FD&C Blue No. 4, FD&C Green No. 5, FD&C Green No. 6, FD&C Orange No. 4, FD&C Orange No. 5, FD&C Orange No. 10, FD&C Orange No. 11, FD&C Orange No. 6, FD&C Red No. 7, FD&C Red No. 17, FD&C Red No. 21, FD&C Red No. 22, FD&C Red No. 27, FD&C Red No. 28, FD&C Red No. 30, FD&C Red No. 31, FD&C Red No. 33, FD&C Red No. 34, FD&C Red No. 36, FD&C Violet No. 2, FD&C Yellow No. 7, FD&C Yellow No. 8, FD&C Yellow No. 10.	Listing Terminated (Does not form lakes).	D&C Green No. 6, D&C Red No. 17, D&C Red No. 30, D&C Red No. 36, D&C Violet No. 2.
		Listing Terminated (No batches certified):.	D&C Green No. 5, D&C Orange No. 11, D&C Yellow No. 7, D&C Yellow No. 8.
(Subpart D— Externally Applied Drugs and Cosmetics).	Ext. D&C Yellow No. 7	Listing Terminated (No confirmation of stability during laking).	Ext. D&C Yellow No. 7.

C. Issues Relating to Definition of Lakes and Termination of Certain Provisional Listings

1. Straight Colors

A summary of the current and proposed regulatory status of straight colors for use in lakes is given in Table 1.

CTFA's comments on the 1979 NOI include information on the chemical structure of the straight colors currently listed for use in lakes. Based on its evaluation of these data and other information from the published literature, the agency tentatively concludes that, to form a lake, a straight color must contain a salt-forming group (i.e., a salt, an acid, or a lactone group) as part of its chemical structure. The agency finds that the following straight colors listed in part 82 contain a salt-forming group and thus are capable of forming a lake: FD&C Red No. 4, D&C Red No. 6, D&C Red No. 7, D&C Red No. 21, D&C Red No. 22, D&C Red No. 27, D&C Red No. 28, D&C Red No. 31, D&C Red No. 33, D&C Red No. 34, FD&C Blue No. 1, FD&C Blue No. 2, D&C Blue No. 4, FD&C Green No. 3, D&C Green No. 5, D&C Orange No. 4, D&C Orange No. 5, D&C Orange No. 10, D&C Orange No. 11, FD&C Yellow No. 5, FD&C Yellow No. 6, D&C Yellow No. 7, D&C Yellow No. 8, D&C Yellow No. 10, and Ext. D&C Yellow No. 7.

However, based on the same information, the agency notes that the following five straight colors listed in part 82 do not contain a salt-forming group as part of their chemical structure and therefore cannot form lakes: D&C Red No. 17, D&C Red No. 30, D&C Red No. 36, D&C Violet No. 2, and D&C Green No. 6. CTFA's comment on the 1979 NOI also stated that D&C Green No. 6 does not form a lake. Therefore, the agency tentatively concludes that combinations of these straight colors with substrata do not meet the definition of lake in § 70.3(l). Consequently, the agency is proposing to terminate the listing of D&C Red No. 17, D&C Red No. 30, D&C Red No. 36, D&C Violet No. 2, and D&C Green No. 6 as components of lakes. This proposed action would not affect the listing of these color additives as straight colors. Under the proposal, combinations of these straight colors with substrata that are approved diluents or approved color additives would be color additive mixtures rather than lakes. Such mixtures would be exempt from certification under § 80.35(b).

2. Diluents in Color Additive Mixtures for Cosmetic and Drug Use

a. *Cosmetics.* The agency notes that its proposed action to terminate the listing of five straight colors as components of lakes would not affect the use of these straight colors in cosmetic products. Combinations of D&C Red No. 17, D&C Red No. 30, D&C Red No. 36, D&C Violet No. 2, or D&C Green No. 6 with substrata listed in § 82.1051 are color additive mixtures as defined in § 70.3(k), and the ''substrata'' used in these combinations are diluents as defined in § 70.3(m). Because no regulation limits the diluents that may be used in color additive mixtures intended for use in cosmetic products, the proposed action to terminate the listing of D&C Red No. 17, D&C Red No. 30, D&C Red No. 36, D&C Violet No. 2, and D&C Green No. 6 for use in lakes would not affect their use in cosmetics as color additive mixtures containing, as diluents, the substances now listed as substrata in § 82.1051 (alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, and calcium carbonate).

b. *Drugs.* The proposed action to terminate the listing of D&C Red No. 17, D&C Red No. 30, D&C Red No. 36, D&C

Violet No. 2, and D&C Green No. 6 for use in lakes would not affect their use in drugs as color additive mixtures containing the following substrata now listed in § 82.1051: Alumina, calcium carbonate, talc, titanium dioxide, and zinc oxide. Alumina, calcium carbonate, talc, and titanium dioxide are listed in §§ 73.1010, 73.1070, 73.1550, and 73.1575, respectively, as color additives exempt from certification for use in drugs generally (ingested drugs and externally applied drugs). Therefore, combinations of these substances with D&C Red No. 17, D&C Red No. 30, D&C Red No. 36, D&C Violet No. 2, and D&C Green No. 6 are permitted as color additive mixtures under existing regulations. Zinc oxide is listed in § 73.1991 as a color additive exempt from certification for use in coloring externally applied drugs. In addition, zinc oxide is generally recognized as safe (GRAS) for use as a dietary supplement (§ 182.5991 (21 CFR 182.5991)) and as a nutrient in food (§ 182.8991 (21 CFR 182.8991)). Section 73.1001 permits the use of substances listed in § 73.1(a) as diluents in color additive mixtures for ingested drug use. In turn, § 73.1(a) permits the use of substances that are GRAS under section 201(s) of the act (21 U.S.C. 321(s)). Therefore, the agency concludes that zinc oxide may be used with D&C Red No. 17, D&C Red No. 30, D&C Red No. 36, D&C Violet No. 2, and D&C Green No. 6 either as an approved diluent in color additive mixtures for coloring ingested drugs or as a straight-color ingredient in color additive mixtures for coloring externally applied drugs.

Rosin is currently listed in § 73.1(b)(1)(i) as a diluent in color additive mixtures for use in inks for marking food supplements in tablet form, gum, and confectionery, and by reference, for use under § 73.1001(a)(2) in inks for branding pharmaceutical forms. In its review of the safety of the substrata currently listed in § 82.1051 (see section V.A.2.j. of this document), the agency determined that the ingested uses of rosin are safe. However, in this same review, the agency stated that it was aware of literature reports of dermal irritation due to rosin (Ref. 13). Recently submitted data on human skin sensitization and photoreaction to commercially available cosmetic products colored with rosin lakes (Ref. 14) establish that lakes containing rosin as a substratum are safe for externally applied drugs and cosmetics. However, the rosin present in lakes, where it is a component of an insoluble pigment, is not identical to free rosin present as a diluent in color additive mixtures. Therefore, the agency tentatively concludes that the data submitted on the safety of externally applied rosin lakes do not resolve the safety issues presented by the use of free rosin as a diluent in externally applied drug products, such as the risk of allergic contact dermatitis and occupational asthma.

Based on its safety review of rosin, the agency is proposing to amend § 73.1001 to list rosin as a diluent in color additive mixtures for ingested drug use only. However, if the agency receives information that adequately supports the safety of rosin as a diluent in color additive mixtures for use in externally applied drugs, the agency will consider listing rosin as a diluent for color additive mixtures for both ingested and externally applied drugs. Anyone interested in the listing of rosin for such use should submit information on the identity, specifications, and dermal safety of the rosin for which listing is sought.

The current regulations do not allow for the use of aluminum benzoate, blanc fixe, clay, and gloss white as diluents in color additive mixtures for drug use, because only the diluents provided for in § 73.1001 may be used in color additive mixtures for coloring drugs. However, FDA has evaluated the safety of these substances, or the materials used to make them, as part of its review of substrata in lakes for drug and cosmetic use in section V.A.2. of this document. This review included data on the ingested and dermal uses of barium sulfate (blanc fixe), kaolin (clay), benzoic acid, and benzoates. Specifically, the agency considered literature reviews of aluminum salts, barium sulfate, kaolin and bentonite (a silicate); information from the color additive petitions for use of certain aluminum lakes in eye-area cosmetics; and safety reviews of aluminum compounds, benzoic acid and benzoates, and kaolin and bentonite as food ingredients. These safety reviews were conducted by the Select Committee on GRAS Substances of the Federation of American Societies for Experimental Biology and the Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Expert Committee on Food Additives.

Based on its review, which is discussed in section V.A.2. of this document, the agency tentatively concludes that barium sulfate (blanc fixe), aluminum benzoate, and kaolin (clay) are safe for use as diluents in color additive mixtures for drug use. Therefore, as part of its disposition of the provisional listings in part 82, the agency is proposing to amend § 73.1001 to list barium sulfate, aluminum benzoate, and kaolin as diluents that may be safely used in color additive mixtures exempt from certification that are intended for use in ingested and externally applied drugs. The agency notes that gloss white is a mixture of alumina and barium sulfate and thus would be permitted for any use in color additive mixtures for which both alumina and barium sulfate are permitted.

For the reasons discussed above, the agency tentatively concludes that the proposed action to terminate the listing of D&C Red No. 17, D&C Red No. 30, D&C Red No. 36, D&C Violet No. 2, and D&C Green No. 6 as components of lakes would not affect their use in drugs as color additive mixtures containing alumina, calcium carbonate, kaolin (clay), talc, zinc oxide, barium sulfate (blanc fixe), aluminum benzoate, titanium dioxide, gloss white, or rosin (ingested drugs only). However, the proposed termination would mean that those straight colors could no longer be used in externally applied drugs as color additive mixtures containing rosin, unless the agency receives data that establish the safety of rosin as a diluent for externally applied uses.

3. Extended Toners

In the 1979 NOI, the agency requested information to identify certain insoluble color additives, commercially described as extended toners, that are classified as lakes under part 82. The agency requested comments on the need to modify existing regulations or to promulgate new regulations to address these color additives. FDA noted its intent, in the absence of comments to the contrary, to exclude these products from the definition of lakes.

CTFA's comment on the 1979 NOI provided information that identified the composition of extended toners and of related insoluble color additives known as resinated toners, extended resinated toners, and toners. The comment requested revision of the definitions in 21 CFR 70.3 to better describe these substances. The agency has evaluated the available information and determined that the color additives described commercially as toners, resinated toners, extended toners, and extended resinated toners are not lakes. These substances are either water-insoluble straight colors or mixtures of water-insoluble straight colors with insoluble diluents. Therefore, the agency tentatively concludes that no new or modified regulations are needed to address toners, resinated toners, extended toners, and extended resinated

toners because these substances are mixtures as defined in § 70.3(k), and the ''substrata'' used in these combinations are diluents, as defined in § 70.3(m).

The proposed reclassification of toners, resinated toners, extended toners, and extended resinated toners as color additive mixtures containing as diluents the ingredients now listed as substrata in § 82.1051 would not affect their use in drugs, because, as discussed in section III.C.2. of this document, these substrata (except rosin for use in externally applied drugs) are listed as GRAS in part 182, 184, or 186 (21 CFR part 182, 184, or 186), approved as color additives for drug use in part 73, or the agency is proposing to list them in § 73.1001 as diluents in color additive mixtures for drug use. Because there is no regulation that limits the diluents that can be used in color additive mixtures for cosmetic use, the proposed reclassification of this group of color additives from lakes to color additive mixtures would not affect their use in cosmetics.

4. Requests for Listing of Additional Lake Components

CTFA's comments on the 1979 NOI included a request that FDA authorize for use in lakes the following straight colors: D&C Brown No. 1, D&C Green No. 8, and Ext. D&C Violet No. 2. These three straight colors are currently listed in part 74 for cosmetic use. In addition, D&C Green No. 8 is currently listed in part 74 for drug use. However, the agency notes that these straight colors are not listed either permanently in part 74 or provisionally in part 82 for use in preparing lakes. Therefore, the agency tentatively concludes that consideration of these straight colors for use in lakes is outside the scope of this proposal, which addresses only the provisionally listed lakes and their components. Interested persons may submit a color additive petition under § 71.1 (21 CFR 71.1) to amend the regulations to permit the use of these straight colors in lakes.

CTFA's comments on the 1979 NOI also suggested that bismuth oxychloride and mica should be listed as acceptable substrata in lakes for coloring drugs and cosmetics. IACM's comments requested the listing of titanium dioxide as a substratum for lakes for coloring foods. However, bismuth oxychloride and mica are not provisionally listed in part 82 as substrata in lakes for drug or cosmetic use, and titanium dioxide is not provisionally listed in part 82 as a substratum in lakes for food use. Therefore, the agency tentatively concludes that consideration of the requested uses of these substances as substrata in lakes is outside the scope of this rulemaking, which addresses provisionally listed lakes and their components. Interested persons may submit a color additive petition under § 71.1 to amend the regulations to permit use of these substances in lakes.

5. Definition of Lakes Versus Mixtures

CTFA's comments on the 1979 NOI noted that the straight-color component of a lake, and not the substratum, provides the coloring effect and, therefore, requested that the agency classify lakes as color additive mixtures and list permitted substrata as diluents for color additive mixtures.

As discussed in section III.C.1. of this document, the agency agrees that combinations of non-salt-forming straight colors with substrata should be classified as mixtures rather than lakes. As to salt-forming straight colors, however, the agency disagrees with CTFA's interpretation. Lakes are very different from color additive mixtures because of the chemical reaction required to produce a lake. The agency finds that, under both the current and proposed definitions of a lake, the substratum is an integral part of the lake. In a mixture, there is little if any chemical interaction between the components, which function as separate ingredients. In the preparation of a lake, however, there is a chemical reaction between the components, and the physical properties of the resulting lake are very different from those of the straight-color component (see section I. of this document). Therefore, the agency tentatively concludes that lakes are not mixtures and that substrata used to prepare a lake are not separate ingredients, but are components of the finished color additive.

6. Pre-Amendments Certification of Provisionally Listed Lakes

As discussed in section II.A. of this document, the transitional provisions of the 1960 amendments limited the provisional listing of certifiable color additives to those for which at least one batch had been certified prior to July 12, 1960, the enactment date of the 1960 amendments. In establishing the provisional list (25 FR 9759), FDA removed 32 colors from listing because the agency had never certified any batches of these colors. In preparing this document, the agency reviewed its batch certification records to confirm that each straight color, substratum, and precipitant included in the provisional listing regulations for lakes was a component of at least one batch of a lake certified between 1939 and July 12, 1960.

a. *Straight Colors.* The agency's search of color certification records between 1939 and the enactment of the 1960 amendments established that the agency did not certify any batches of lakes of D&C Orange No. 11, D&C Yellow No. 7, D&C Yellow No. 8, or D&C Green No. 5 during that time. The agency tentatively concludes that its original provisional listing of these color additives for use in lakes for drugs or cosmetics was therefore incorrect. Accordingly, the agency is proposing to terminate the provisional listings of D&C Orange No. 11, D&C Yellow No. 7, D&C Yellow No. 8, and D&C Green No. 5 as components of lakes for use in drugs or cosmetics. Any future consideration of the use of these color additives as components of lakes would be through the color additive petition process (§ 71.1).

b. *Substrata.* The agency's color certification records show that all of the substrata listed in §§ 82.51, 82.1051, and 82.2051, except calcium carbonate, have been in continuous use in lakes because certification was initiated in 1939 (Ref. 15). The agency added calcium carbonate to the list of permitted substrata in 1959 (24 FR 3818) and certified at least one batch of a lake containing this substratum for drug or cosmetic use before the enactment of the 1960 amendments.

c. *Precipitants.* Section 82.51 lists two cations (calcium and aluminum) as components of precipitants in lakes for food use. The agency certified batches of FD&C aluminum lakes before the enactment of the 1960 amendments. However, in the 1979 NOI, the agency proposed to delete calcium as a listed cation in lakes for food use because the agency had never certified any batches of FD&C calcium lakes.

Comments on the 1979 NOI from IACM and CTFA requested the agency not to take this action. However, because these comments provided no information to document agency certification of any batches of FD&C calcium lakes before the enactment of the 1960 amendments, the agency tentatively concludes that its original provisional listing of these lakes was incorrect. Therefore, the agency is proposing to terminate the provisional listing of calcium as a precipitant in the preparation of lakes for food use. Any future consideration of the use of lakes containing calcium precipitants for coloring food would be through the color additive petition process (§ 71.1).

Sections 82.1051 and 82.2051 list seven cations (sodium, potassium, aluminum, barium, calcium, strontium, and zirconium) as components of precipitants in lakes for drug or cosmetic use. The agency certified

batches of lakes containing each of these seven cations for drug or cosmetic use before the enactment of the 1960 amendments.

IV. Safety Review and Proposed Actions for Lakes for Use in Foods

A. Review of Components of Lakes for Use in Foods

The current regulation for provisionally listed lakes for use in foods (21 CFR 82.51) provides for use of the following components in such lakes: (1) Certified batches of the straight colors FD&C Blue No. 1 (21 CFR 82.101), FD&C Blue No. 2 (21 CFR 82.102), FD&C Green No. 3 (21 CFR 82.203), FD&C Yellow No. 5 (21 CFR 82.705), FD&C Yellow No. 6 (21 CFR 82.706); (2) the substratum alumina; (3) precipitants containing the cations aluminum (Al^{+3}) and calcium (Ca^{+2}). Additionally, 21 CFR 74.340 permanently lists lakes of FD&C Red No. 40 that are prepared as described in 21 CFR 82.51 and that meet the specifications and labeling requirements prescribed by § 82.51.

The identity and specifications for the straight colors used in the preparation of the provisionally listed lakes for food use are provided in the regulations for the straight-color components of lakes in part 82, which are cited above. The regulations in part 82 cross-reference the permanent listings of the straight colors in part 74. As to substrata, § 82.3 defines alumina, but provides no specifications for alumina or for the materials used to prepare it in situ. Finally, with regard to precipitants, part 82 does not identify or prescribe specifications for the precipitants that may be used in the preparation of these lakes, other than specifying the cation component and providing specifications that limit the level of soluble chlorides and sulfates in the lake.

1. Straight Colors

a. *Identity.* The agency has already reviewed the identity and safety of the straight colors currently permitted as components of lakes for food use, either as part of its scientific review of provisionally listed straight colors or in response to petitions for the review of new color additives. Based on these reviews, the agency concluded that FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, FD&C Yellow No. 5, FD&C Yellow No. 6, and FD&C Red No. 40 are safe for use in foods and permanently listed these straight colors in 21 CFR part 74, subpart A. The agency is proposing to continue to permit the use of these straight colors as components of lakes for use in food, subject to the proposed requirements discussed below.

b. *Use of previously certified batches.* Currently, under § 82.51, manufacturers are required to prepare lakes for food use from previously certified batches of straight colors. This requirement was intended to ensure that the levels of intermediates, subsidiary colors, and other impurities in straight colors that are used to prepare lakes for food use are within the levels specified in the applicable regulations. Impurities in the straight color, especially the carcinogenic constituents present in some straight colors, are a primary safety concern with the use of these color additives and their lakes in food.

In the 1979 NOI, the agency requested submission of information about available methods for the determination of total (free plus bound) intermediates, as well as subsidiary colors and other impurities, and stated that without appropriate analytical methodology it might be necessary to require that all lakes be produced from certified batches of straight colors. The agency stated that there was no satisfactory analytical method to determine total intermediates in lakes. The available methods detected free intermediates but not necessarily the intermediates that, like the straight color, are bound to the substratum.

The comments on the 1979 NOI did not provide suitable methodology for the analysis of intermediates and other impurities in lakes. CTFA's comment stated that these problems could be addressed only through a time-consuming and difficult undertaking to develop satisfactory analytical methods. The comment suggested that the issue of certification methodology should be separated from that of the permanent listing of lakes, thus allowing these lakes to be permanently listed while the industry and the agency went on to address the issue of certification methodology jointly.

Section 721(b)(5)(A)(iv) of the act provides that in determining whether the proposed use of a color additive is safe, the agency must consider, among other relevant factors, the availability of any needed practicable methods of analysis for determining the identity and quantity of intermediates and other impurities contained in the color additive. If lakes are prepared from uncertified batches of straight colors, the only way to ensure that the intermediates, subsidiary colors, and other impurities derived from the straight color do not exceed the specification limits for the lake is to analyze the lake itself for those impurities. However, as indicated above, the analytical methods to accomplish this purpose are not currently available. Therefore, the agency tentatively concludes that the lack of adequate analytical methods to determine the levels of intermediates and other impurities in lakes precludes the agency from prescribing conditions of safe use for lakes prepared from uncertified batches of straight colors. Accordingly, to ensure the continued safety of lakes for food use, the agency is proposing to retain the requirement that these lakes be prepared from certified batches of straight colors. As discussed in section V.A. of this document, FDA is also proposing to require that lakes for use in drugs and cosmetics be prepared from certified batches of straight colors.

c. *Stability.* In the 1979 NOI, the agency asked for information about the chemical stability of straight colors during the laking process. The agency stated that if previously certified batches of straight colors are used in the preparation of lakes, the levels of intermediates and subsidiary colors in these lakes should be proportional to those in the original batch of the straight color. However, the agency was concerned that the laking process could cause an unstable straight color to deteriorate and, consequently, increase the levels of intermediates and subsidiary colors.

The agency requested data to confirm the stability of previously certified batches of straight colors during the laking process. The agency stated that, if such data were submitted, the agency would not require specifications for intermediates and subsidiary colors in lakes prepared from certified batches of straight colors. The agency also noted the lack of satisfactory methodology for identifying and quantifying intermediates and certain other contaminants in many lakes, but added that the lack of such methodology does not pose a problem for lakes produced from previously certified batches of colors, provided that there is no measurable degradation of the color during the laking process.

The straight colors that FDA proposes to permit as components of lakes for food use fall into the following four groups, based on chemical structure (the Color Index Structural classification (Ref. 16), as further refined by Marmion (Ref. 17)): Monoazo (FD&C Red No. 40, FD&C Yellow No. 6); pyrazolone (FD&C Yellow No. 5); triphenylmethane (FD&C Blue No. 1, FD&C Green No. 3); and indigoid (FD&C Blue No. 2). The FD&C lakes of these straight colors made up about 80 percent of the total poundage of lakes certified in fiscal year 1995 (FY–95) (Ref. 18). FD&C lakes of three

straight colors (FD&C Yellow No. 5, FD&C Yellow No. 6, and FD&C Red No. 40) made up about 90 percent of the FD&C lakes certified in FY–95. Lakes of FD&C Blue No. 1 and FD&C Blue No. 2 made up the remaining 10 percent. No batches of FD&C Green No. 3 lakes were certified in FY–95. Because lakes of monoazo and pyrazolone dyes make up such a high proportion of lakes certified, the agency is particularly concerned about possible degradation of FD&C lakes of these dyes.

CTFA submitted data (Ref. 19) to confirm the stability during laking on alumina of three straight colors (FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5) that represent three of the four structural groups. The data presented a comparison of the high performance liquid chromatography (HPLC) evaluations of each of five samples of FD&C Red No. 40, FD&C Yellow No. 5, and FD&C Blue No. 1 with the corresponding lake made from each sample. FDA has evaluated the data submitted by CTFA. A quantitative comparison of the levels of intermediates and subsidiary colors present in the straight color and the corresponding lake confirmed that the levels of intermediates and subsidiary colors in the lakes (after adjustment for the percent straight color in the lake) did not differ significantly from those in the corresponding straight colors (Ref. 20).

The agency also conducted a brief study on the stability of FD&C Blue No. 2 during the laking process (Ref. 21). This study presented a comparison of the HPLC evaluations of a sample of a certified batch of FD&C Blue No. 2 and a sample of a certified batch of the aluminum lake prepared from this batch. A quantitative comparison of the levels of intermediates and subsidiary colors present in the straight color and the corresponding lake confirmed that the levels of intermediates and subsidiary colors in the lake (after adjustment for the percent straight color in the lake) did not differ significantly from those in the corresponding straight color.

The data evaluated by the agency provide evidence that lakes of the straight colors FD&C Yellow No. 5, FD&C Red No. 40, FD&C Blue No. 1, and FD&C Blue No. 2 can be produced without significant degradation of the straight color. When produced under conditions of current good manufacturing practice (CGMP), these lakes meet the specifications for intermediates and subsidiary colors in the straight color, after adjustment for total color content of the lake. Although data have not been submitted for all of the straight colors FDA proposes to permit as components of lakes for food use, the remaining such straight colors (FD&C Green No. 3 and FD&C Yellow No. 6) have chemical structures that are similar to other straight colors (FD&C Blue No. 1 and FD&C Red No. 40, respectively) discussed above. The stability of FD&C Yellow No. 6 aluminum lake, which makes up over 25 percent of the total poundage of FD&C lakes certified in FY–95, is also supported by published studies. In these studies, the FD&C Yellow No. 6 aluminum lake showed greater thermal stability than did FD&C Red No. 40 aluminum lake (Ref. 22), and the straight color FD&C Yellow No. 6 was as stable as the straight color FD&C Red No. 40 under the pH conditions studied, showing no appreciable change over a week's exposure (Ref. 17). The agency tentatively finds that because of the similarity of chemical structure, the data available for the lakes of FD&C Blue No. 1 and FD&C Red No. 40 are adequate to confirm the stability of FD&C Green No. 3 and FD&C Yellow No. 6, respectively, during the manufacture of lakes in accordance with CGMP. In addition, the published data on FD&C Yellow No. 6 and its aluminum lake provide corroborative evidence for the stability of this straight color during the laking process when conducted under conditions consistent with CGMP.

Based on its previous evaluations of the safety of the straight colors that FDA proposes to permit as components of lakes for food use and on the scientific evidence that lakes of these straight colors can be produced under conditions consistent with CGMP without significant degradation of the straight color, the agency now tentatively concludes that certified batches of FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, FD&C Yellow No. 5, FD&C Yellow No. 6, and FD&C Red No. 40 are safe for use as components of lakes for food use that are prepared under conditions of CGMP. Therefore, the agency is proposing to permit certified batches of these straight colors as components of lakes for food use in § 74.50.

The agency is not, however, proposing to establish any definition of CGMP for the preparation of lakes for food use. FDA recognizes that CGMP for laking will vary with the straight color used, may include a variety of combinations of conditions, and may change over time with the introduction of new combinations of conditions. The agency's regulatory goal is to protect the public health by assuring that laking is conducted in a manner such that no significant degradation of the straight color occurs, not to prescribe the details of industry practice. Safety issues relating to the use of CGMP in preparing lakes are discussed further in sections IV.B.5 and IV.C. of this document.

d. *Use of more than one straight color in a lake.* The agency also tentatively concludes that the current prohibition on the use of more than one straight color in a lake is unnecessary. This prohibition was instituted as part of the original listing of lakes as certified colors in 1939 (4 FR 1922, 4 FR 3931, and 5 FR 1138). At that time, the regulations did not require that lakes be prepared from previously certified batches of straight color, and the only food use for which lakes were listed was for dyeing eggs in the shell. The requirement that lakes for food use be prepared from previously certified batches of straight color was initiated in 1959, when the regulations were amended to permit, for the first time, the use of certain lakes in foods generally (24 FR 3818 and 24 FR 5302). The agency now tentatively concludes that, because of the proposed requirement that certified batches of straight colors be used in preparing all lakes, the evidence for the stability of straight colors during the laking process, and the proposed certification requirement for lakes (discussed in section IV.C. of this document), the prohibition against the use of more than one straight color to make a lake is unnecessary. Therefore, the agency is proposing to permit the preparation of a lake from certified batches of more than one straight color.

2. Substratum—Alumina

Alumina is the only substratum provisionally listed for lakes for food use. Section 82.3(g) defines alumina as ''a suspension in water of precipitated aluminum hydroxide'' but prescribes no quality requirements for alumina substratum. This definition covers both preformed (precipitated and dried) alumina that is subsequently suspended in water and alumina that is prepared in situ, without subsequent recovery and drying.

As noted in section I. of this document, alumina may be prepared in situ from aluminum sulfate and sodium hydroxide or sodium carbonate during the manufacture of lakes. Aluminum sulfate is GRAS for food use (§ 182.1125) and is subject to the specifications in the Food Chemicals Codex 2d. ed. (1972) (§ 170.30(h)(1) (21 CFR 170.30(h)(1))). Sodium carbonate and sodium hydroxide are affirmed as GRAS for food use (§§ 184.1742 and 184.1763, respectively) and are required

to meet the specifications in the Food Chemicals Codex, 3d. ed. (1981).

In addition, § 73.1010 lists alumina (dried aluminum hydroxide) as a color additive for use in drugs and provides identity and specifications for alumina as a color additive. The agency tentatively concludes that, although the listed use of alumina (dried aluminum hydroxide) is for coloring drug products, alumina that meets the identity and quality requirements in § 73.1010 (a)(1) and (b) is safe as a substratum for lakes for food use (Ref. 13).

The agency has evaluated the available data relating to the safety of aluminum salts. These data included literature reviews, information from a color additive petition for use of several aluminum lakes on alumina in eye-area cosmetics, and safety reviews of aluminum compounds (including aluminum salts) as food ingredients by the Select Committee on GRAS Substances of the Federation of American Societies for Experimental Biology and the Joint FAO/WHO Expert Committee of Food Additives. Based on this evaluation, the agency tentatively concludes that alumina conforming to the identity and quality requirements set forth in § 73.1010 (a)(1) and (b) (Refs. 13, 23, and 24) is safe for use as a substratum in lakes for food use. The agency also tentatively concludes that alumina prepared from aluminum sulfate and sodium carbonate or sodium hydroxide that meet the requirements for these compounds in the Food Chemicals Codex 2d ed. (1971) (aluminum sulfate) or 3d ed. (1981) (sodium carbonate and sodium hydroxide) is safe as a component of lakes for food use.

3. Precipitants

a. *Aluminum cation (Al^{+3})*. In its safety review of alumina (see section IV.A.2. of this document), the agency evaluated the safety of the use of the aluminum salts (salts containing the aluminum cation (Al^{+3})). Based on this safety review, the agency tentatively concluded that the use of alumina as a substratum in lakes is safe. Based on the same data, the agency also tentatively concludes that the use of the aluminum cation as a component of precipitants used in the preparation of lakes for food use is safe (Ref. 13, 23, and 24). Aluminum cation is added as a precipitant with an accompanying anion. If an aluminum salt is added as a precipitant, the anion is added as part of the salt. Alternatively, if aluminum oxide or hydroxide is used as a precipitant, the anion is added as an acid to ensure the solubility of the aluminum cation to function as a precipitant. The anions that the agency proposes to permit for use in lakes are discussed in section IV.A.3.c. of this document.

The agency is not proposing to establish quality requirements for precipitants used in the preparation of lakes for food use. The agency recognizes that a variety of precipitant ingredients can be used to produce the aluminum cation that functions as a precipitant in lakes for food use. Furthermore, the agency does not anticipate that the use of precipitant ingredients that form the aluminum cation, under conditions consistent with CGMP, would introduce contaminants that require limitation by specifications for the precipitant ingredients. Precipitants are used at low levels (a small percentage of the total batch weight) and, by virtue of their function in the laking process, are always water-soluble cations. Because lakes are washed when prepared in accordance with CGMP, the agency anticipates that only low levels of water-soluble contaminants will remain in the finished lake. The only possible concern would be the presence of heavy metals deriving from contaminants in the precipitants. To address this potential problem, as discussed below, the proposed specifications for lakes will limit the levels of heavy metal contaminants permitted in the end product. Therefore, the agency tentatively concludes that quality requirements for the ingredients used to form precipitants in lakes for food use are unnecessary.

b. *Calcium cation (Ca^{+2})*. As discussed in section III.C.6.c. of this document, the agency is proposing to terminate the listing of calcium as a cation in lakes for food use because calcium lakes were not used in food in 1960 and thus should not have been provisionally listed. Any future consideration of the use of calcium lakes for coloring foods would be through the color additive petition process (§ 71.1).

c. *Accompanying anions.* The use of the aluminum cation in preparation of lakes results in the formation of chloride or sulfate anions. Chloride and sulfate are components of many food ingredients that the agency has listed or affirmed as GRAS for general food use (for example: Aluminum sulfate, § 182.1125; calcium sulfate, § 184.1230; table salt (sodium chloride), § 182.1(a); potassium chloride, § 184.1622). In the safety reviews conducted as part of the GRAS rulemakings for these ingredients, the agency found that ingestion of chloride and sulfate (in the presence of the accompanying cation) was safe at levels that vastly exceed possible levels of exposure to these anions as components of lakes. Therefore, the agency tentatively concludes that the presence of these anions in lakes for food use is safe when CGMP is observed (Ref. 13).

B. Specifications for Lakes for Use in Foods

1. Intermediates and Other Impurities Derived From Straight Colors

A typical straight color contains, in addition to the primary color component, intermediates and subsidiary colors. Intermediates are unreacted starting materials used to synthesize the primary color. Subsidiary colors are colored by-products of the synthesis of the primary color. As discussed in section IV.A.1.b. of this document, the agency is proposing to require that lakes be prepared from certified batches of straight color. The regulations for straight colors contain specifications that limit the levels of intermediates and subsidiary colors that may be present in the straight color. In this proposal, the agency has also tentatively concluded that the straight colors in lakes for food use do not degrade significantly during preparation of the lakes under conditions consistent with CGMP. Therefore, the agency tentatively concludes that the specifications for intermediates and subsidiary colors in straight colors are sufficient to ensure the safety of lakes prepared from certified batches of straight colors and that separate specifications for intermediates and subsidiary colors in lakes are unnecessary.

2. Heavy Metals

The current specifications for lakes for food use (§ 82.5) establish limits of 10 ppm lead, 1.4 ppm arsenic, and ''not more than trace'' levels of total heavy metals (other than lead and arsenic). In the 1979 NOI, the agency proposed adding a specification for mercury in lakes. The agency tentatively finds that the manufacturing processes for lakes use metal salts that are sources of potential contamination by heavy metals; moreover, in its certification of lakes, the agency has rejected batches because of the presence of heavy metals, including lead. Therefore, the agency tentatively concludes that specifications to limit the levels of lead, arsenic, and mercury in lakes are necessary to ensure their safe use in food. As a result of its safety reviews of the straight colors used in food, the agency established limits of not more than 10 parts per million

(ppm) lead, 3 ppm arsenic, and 1 ppm mercury in the specifications for most color additives permanently listed for food use in parts 73 and 74. The agency tentatively concludes that such specifications are also sufficient to ensure the safety of lakes.

FDA is unaware of any heavy metals, other than lead, arsenic, and mercury, that have a significant level of toxicity and that would be expected to occur in lakes. Therefore, the agency tentatively concludes that a general heavy metal specification is unnecessary to ensure the safety of lakes for food use.

One comment received in response to the 1979 NOI suggested that a limitation on iron be included in the specifications for lakes for food use. Iron salts may be present in lakes as contaminants inadvertently introduced during the manufacturing process. For example, a batch of lake prepared using rusted equipment or water with a high iron content may contain iron salts.

The agency has evaluated the safety of iron salts as a contaminant in lakes to determine whether their presence would present a sufficient safety hazard to warrant inclusion of a specification for iron. The agency notes that iron is an essential mineral, and that iron and many of its salts are affirmed as GRAS in part 184 for use as nutrients in food (for example, elemental iron, § 184.1375; ferric ammonium citrate, § 184.1296; ferric chloride, § 184.1297; ferric sulfate, § 184.1307; ferrous carbonate, § 184.1307b; ferrous sulfate, § 184.1315). However, the agency also notes that high levels of iron consumption can be toxic, especially for certain subpopulations. (See, e.g., 59 FR 51030, October 6, 1994).

Lakes are generally used at low levels (typically less than 0.05 percent) in foods, except for some low-consumption food items such as candy and candy coatings, colored sugar and frostings, dietary supplements, seasonings, flavorings, and chewing gum (Ref. 25). Therefore, consumption of iron due to its presence in lakes as a contaminant would be low. Under these circumstances, the agency finds no evidence of a safety hazard from exposure to iron as a contaminant in lakes for food use. Therefore, the agency tentatively concludes that a specification to limit the level of iron is unnecessary to ensure the safety of lakes for food use. Moreover, the agency notes that the conditions and practices that lead to the presence of iron salts as a contaminant in a batch of lake are addressed by the proposed requirement that lakes be prepared in accordance with CGMP (see section IV.B.5. of this document).

3. Soluble Chlorides and Sulfates

Current § 82.51 contains a specification that limits the content of the soluble chloride and sulfate anions in lakes for food use. The agency finds that the washing of the lake during the manufacturing process removes most of these water-soluble anions. Furthermore, as discussed above in section IV.A.3.c. of this document, the agency found in safety reviews conducted as part of several GRAS rulemakings that soluble chloride and sulfate anions are safe in foods at levels considerably greater than those found in lakes (Ref. 13). Therefore, the agency tentatively concludes that a specification to limit the levels of soluble chlorides and sulfates is unnecessary to ensure the safety of lakes prepared in conformity with CGMP for food use.

4. Inorganic Material Insoluble in HCl

Current § 82.51 contains specifications that limit the content of inorganic material insoluble in HCl in lakes. This specification was intended to ensure that the lake was prepared in accordance with CGMP and that no foreign material was inadvertently added during the laking process. However, agency certification records for lakes for food use in the past 20 years show that only one batch of lake has been denied certification based on this specification. Even without the specification for inorganic material insoluble in HCl, this batch of lake would not have met the requirements in this proposal because the alumina used as a substratum would not have met the applicable quality requirements. Furthermore, the agency is proposing to include in the specifications for lakes a provision to require that lakes be prepared in accordance with CGMP. Therefore, the agency tentatively concludes that a specification for material insoluble in HCl is unnecessary for lakes that meet the other proposed requirements for lakes, and such a specification is not included in this proposal.

5. Other Impurities and Contaminants

The agency has tentatively concluded above that specifications to limit the level of total heavy metals (except lead, arsenic, and mercury), soluble chlorides and sulfates, and material insoluble in HCl are unnecessary to ensure the safety of lakes for food use as long as a general provision is included in the specifications for lakes to ensure that they are prepared in conformity with CGMP. The identity requirements and specifications in color additive regulations include impurities that are expected to occur at significant levels in a color additive that has been prepared in accordance with CGMP. In its certification of color additives, FDA has occasionally denied certification for batches of color additives due to the presence of significant levels of impurities for which the listing regulation contains no specifications. In a few instances, these impurities could be linked to improper storage of the color additive or to cross-contamination from insufficiently cleaned processing equipment. In most cases, the source of the impurity was unknown. Based on the agency's experience in certifying thousands of batches of color additives annually, corroborated by the agency's analyses of reference standards (reference batches of color additives) used in toxicological studies of various straight colors as part of the safety reviews of these color additives, FDA believes that the impurities in the rejected batches would not have been present had the color additives been manufactured under conditions consistent with CGMP.

As noted above in section IV.A.1.c. of this document, it is important that lakes be prepared in accordance with CGMP to ensure that the straight color does not degrade during preparation of the lake. Manufacturing conditions must be controlled so that levels of uncolored components in the straight color, including the carcinogenic constituents in certain monoazo and pyrazolone straight colors, do not increase during preparation or handling of the lake. CGMP includes use of proper temperatures, especially during drying, to avoid affecting the composition of the lake, and sufficient washing of the lake to remove water-soluble impurities. For example, the agency recently rejected a batch of a monoazo straight color because the batch exceeded the specifications for certain carcinogenic constituents. Subsequent discussions with the manufacturer revealed that the batch had been previously certified, but had failed to meet the manufacturer's microbiological specifications and had been reprocessed (redried). After redrying, the batch no longer met the specification for trace-level carcinogenic constituents. The agency notes, however, that because of their chemical properties, such carcinogenic constituents are unlikely to be incorporated into lakes to the same extent as into straight colors, and sufficient washing of the lake could significantly decrease the levels of these constituents.

To ensure the safety of lakes for use in foods, FDA is proposing to continue

the requirement in existing § 82.5 that lakes shall be free from impurities other than those named in the specifications, to the extent that such impurities may be avoided by CGMP. However, the agency is not proposing to define specific conditions that would constitute CGMP in the preparation of lakes. The agency recognizes that appropriate manufacturing conditions may differ for the preparation of different lakes and, in fact, may change over time. Furthermore, even the preparation of a single lake that meets the requirements of part 74 may be accomplished using different conditions of manufacture. The agency wants to retain the current flexibility in preparation of lakes for food use, but maintain the assurance that there will be no significant degradation of the straight color during preparation of the lake and that the resulting lake will be otherwise in compliance with the requirements of part 74. To accomplish this objective, the agency is not proposing to define any specific conditions of CGMP; however, in its review of notices claiming certification for batches of lake, the agency is proposing to use the accountability of the straight color in the lake, calculated as described below, as an indicator of the use of CGMP in the preparation of the lake.

Under the current certification procedure for FD&C lakes, the agency can monitor both the use of certified batches of straight color in lakes for food use and indicators for the use of CGMP in the preparation or repack of a batch of lake. In a request for certification for a batch of lake, the firm must declare the certified lot number and the poundage from that lot for the straight color that is added to prepare the lake. The agency can determine a poundage accountability of the batches of straight colors that are used to prepare FD&C lakes. This accountability ensures that no more straight color is used in FD&C lakes than has been certified. For example, a firm that owns a 100-pound batch of straight color cannot credibly claim to use 1,000 pounds from that batch to make lakes.

From the information in the request for certification and from analysis of the sample submitted with the request, the agency determines the total color accountability for each batch of lake (the amount of total color that was added to the batch of lake compared to the total color of the resulting batch). This accountability for total color is an indicator for the use of CGMP in the preparation or repack of a batch of lake. In its determination of accountability of the straight color in lakes for food use, the agency calculates a theoretical range for the expected total color content of a lake based on the minimum total color permitted in the listing regulation for the straight color, the maximum total color possible for the straight color (100 percent), the weight of straight color used to prepare the lake, and the weight of the lake. For example, for a 100-pound batch of FD&C Yellow No. 5 aluminum lake on alumina that was prepared from 25 pounds of FD&C Yellow No. 5, the theoretical range for the expected total color content of the lake would be from 21.8 percent to 25 percent. This theoretical range allows for variations in total color resulting from factors that normally occur during the manufacture of a lake, such as incomplete laking of the color and bleeding of the color during washing.

The agency is requesting comments on the usefulness of total color accountability as an indicator of the use of CGMP in the preparation and repacking of batches of lake.

C. Certification Requirement

The agency has evaluated the necessity, in the interest of public health, for the certification of lakes prepared from certified batches of straight color. The agency tentatively concludes that continued batch certification of lakes is necessary to protect the public health. The agency bases this tentative conclusion on two safety issues: The need to ensure the safety of the components (straight colors, precipitants, and substrata) used to prepare a lake; and the need to ensure that lakes are prepared and repacked under conditions of CGMP to prevent degradation of the straight color.

The agency's traditional means for postmarket assurance of product safety is the collection and analysis of a sample. However, as discussed in section IV.A.1.b. of this document, suitable analytical methodology is not available to identify and quantify all potentially harmful impurities that may be present in lakes. Therefore, the agency tentatively concludes that the premarket controls afforded by the certification requirement are necessary to allow FDA to verify that the conditions for safe use of lakes are being met. Therefore, the agency is proposing to list lakes in part 74 as color additives subject to certification.

Certification will allow the agency to confirm, before a lake is marketed, that only safe and suitable components have been used to prepare it; that any batches of straight color used in the lake were previously certified; and that the straight-color component of the lake has not degraded during manufacture or repacking. The agency tentatively concludes, however, that not all aspects of the current batch certification procedure are necessary to accomplish these objectives, and is proposing a simplified procedure for certifying batches of lakes. This proposed procedure is discussed in section VI.B. of this document.

The agency is specifically requesting, as comments on this proposal, comments on the usefulness of its proposed certification procedure for the intended purpose of protecting the public health.

D. Provisions of Proposed § 74.50 Lakes for Use in Foods

The agency is proposing new § 74.50 to list lakes permanently for use in foods as color additives subject to certification. Section 74.50(a)(1), (a)(2), and (a)(3) would designate the components permitted for use in lakes for coloring food. These paragraphs would authorize the use of certified batches of one or more of the straight colors FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, FD&C Yellow No. 5, FD&C Yellow No. 6, and FD&C Red No. 40; the substratum alumina that either conforms to the requirements for alumina under § 73.1010(a)(1) and (b), or is a suspension in water of precipitated aluminum hydroxide prepared from aluminum sulfate that meets the requirements of the Food Chemicals Codex 2d ed. (1972) and sodium carbonate or sodium hydroxide that meets the requirements of the Food Chemicals Codex 3d ed. (1981); and precipitants that form the aluminum cation (Al^{+3}) and the anion chloride (Cl^{-1}) or sulfate (SO_4^{-2}).

Proposed § 74.50(a)(4) would provide that only diluents that are permitted in mixtures of straight colors for food use may be used in color additive mixtures containing lakes for such use.

Proposed § 74.50(b) would prescribe the following specifications for lakes for food use: Lead (not more than 10 ppm), arsenic (not more than 3 ppm), mercury (not more than 1 ppm). It would also state that lakes shall be free from impurities other than those named in the specifications, to the extent that such impurities may be avoided by CGMP.

Proposed § 74.50(c)(1) would permit the use of lakes in foods generally, except in foods subject to a standard of identity that does not authorize such use. The proviso relating to standardized foods would clarify that authorization for use of lakes in this regulation does not take precedence over any restrictions on color additive use in a food standard regulation.

Currently, all the straight colors authorized for use in lakes for food use are approved for the same food uses. Because this may not always be the case, however, proposed § 74.50(c)(2) would restrict the use of a lake manufactured from more than one straight color to those uses common to all of the straight colors in the lake.

Proposed § 74.50(d) would identify each lake made as prescribed in § 74.50(a) as a listed color and would prescribe the formation of its listed name from the names of the certified straight colors present in the lake (in descending order of predominance), followed by the name of the cation of the precipitant (aluminum) and followed by the words ''lake on alumina.'' The anion component of the precipitant would not be included in the name of the lake because this anion is removed during processing under conditions of CGMP and is not a component of the final lake.

Proposed § 74.50(e)(1) would require that the label of the lake and of any mixtures prepared from it for coloring purposes conform to the requirements of § 70.25. Proposed § 74.50(e)(2) would require that the label of food products that contain a lake declare the presence of the lake in accordance with § 101.22(k) (21 CFR 101.22(k)). Proposed § 74.50(e)(3) would require that butter, cheese, and ice cream that contain a lake of FD&C Yellow No. 5 or FD&C Yellow No. 6 be labeled in accordance with § 101.22(k)(1). These proposed labeling provisions are discussed more fully in sections VI.C.2. and VI.C.3. of this document.

Proposed § 74.50(f) would require that all batches of lakes be certified in accordance with proposed regulations in part 80.

V. Safety Review and Proposed Actions for Lakes for Use in Drugs and Cosmetics

A. Review of Components of Lakes for Use in Drugs and Cosmetics

The current provisional listing regulations for lakes for use in drugs and cosmetics generally (§ 82.1051) and for use in external drugs and cosmetics only (§ 82.2051) provide for use of the following components: (1) The straight colors FD&C Blue No. 1 (§ 82.101), FD&C Blue No. 2 (§ 82.102), FD&C Green No. 3 (§ 82.203), FD&C Yellow No. 5 (§ 82.705), FD&C Yellow No. 6 (§ 82.706), D&C Blue No. 4 (§ 82.1104), D&C Green No. 5 (§ 82.1205), D&C Green No. 6 (§ 82.1206), D&C Orange No. 4 (§ 82.1254), D&C Orange No. 5 (§ 82.1255), D&C Orange No. 10 (§ 82.1260), D&C Orange No. 11 (§ 82.1261), FD&C Red No. 4 (§ 82.304), D&C Red No. 6 (§ 82.1306), D&C Red No. 7 (§ 82.1307), D&C Red No. 17 (§ 82.1317), D&C Red No. 21 (§ 82.1321), D&C Red No. 22 (§ 82.1322), D&C Red No. 27 (§ 82.1327), D&C Red No. 28 (§ 82.1328), D&C Red No. 30 (§ 82.1330), D&C Red No. 31 (§ 82.1331), D&C Red No. 33 (§ 82.1333), D&C Red No. 34 (§ 82.1334), D&C Red No. 36 (§ 82.1336), D&C Violet No. 2 (§ 82.1602), D&C Yellow No. 7 (§ 82.1707), D&C Yellow No. 8 (§ 82.1708), D&C Yellow No. 10 (§ 82.1710), and Ext. D&C Yellow No. 7 (§ 82.2707a); (2) the substrata alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, and calcium carbonate; (3) precipitants containing the cations sodium (Na^{+1}), potassium (K^{+1}), aluminum (Al^{+3}), barium (Ba^{+2}), calcium (Ca^{+2}), strontium (Sr^{+2}), and zirconium (Zr^{+4}). Additionally, the lakes of FD&C Red No. 40 prepared with the substrata and precipitants listed above are permanently listed in §§ 74.1340 and 74.2340.

The identity and specifications for the straight colors used to prepare lakes are provided in the regulations cited above and generally cross-reference the requirements of the permanent listing for the straight color in part 74. As to substrata, § 82.3 defines three of the substrata used in lakes (alumina, blanc fixe, gloss white), but provides no specifications for the materials to be used. Part 82 does not identify or prescribe specifications for other substrata (clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, and calcium carbonate) for lakes for drug or cosmetic use, or for the precipitants to be used in the preparation of these lakes.

1. Straight Colors

a. *Identity and uses.* As discussed in sections III.C.1. and III.C.6.a. of this document, the agency has tentatively concluded that several of the straight colors currently listed for use in lakes for coloring drugs and cosmetics either do not form lakes (D&C Red No. 17, D&C Red No. 30, D&C Red No. 36, D&C Violet No. 2, and D&C Green No. 6) or were not present in any batch of lake certified for drug or cosmetic use before the enactment of the 1960 amendments (D&C Orange No. 11, D&C Yellow No. 7, D&C Yellow No. 8, and D&C Green No. 5). The proposed termination of the provisional listing of these straight colors for use in lakes would mean that lakes of these straight colors would no longer be permitted for coloring drugs and cosmetics. (See Table 1 in section III.C. of this document for a summary of the current and proposed regulatory status of straight colors addressed in this rulemaking.)

The agency has already reviewed the identity and safety of the remaining straight colors currently permitted as components of lakes for coloring drugs and cosmetics, either as part of its scientific review of provisionally listed straight colors or in response to petitions for the review of new color additives (§ 71.1). On the basis of these reviews, the agency concluded that these straight colors are safe for use in drugs and cosmetics and issued regulations in part 74 permanently listing them for such uses. The agency is proposing to continue to permit the use of these straight colors as components of lakes for use in drugs and cosmetics, subject to the exceptions and proposed requirements discussed below.

In the Federal Register of September 30, 1975 (40 FR 44812), the agency restricted the provisional listing of FD&C Blue No. 2 to uses in foods and ingested drugs, the uses for which a petition had been filed for the permanent listing of the color additive. In the Federal Register of February 4, 1983 (48 FR 5252), the agency published a final rule permanently listing FD&C Blue No. 2 for use in food (§ 74.102) and ingested drugs (§ 74.1102). However, the provisional listing for the lake of FD&C Blue No. 2 (§ 82.102) was not amended accordingly. Therefore, despite the lack of a listing in part 74 authorizing the use of FD&C Blue No. 2 in cosmetics, the provisional listing regulations still permit the use of lakes of FD&C Blue No. 2 in cosmetics. Proposed § 74.2050 would correct this inconsistency by excluding FD&C Blue No. 2 from the straight colors permitted as components of lakes for cosmetic use.

The lakes of D&C Red No. 34 are provisionally listed in part 82 for use in drugs and cosmetics without any restrictions. However, the straight color is listed in part 74 for external drug and external cosmetic uses only (§§ 74.1334 and 74.2334), based on the agency's safety evaluation of the straight color. The proposed permanent listings for lakes for drug and cosmetic use (§§ 74.1050 and 74.2050) would correct this inconsistency by limiting the use of a lake to the use(s) permitted for the straight-color component(s) of the lake. Thus, under the proposed regulations, any lake containing D&C Red No. 34 would be allowed for use only in externally applied drugs and externally applied cosmetics.

b. *Use of previously certified batches.* Currently, under §§ 82.1051 and 82.2051, manufacturers may use uncertified batches of straight colors to

prepare most lakes for drug and cosmetic use. The resulting lake is then subject to batch certification. The exceptions are the lakes of D&C Red No. 33 (§ 82.1333), D&C Red No. 36 (§ 82.1336), and FD&C Yellow No. 6 (§ 82.706), which must be prepared from previously certified batches of the straight color. (As discussed in section III.C.1. of this document, the agency is proposing to terminate the listing of D&C Red No. 36 as a straight-color component of a lake for drug or cosmetic use because it does not contain a salt-forming group.)

For the reasons discussed in section IV.A.1.b. of this document, the agency tentatively concludes that the lack of adequate analytical methods to determine levels of intermediates and other impurities in lakes prepared from uncertified batches of straight colors precludes the agency from prescribing conditions of safe use for lakes prepared from uncertified batches of straight colors. Accordingly, the agency is proposing to require that lakes for use in drugs and cosmetics, including externally applied drugs and cosmetics, be prepared from certified batches of straight colors.

As discussed above, under current regulations the lakes of many D&C straight colors are prepared from uncertified batches of the straight colors. However, lakes of D&C Red Nos. 6, 7, 31, and 34 are commonly produced in situ (a process described in section I. of this document). In FY–95 (Ref. 18), lakes of these straight colors represented about 55 percent of the total quantity of D&C lakes certified. The agency recognizes that its proposal to require the use of certified batches of straight color to prepare lakes for coloring drugs and cosmetics would, in effect, prohibit use of the in situ process for preparing lakes. However, as noted above, the reason for this proposed requirement is that the safety of lakes prepared from uncertified batches of straight color (including lakes prepared in situ) has not been demonstrated. Specifically, the agency is not aware of the existence of any methods that may be used to demonstrate that lakes produced by the in situ process meet the specifications for impurities, including carcinogenic constituents (e.g., para-toluidine in D&C Red Nos. 6 and 7), in the listing regulation for the straight color. Because FDA has the responsibility to ensure that color additives in foods, drugs, and cosmetics are safe for their intended uses, the fact that no methods that allow the safety of lakes produced in situ to be demonstrated appear to be available leads the agency to propose that use of the in situ method be discontinued. FDA recognizes, however, that the potential costs associated with this proposed action may be considerable, and therefore solicits proven methodology for analysis of the lake for the impurities specified in the listing regulation for the straight color. If such information is received in response to this proposal, the need to prohibit the use of lakes prepared by the in situ process will be obviated.

c. *Stability*. The straight colors that FDA proposes to permit as components of lakes for drug or cosmetic use fall into the following eight groups, based on chemical structure (Refs. 16 and 17): Triphenylmethane (FD&C Blue No. 1, FD&C Green No. 3, D&C Blue No. 4); pyrazolone (FD&C Yellow No. 5); monoazo (FD&C Red No. 4, FD&C Red No. 40, FD&C Yellow No. 6, D&C Orange No. 4, D&C Red No. 6, D&C Red No. 7, D&C Red No. 31, D&C Red No. 33, and D&C Red No. 34); indigoid (FD&C Blue No. 2); fluoran (D&C Orange No. 5, D&C Orange No. 10, D&C Red No. 21, and D&C Red No. 27); xanthene (D&C Red No. 22 and FD&C Red No. 28); quinoline (D&C Yellow No. 10), and nitro (Ext. D&C Yellow No. 7). In FY–95, D&C lakes accounted for approximately 20 percent of the total poundage of lakes certified (Ref. 18). Of the D&C lakes certified in FY–95, approximately 55 percent were lakes of the monoazo dyes (primarily lakes of D&C Red Nos. 6 and 7), about 20 percent were lakes of the fluoran and xanthene dyes (primarily lakes of D&C Red Nos. 21 and 27), and about 15 percent were lakes of quinoline dye (D&C Yellow No. 10). No batches of lakes of the nitro dye (Ext. D&C Yellow No. 7) were certified in FY–95.

Section IV.A.1.c. of this document sets forth the agency's evaluation of data confirming the stability of certain straight colors in the triphenylmethane, pyrazolone, monoazo and indigoid classes during the laking process. This information includes data received from CTFA in response to the 1979 NOI (Ref. 19), data generated by FDA (Ref. 21), and published studies (Refs. 17 and 22). In addition to these data, the agency received a preliminary stability study for two additional lakes prepared from monoazo dyes (FD&C Red No. 4 and D&C Orange No. 4) (Ref. 26). The study, which was conducted by a color additive manufacturer, compared the levels of total color, uncombined intermediates, and subsidiary color in a certified batch of each straight color to the levels of these materials in an aluminum lake prepared from the batch. The study found no evidence that the straight color degraded during manufacture of the lake.

Based on its evaluation of all these data, the agency tentatively concludes that when prepared in accordance with CGMP,straight colors in the monoazo, triphenylmethane, pyrazolone, and indigoid classes do not degrade significantly during preparation of lakes for use in drugs or cosmetics.

The agency received no studies evaluating the stability of the straight colors in the fluoran, xanthene, quinoline, or nitro groups during the laking process. However, the agency has reviewed certification records for batches of lakes made from straight colors in the fluoran, xanthene (Ref. 27), and quinoline (Ref. 28) classes. The agency has not certified a batch of lake of Ext. D&C Yellow No. 7 since 1975; therefore, no recent certification data are available for lakes of Ext. D&C Yellow No. 7.

The lakes of straight colors in the fluoran, xanthene, and quinoline groups are not required to be prepared from certified batches of straight color. Nevertheless, for lakes of the quinoline dye, D&C Yellow No. 10, the agency determined that one manufacturer used certified lots of D&C Yellow No. 10 to prepare the lake. The agency evaluated certification reports for the 36 such batches of D&C Yellow No. 10 lake that were certified in FY–95. The agency compared the levels, adjusted for total color content of the lake, of one intermediate (24 batches) and one subsidiary color (36 batches) in the batches certified to the levels permitted for these impurities in the straight color. The agency also determined total color accountability for all 36 batches. As discussed in section IV.B.5. of this document, the total color accountability was determined by comparing the actual total color content of each batch of lake with the range of estimated total color content for the same batch. The actual total color content of the batch of lake was determined during certification of the batch. The range of expected total color content of the lake was determined from the amount (weight) of straight color in the batch, multiplied by the range of expected total color content of the batch of straight color (as a percentage), and divided by the weight of the batch of lake. The lower limit of the range of expected total color content of the straight color was the minimum total color permitted by the applicable specification in the listing regulation for the straight color. The upper limit of the range was assumed to be 100 percent.

All but one of the batches contained levels of the intermediate and subsidiary color that, adjusted for total color content of the lake, were within the limit set by the specification for the

straight color. These data show that it is technologically feasible to prepare lakes of D&C Yellow No. 10 from certified batches of straight color without significant increases in impurities derived from the straight color. Over 40 percent of the batches had a total color content within the theoretical range of expected color content. The data showed that, after an adjustment for the total color content of the lake, the levels of sulfonated quinaldines, which are presumptive products of decomposition, remained within the specification limit for the straight color. Therefore, the agency tentatively finds that the data are adequate to conclude that there is no significant degradation of D&C Yellow No. 10 during laking under conditions of CGMP.

The agency also evaluated FY–95 certification reports for lakes of the fluoran and xanthene straight colors. These lakes were all prepared from uncertified batches of straight color. To make its evaluation as accurate as possible, the agency compared levels (adjusted for total color content of the lake) of impurities found in the lakes to the maximum levels permitted for the same impurities in certified batches of straight color. The agency combined the data from the fluoran and xanthene classes of lakes because, during the laking process, the lactone group in the xanthene dyes is converted to the corresponding salt. Therefore, lakes of straight colors from the xanthene class are structurally identical to the lakes of comparable straight colors from the fluoran class.

The agency evaluated the certification reports from the 104 batches of lakes of the fluoran and xanthene straight colors that had been certified in FY–95, including 16 reports for lakes of the xanthene straight colors D&C Red No. 22 (3 batches) and D&C Red No. 28 (13 batches) and 88 reports for lakes of the fluoran straight colors D&C Orange No. 5 (4 batches), D&C Red No. 21 (23 batches), and D&C Red No. 27 (61 batches). The agency compared the levels (adjusted for total color content of the lake) of three intermediates (55 batches) and one subsidiary color (104 batches) in these batches to the levels of these impurities permitted by the specifications in the listing regulation for the straight color. The agency also determined the total color accountability for 104 batches. (The theoretical range of expected total color content for these batches of lakes was determined in the same manner as described above for batches of D&C Yellow No. 10 lakes.) All but four of the batches contained levels of the intermediates and subsidiary color that, after adjusting for the total color content of the batch, met the specifications for the straight color. These data show that it is technologically feasible to prepare lakes of the fluoran and xanthene straight colors without significant degradation of the straight color. Over 60 percent of the batches had a total color content that was within the theoretical range of expected color content. The analyses showed that, after adjustment for the total color content of the lake, levels of the subsidiary colors tribromofluoresceins (D&C Red Nos. 21 and 22) and the lower halogenated fluoresceins (D&C Red Nos. 27 and 28), which are prime indicators of possible dehalogenation (a decomposition reaction) of the parent compound, remained within the applicable specifications for the straight color. Therefore, the agency tentatively finds that the data are adequate to conclude that no significant degradation of these straight colors occurs during preparation of lakes under conditions consistent with CGMP.

The agency tentatively concludes that the available information provides sufficient evidence for the stability of the straight-color component of lakes prepared from colors in the monoazo, pyrazolone, triphenylmethane, indigoid, fluoran, xanthene, and quinoline classes. Although the agency has not evaluated data for all of the straight colors that FDA is proposing to approve as components of lakes for drug and cosmetic use, the agency tentatively concludes that the available information is adequate to conclude that there is no significant degradation of straight colors in these classes during the preparation of lakes in accordance with CGMP.

The agency has no data on the stability of the nitro straight color, Ext. D&C Yellow No. 7, during the laking process. No lakes of this straight color were certified in FY–95; the last batch of this lake was certified by the agency in 1975. Based on the absence of data concerning the stability of Ext. D&C Yellow No. 7 during the laking process, the agency tentatively concludes that it has insufficient data to ensure the safety of lakes prepared with Ext. D&C Yellow No. 7. Therefore, the agency is not proposing to permit the use of Ext. D&C Yellow No. 7 as a component of lakes for drug or cosmetic use. Consequently, the proposed termination of the provisional listings of lakes (see section VI.A.2. of this document) would remove the listing for lakes of Ext. D&C Yellow No. 7. Anyone interested in the permanent listing of lakes of Ext. D&C Yellow No. 7 should submit, as a comment on this proposal, data showing the stability of Ext. D&C Yellow No. 7 during the laking process. If data on the stability of Ext. D&C Yellow No. 7 lakes are received as a comment on this proposal, the agency will consider permanently listing the lakes of Ext. D&C Yellow No. 7 in the final rule.

The agency has also considered the safety evaluations for the straight colors discussed above. Based on these safety evaluations and the data showing the stability of straight colors when the laking process is conducted in accordance with CGMP, the agency tentatively concludes that, when lakes are prepared under conditions of CGMP, the certified batches of straight colors listed in proposed §§ 74.1051 and 74.2051 are safe for use in lakes for the same drug and cosmetic uses as part 74 allows for the straight colors. Therefore, the agency is proposing to permit certified batches of these straight colors as components of lakes for drug or cosmetic use.

As discussed in section IV.A.1.c. of this document, the agency is not proposing to establish a definition of CGMP for the preparation of lakes. Rather, FDA is proposing to permit any manufacturing method that ensures that straight colors do not significantly degrade during laking.

d. *Use of more than one straight color in a lake.* For the reasons discussed in section IV.A.1.d. of this document, the agency is also proposing to permit the preparation of a lake from certified batches of more than one straight color.

2. Substrata

a. *Regulatory approach.* The agency is proposing to include the following in its permanent listing regulations for lakes for drug and cosmetic use as substrata permitted for preparing such lakes: alumina, barium sulfate, kaolin, titanium dioxide, zinc oxide, talc, aluminum benzoate, calcium carbonate, and rosin. In addition, gloss white will also be permitted, although not explicitly listed in the regulations, because FDA is proposing to allow combinations of substrata. Thus, all of the substrata currently permitted as components of lakes for drug and cosmetic use under §§ 82.1051 and 82.2051, the provisional listing regulations, will continue to be permitted under the proposed regulations.

Ordinarily, the agency establishes identity and specification requirements for the color additive, rather than for the components used to make the color additive. However, because of the unique characteristics of lakes, the agency is proposing to regulate them under a broadly based, flexible system that permits the use, in drug and

cosmetic products, of lakes that may contain a variety of components at varying levels. As noted above in section V.A.1.b. of this document, the agency is proposing to establish quality requirements (identity and specifications) for the straight-color components of lakes by requiring the use of certified batches of straight colors to prepare lakes. To ensure the safety of lakes prepared with the substrata listed above, and at the same time to permit manufacturers the continued flexibility to prepare lakes using any one or mixtures of these substrata at varying levels, the agency is proposing to establish quality requirements (identity and specifications) for these substrata or their components. In this way, the agency can ensure the safety of substrata used to prepare lakes without setting rigid specifications for the finished lake to limit impurities in substrata, which may be present at varying levels in a lake, and without requiring analysis of the lake itself for these impurities.

b. *Alumina.* In section IV.A.2. of this document, the agency reviewed the identity and safety of alumina, and tentatively concluded that alumina is safe as a substratum in lakes for food use. Furthermore, alumina is listed in § 73.1010 as a color additive for use in drugs generally at levels consistent with CGMP. Based on its review of the use of alumina as a substratum in lakes for food use and on the listing of alumina as a color additive safe for general use in drugs, the agency tentatively concludes that alumina is also safe for use as a substratum in lakes for drug and cosmetic use, provided that it either conforms to the identity and specification requirements in § 73.1010 (a)(1) and (b), or is a suspension in water of precipitated aluminum hydroxide prepared from aluminum sulfate and sodium carbonate or sodium hydroxide that meet the requirements of Food Chemicals Codex 2d ed. (1972) (aluminum sulfate) or Food Chemicals Codex 3d ed. (1981) (sodium carbonate and sodium hydroxide).

c. *Barium sulfate (blanc fixe).* Section 82.3(h) defines blanc fixe as ''a suspension in water of precipitated barium sulfate.'' The definition provides no quality requirements for blanc fixe as a substratum. This definition covers both preformed barium sulfate that is subsequently suspended in water and barium sulfate that is prepared in situ, without subsequent recovery and drying.

The United States Pharmacopeia 23d ed. (1990) (USP) defines barium sulfate as ''$BaSO_4$ 233.39; sulfuric acid, barium salt (1:1); Barium sulfate (1:1) [7727–43–7]'' and provides specifications. The act recognizes the USP as an official drug compendium whose specifications are applicable to drug uses of substances listed therein (21 U.S.C. 321(g)(1)(a) and 351(b)). Although the USP specifications for barium sulfate and other compounds discussed below that are recognized by the USP are not directly applicable for purposes of this proposal, the agency tentatively concludes that the USP specifications for these compounds when used as drugs are also appropriate for these compounds when they are used as substrata for lakes to color drugs.

The agency has approved barium sulfate for use in adhesives (§ 175.105) and as a colorant for food-contact use (§§ 178.3297 (21 CFR 178.3297) and 176.170(b)(2)). As part of the current rulemaking, the agency also evaluated data relating to the safety of ingested and dermal uses of barium sulfate, and found no reports in the scientific literature of adverse effects resulting from topical use of barium sulfate. Moreover, scientific data establish that barium sulfate is highly insoluble. For example, the CRC Handbook of Chemistry and Physics (59th ed., 1978) reports that precipitated blanc fixe ($BaSO_4$) has a solubility in water of 0.246 milligram (mg)/100 gram (g) at 26 °C and 0.4113 mg/100g at 100 °C and 60 mg/100g in 3 percent HCl. Consequently, its absorption and toxicity are low. However, to provide further assurance of safety, the agency is proposing to retain the current specification for soluble barium of not more than 0.05 percent in lakes that contain a barium salt (§ 82.5(b)(3)). The agency tentatively concludes that barium sulfate that meets the requirements of the USP is safe for use as a substratum in lakes for drug and cosmetic use (Ref. 13).

The definition in § 82.3(h) for blanc fixe and the definition in § 82.3(i) for gloss white (a suspension in water of co-precipitated aluminum hydroxide and barium sulfate) suggest that barium sulfate may be prepared in situ either alone or with alumina during the manufacture of lakes. The International Pharmacopoeia 3d ed. (1979) describes the preparation of barium sulfate suspension by mixing barium chloride solution, sulfate-free ethanol, and potassium sulfate solution. The WHO's Specifications for Reagents Mentioned in the International Pharmacopoeia (1963) describes barium chloride and potassium sulfate and provides specifications for each. However, the agency has no information to confirm that the International Pharmacopeia method and the identity and specifications for barium chloride in the WHO publication represent CGMP for preparing barium sulfate in situ as substrata for lakes for drug or cosmetic use. Therefore, the agency requests comments on appropriate methodology for the in situ preparation of barium sulfate as a substratum, and on identity requirements and specifications for reagents used to prepare this substratum. If such comments are received and the information provided is satisfactory, the agency will list barium sulfate prepared in situ as a substratum in lakes for use in drugs and cosmetics.

The agency is also proposing to substitute the name ''barium sulfate'' for ''blanc fixe.'' CTFA's comment on the 1979 NOI suggested this change in terminology. The agency notes that, in the past, the name ''blanc fixe'' was typically used to identify the substratum composed of barium sulfate in requests for certification of lakes. However, more recently, the name typically used for this substratum in requests for certification is ''barium sulfate.'' Therefore, the agency agrees with CTFA's comment and is proposing to substitute the name ''barium sulfate'' for the name ''blanc fixe.''

d. *Gloss white.* Section 82.3(i) defines gloss white as ''a suspension in water of co-precipitated aluminum hydroxide and barium sulfate''. As discussed above, the agency is proposing to permit both alumina and barium sulfate as substrata in lakes for drug or cosmetic use.

Therefore, the agency is proposing not to list gloss white as a substratum in lakes for drug and cosmetic use, because the proposed regulations provide for combinations of substrata.

e. *Kaolin (clay).* In the 1979 NOI, the agency stated that the term ''clay'' does not adequately identify the chemical structure of this material. The NOI requested comments identifying the material and suggesting specifications to ensure its safe use as a substratum in lakes. CTFA's comment, submitted in response to the 1979 NOI, identified kaolin as the substratum material used in lakes.

The USP (23d ed., 1995) defines kaolin as ''a native hydrated aluminum silicate, powdered and freed from gritty particles by elutriation,'' and provides specifications. The agency has affirmed clay (kaolin) as GRAS in § 186.1256 as an indirect food ingredient. Section 186.1256 identifies clay (kaolin) as hydrated aluminum silicate ($Al_2O_3.2SiO_2.nH_2O$) and provides a CAS Registry number of 1332–58–7.

The agency has reviewed data relating to the safety of ingested and dermal uses of kaolin and bentonite (a related

mineral containing magnesium aluminum silicate). These data included data developed for the GRAS review of these compounds and data in a color additive master file, which included dermal toxicity data. The agency also considered a 90-day feeding study on magnesium aluminum silicate.

Based on its review, the agency finds that kaolin is inert when applied externally and is not absorbed by the gastrointestinal tract. A search of the scientific literature revealed no reports of adverse effects resulting from topical use of kaolin. Therefore, the agency tentatively concludes that kaolin that meets USP specifications is safe for use as a substratum in lakes for drug and cosmetic use (Ref. 13).

f. *Titanium dioxide.* The color additive regulation for titanium dioxide (§ 73.575) identifies titanium dioxide as ''synthetically prepared TiO_2'' and provides specifications. Titanium dioxide is listed as a color additive exempt from certification for use in food (§ 73.575), in drugs generally (§ 73.1575), in cosmetics generally (§ 73.2575), and in certain medical devices (§ 73.3126). The USP (23d ed., 1995) recognizes titanium dioxide, defines it as ''TiO_2 79.88; Titanium oxide (TiO_2); Titanium oxide (TiO_2) [13463–67–7],'' and provides specifications.

The agency has evaluated the available data relating to the safety of ingested and dermal uses of titanium dioxide, including data supporting its use as a color additive, and more recent genetic and chronic toxicity studies in rats and mice. Based on these data, the agency tentatively concludes that titanium dioxide that meets the requirements of § 73.575 (a)(1) and (b) is safe for use as a substratum in lakes for drug and cosmetic use (Ref. 13).

g. *Zinc oxide.* The color additive regulation for zinc oxide (§ 73.1991) identifies zinc oxide as ''a white or yellow-white amorphous powder manufactured by the French process (described as the indirect process whereby zinc metal isolated from the zinc-containing ore is vaporized and then oxidized).'' Section 73.1991(b) provides specifications for zinc oxide. The USP (23d ed., 1995) recognizes zinc oxide, defines it as ''ZnO 81.39; Zinc oxide; Zinc Oxide [1314–13–2],'' and provides specifications.

Zinc oxide is listed as a color additive exempt from certification for use in externally applied drugs (§ 73.1991) and in cosmetics generally (§ 73.2991). Zinc oxide is also GRAS for use as a dietary supplement (§ 182.5991) and as a nutrient (§ 182.8991).

The agency has evaluated data relating to the safety of ingested and dermal uses of zinc oxide, including a safety review of zinc compounds as food ingredients by the Select Committee on GRAS Substances of the Federation of American Societies for Experimental Biology and the data supporting the safety of zinc oxide as a color additive. Based on these data, the agency tentatively concludes that zinc oxide that meets the requirements of § 73.1991 (a)(1) and (b) is safe for use as a substratum in lakes for drug and cosmetic use (Ref. 13).

h. *Talc.* The color additive regulation for talc (§ 73.1550) identifies talc as ''a finely powdered, native, hydrous magnesium silicate sometimes containing a small proportion of aluminum silicate'' and provides specifications. Talc is a color additive exempt from certification for use in coloring drugs generally (§ 73.1550) and is GRAS for certain indirect food uses (§§ 182.70 and 182.90). The USP (23d ed., 1995) defines talc as ''a native, hydrous magnesium silicate, sometimes containing a small proportion of aluminum silicate,'' and provides specifications.

The agency has evaluated the available data relating to the safety of ingested and dermal uses of talc, including a safety review of silicates (including talc) as food ingredients by the Select Committee on GRAS Substances of the Federation of American Societies for Experimental Biology and the data supporting the safety of talc as a color additive. Based on these data, the agency tentatively concludes that talc that meets the requirements of § 73.1550 (a)(1) and (b) is safe for use as a substratum in lakes for drug and cosmetic use (Ref. 13).

i. *Aluminum benzoate.* During the preparation of a lake with aluminum benzoate as a substratum, aluminum benzoate is produced in situ using benzoic acid and the aluminum cation. The Merck Index (11th ed., 1989) identifies aluminum benzoate as $C_{21}H_{15}AlO_6$ or $Al(C_6H_5COO)_3$ with a molecular weight of 390.30. The USP (23d ed., 1995) recognizes aluminum chloride, aluminum sulfate, and benzoic acid (the components used to prepare aluminum benzoate). The USP (23d ed., 1995) defines benzoic acid as ''$C_7H_6O_2$ 122.12; Benzoic acid; Benzoic acid [65–85–0]'' and provides specifications. The U.S.P. (23d ed., 1995) defines aluminum chloride as ''$AlCl_3$ $6H_2O$; Aluminum chloride, hexahydrate; Aluminum chloride hexahydrate [7784–13–6]; Anhydrous 133.34 [7446–70–0]'' and provides specifications. The USP (23d ed., 1995) defines aluminum sulfate as ''$Al_2(SO_4)_3$ xH_2O (anhydrous) 342.16; Sulfuric acid, aluminum salt (3:2), hydrate; Aluminum sulfate (2:3) hydrate [17927–65–0]; Anhydrous 342.16 [10043–01- 3]'' and provides specifications.

The agency has affirmed benzoic acid (§ 184.1021) and sodium benzoate (§ 184.1733) as GRAS for use in food as flavoring agents and adjuvants and as antimicrobial agents. In addition, the standard of identity for margarine (21 CFR 166.110) permits the use of the sodium, potassium, and calcium salts of benzoic acid as preservatives. The agency has also reviewed safety data on the ingested and dermal uses of benzoic acid and benzoates, including a safety review of benzoic acid and benzoates as food ingredients by the Select Committee on GRAS Substances of the Federation of American Societies for Experimental Biology and information identified in a search of the scientific literature published from 1981 to 1987 on benzoic acid and benzoates. The agency's review found no reports of adverse toxicological effects of ingested or topically administered benzoic acid.

The agency's evaluation of the safety of aluminum salts, including aluminum chloride and aluminum sulfate, is discussed in section IV.A.2. of this document under the safety of alumina as a substratum in lakes for food use.

Based on these data, the agency tentatively concludes that aluminum benzoate prepared from benzoic acid and aluminum chloride or aluminum sulfate that meet the USP specifications for these compounds is safe for use as a substratum in lakes for drug and cosmetic use (Ref. 13).

j. *Calcium carbonate.* The color additive regulation for calcium carbonate (§ 73.1070) identifies calcium carbonate as ''a fine, white, synthetically prepared powder consisting essentially of precipitated calcium carbonate ($CaCO_3$).'' Calcium carbonate is listed as a color additive exempt from certification for use in drugs generally (§ 73.1070). Calcium carbonate has also been affirmed as GRAS for general food use (§ 184.1191) and is GRAS for dietary supplement use (§ 182.5191).

The agency has evaluated the available data relating to the safety of ingested and dermal uses of calcium salts, including calcium carbonate. These data, including a safety review of calcium salts as food ingredients by the Select Committee on GRAS Substances of the Federation of American Societies for Experimental Biology and data supporting the safety of calcium carbonate as a color additive, establish that calcium is ubiquitous in nature and

that its salts are commonly found in food. Based on its review, the agency tentatively concludes that calcium carbonate that meets the requirements of § 73.1070 (a)(1) and (b) is safe for use as a substratum in lakes for drug and cosmetic use (Ref. 13).

k. *Rosin.* ''Rosin'' is a generic term encompassing a variety of substances that may vary considerably in their composition. For example, the Merck Index (11th ed., 1989) defines rosin as ''Residue left after distilling off the volatile oil from the oleoresin obtained from'' various species of *Pinus.* Gum rosin is obtained from the oleoresin of living pine trees and wood rosin is extracted from the wood of the stumps of pine trees. Another type of rosin is tall oil rosin, a by-product of the wood pulp industry. The CRC Handbook of Chemical Synonyms and Trade Names (8th ed., 1978) also lists rosin under its synonym 'colophony' and defines it as ''The residue which remains after the volatile oils have been removed by the distillation of crude turpentine.'' The CRC Handbook lists several varieties of rosins obtained from different species of pine.

Rosin is approved as a food additive for use as a natural flavoring substance for alcoholic beverages (§ 172.510). Various rosins and rosin derivatives are approved for other food additive uses: In coatings of fresh citrus fruits (§ 172.210) and as plasticizing materials or softeners in chewing gum base (§ 172.615). Rosin and rosin derivatives are approved as diluents in color additive mixtures for use in inks for marking food supplements in tablet form, gum, confectionery, fruit, and vegetables (§ 73.1(b)) and, by reference, in inks for branding pharmaceutical forms (§ 73.1001(a)(2)). Numerous rosins and rosin derivatives are approved as indirect food additives (substances that are not added to food directly but that may become part of food through migration from materials in contact with the food) (§ 178.3870).

The agency has evaluated the available data relating to the safety of rosin and related compounds, including data supporting the food additive and color additive diluent uses of rosin and rosin derivatives, and data obtained by the agency from searches of the scientific literature in 1988 and 1994 for information concerning rosin. The agency's literature searches did not find any reports of adverse toxicological effects from ingested rosin. However, many publications reported cases of allergic contact dermatitis and occupational asthma resulting from exposure to certain rosin materials (Ref. 13).

In the 1979 NOI, the agency requested information on the chemical composition of rosin and suggestions for specifications to ensure its safe use in lakes for drug and cosmetic use. CTFA's comment on the 1979 NOI provided general information on rosin, but did not identify the specific types of rosin that are used as substrata in lakes. However, the monograph for rosin in the CTFA International Cosmetic Ingredient Dictionary, 5th ed., 1993 defines rosin as ''the residue left after distilling off the volatile oil from the oleoresin obtained from *Pinus palustris* and other species of *Pinaceae* (Ref. 29). Because this definition clearly identifies gum rosin, and not wood rosin or tall oil rosin, the agency tentatively concludes that the rosin used in cosmetic products is gum rosin.

Based on its review of available data (Refs. 29 and 30), the agency has tentatively identified the rosin used as a substratum in lakes for drug and cosmetic use as gum rosin, and is proposing to define and set specifications for rosin based on this tentative conclusion. It is unclear, however, whether all lake manufacturers who use rosin as a substratum are using gum rosin. Therefore, any manufacturer who uses rosin other than gum rosin that meets the requirements in the proposed regulation as a substratum in lakes for drug or cosmetic use should submit information about the identity and specifications of such rosin as a comment on this proposal. The comment should include the manufacturer's product specifications and any analytical data that establish the identity and purity of the rosin. The agency will consider modifying the identity and specifications for rosin if it receives information to substantiate the safe use of rosin other than gum rosin.

In response to the concerns raised by the agency about the topical safety of rosin lakes, the CTFA submitted reports of numerous human sensitization and photosensitization studies on cosmetic products colored with rosinated lakes of D&C Red No. 6, D&C Red No. 7, and D&C Red No. 34. The studies involved a total of 2,381 subjects for sensitization and 312 subjects for photosensitization; products tested included lipsticks, lip liner, blush, rouge, and nail polish. No skin sensitization/photoallergic reactions were reported in any of the test subjects. The agency tentatively concludes that these studies show that there is little risk of developing a skin sensitization reaction from skin contact with various cosmetic products that contain rosinated color additive lakes at levels found in such products, and, therefore, that use of rosin as a substratum in color additive lakes for external drug and cosmetic use is safe (Ref. 14).

3. Precipitants

a. *Aluminum (Al^{+3}), barium (Ba^{+2}), and calcium (Ca^{+2}) cations.* The safety of salts of the cations aluminum, barium, and calcium is discussed in the safety evaluations of alumina (sections IV.A.2. and V.A.2.b. of this document), barium sulfate (blanc fixe) (section V.A.2.c. of this document), and calcium carbonate (section V.A.2.j. of this document). Based on those evaluations, the agency tentatively concludes that these cations are safe as components of precipitants used in the preparation of lakes for drug and cosmetic use (Ref. 13). However, as stated in the discussion of the safety of barium sulfate as a substratum (section V.A.2.c.), the agency is proposing to retain the current specification for soluble barium (0.05 percent) in lakes for drug or cosmetic use.

b. *Zirconium cation (Zr^{+4}).* Zirconium is a rare earth metal that closely resembles aluminum in pharmacological and chemical properties. The agency has evaluated data relating to the safety of ingested and dermal uses of zirconium salts. These data, including a review of published literature on the toxicity, physiological effects, and medicinal uses of zirconium and its salts, revealed nothing to indicate any likelihood of harm from topical administration or ingestion of low levels of zirconium salts (Ref. 13). Therefore, the agency tentatively concludes that zirconium is safe as a component of precipitants used in lakes for drug and cosmetic use.

c. *Sodium (Na^{+}) and potassium (K^{+}) cations.* The salts of the sodium and potassium cations, sodium chloride and potassium chloride, are ubiquitous in nature. Sodium chloride (table salt) is GRAS (§ 182.1(a)) and potassium chloride has been affirmed as GRAS for food use (§ 184.1622). Most of the permanently listed water-soluble straight colors subject to certification, including all the straight colors used as components of lakes under § 82.51, are sodium salts. By virtue of their GRAS status, sodium chloride and potassium chloride are permitted under § 73.1(a)(1) for use as diluents in color additive mixtures for coloring food, and under § 73.1001(a)(1) and (b) are also permitted for use as diluents in color additive mixtures for coloring ingested drugs and externally applied drugs. Therefore, the agency tentatively concludes that these salts are safe for

use as components of precipitants in lakes for drug or cosmetic use.

d. *Strontium cation (Sr^{+2}).* Strontium is an alkaline earth element and is a metabolic analog of calcium. The agency has evaluated published data on the safety of strontium cation. Because strontium can substitute for calcium, it can influence certain physiological parameters; however, the concentrations required to adversely affect these parameters are significantly higher than the levels encountered when strontium is used as a precipitant in a lake. Based on its review of the published data, the agency tentatively concludes that the use of strontium cation is safe as a component of precipitants used in lakes for drug and cosmetic use (Ref. 13).

e. *Accompanying anions.* In section IV.A.3.c. of this document, the agency considered the safety of soluble chlorides and sulfates as components of precipitants in lakes for food use. As discussed more fully in that section, chloride and sulfate anions are found in many GRAS ingredients. In the safety reviews conducted as part of the GRAS rulemakings for these ingredients, the agency found that ingestion of chlorides and sulfates (in the presence of the accompanying cation) was safe at levels that vastly exceed the possible level of exposure to these anions as components of lakes. Therefore, the agency tentatively concludes that the presence of these anions in lakes prepared for food use is safe (Ref. 13). Furthermore, by virtue of their GRAS status, the salts of chloride and sulfate are permitted under § 73.1(a)(1) for use as diluents in color additive mixtures for coloring food, and under § 73.1001 (a)(1) and (b) are also permitted for use as diluents in color additive mixtures for coloring ingested drugs and externally applied drugs. Therefore, the agency tentatively concludes that these anions are safe for use as components of precipitants in lakes for drug or cosmetic use.

f. *Tentative conclusions.* The agency tentatively concludes that the water-soluble chloride and sulfate salts of aluminum, barium, calcium, zirconium, sodium, potassium, and strontium are safe for use as components of precipitants in the preparation of lakes for drug or cosmetic use. The agency notes that, although these substances are discussed as distinct chemical compounds, the proposal would permit their use in other forms to prepare lakes, provided that no substance or ion that is not provided for in the regulation is introduced. For example, the proposal would allow the use of a precipitant formed in situ from the combination of a listed cation (as the hydroxide) and either hydrochloric or sulfuric acid.

4. Diluents in Color Additive Mixtures Containing Lakes

The agency is not proposing any limitations on the diluents permitted in color additive mixtures for cosmetic use that are made with lakes. The part 74 listings for the straight colors that are components of lakes for cosmetic use do not limit the use of diluents in mixtures for coloring cosmetics. Moreover, no regulation in part 73 specifies safe diluents for cosmetic use. However, the agency notes that cosmetic products containing color additive mixtures are subject to the adulteration provisions of section 601 of the act.

B. Specifications for Lakes for Use in Drugs and Cosmetics

1. Intermediates and Other Impurities Derived from Straight Colors

The provisional listing regulations for lakes for drug or cosmetic use (§§ 82.1051 and 82.2051) contain specifications for ether extracts (not more than 0.5 percent) and intermediates (not more than 0.2 percent) in such lakes. The agency established these specifications to limit the levels of intermediates and other impurities in lakes prepared from uncertified batches of straight colors. However, as discussed in section IV.A.1.b. of this document, proven methodology to analyze all lakes for intermediates and other impurities is not available. Therefore, the agency is proposing to require the use of certified batches of straight colors to ensure safe levels of intermediates and other impurities in lakes. In light of this proposed requirement, the agency tentatively concludes that specifications for ether extracts, intermediates, and subsidiary colors in lakes for drug or cosmetic use are unnecessary to ensure the safety of such lakes.

2. Precipitants

Because lakes are washed when prepared in accordance with CGMP, the agency anticipates that only low levels of water-soluble contaminants from these precipitants will remain in the finished lake. Furthermore, the proposed specifications for the lake would limit the levels of contaminants of toxicological concern (primarily heavy metals) permitted in the end product. However, the agency tentatively concluded in its discussion of barium sulfate as a substratum (section V.A.2.c. of this document) and barium as a precipitant (section V.A.3.a. of this document) that a specification to limit soluble barium in lakes for drug or cosmetic use should be retained to provide an extra margin of safety. Based on these considerations, the agency tentatively concludes that specifications for residues from precipitants used in lakes for drug or cosmetic use, except for soluble barium, are unnecessary.

3. Heavy Metals

As discussed in section IV.B.2. of this document, the manufacturing processes for lakes involve reagents that are sources of potential contamination by metals. Currently, lakes are subject to the following general specifications in § 82.5 for provisionally listed colors for drug or cosmetic use: 20 ppm lead, 2 ppm arsenic, 0.003 percent total heavy metals (except for lead and arsenic), and, for those colors that contain a barium salt, a limit of 0.05 percent on soluble barium. As discussed in section IV.B.2. of this document, FDA is proposing limits for lead, arsenic, and mercury in lakes for food use. The agency tentatively concludes that specifications to limit the levels of lead, arsenic, mercury, and soluble barium are also necessary to ensure safe use of lakes in drugs and cosmetics. The agency is unaware of any other heavy metals that have a significant level of toxicity and that would be expected to occur in lakes. Therefore, the agency tentatively concludes that a general heavy metal specification is unnecessary to ensure the safety of lakes for drug or cosmetic use.

The agency is proposing to maintain the specifications of not more than 20 ppm lead and 0.05 percent soluble barium for lakes for drug or cosmetic use and to raise the arsenic specification from not more than 2 ppm to not more than 3 ppm. The agency is also proposing to include a mercury specification of not more than 1 ppm. The proposed levels for arsenic and mercury are the levels that the agency tentatively concludes are necessary to ensure the safety of color additives used in drugs and cosmetics, based on safety evaluations in rulemakings for the permanent listing of numerous straight colors.

4. Soluble Chlorides and Sulfates

Current §§ 82.1051 and 82.2051 contain a specification that limits the content of the soluble chloride and sulfate anions in lakes for drug and cosmetic use. As noted in section IV.B.3. of this document, most of the water-soluble chloride and sulfate anions are washed out during preparation of the lake under CGMP conditions. In its safety review, the agency found that these anions are safe in foods, drugs, and cosmetics at levels considerably greater than those found in lakes (Ref. 13). Therefore, the agency

tentatively concludes that a specification to limit the levels of soluble chlorides and sulfates is unnecessary to ensure the safety of lakes prepared in conformity with CGMP for drug or cosmetic use.

5. Other Residues

The 1979 NOI requested information on certain other chemicals occasionally used in the laking process, such as citrate, acetate, and surfactants. CTFA's comment did not provide a list of such substances, but stated that the substances used were GRAS. A comment from a color manufacturer identified specific substances that the company uses in the manufacture of lakes and characterized them as food additives or GRAS substances. The company stated that the surfactants were used at very low concentrations and that the nature of the use prevented any significant amount from being present in the final lake.

The agency recognizes that it is impracticable to set specifications for every chemical used in the manufacture of a color additive. The agency generally sets specifications to limit the substances that are normally expected to be present in the final additive, especially those substances that could present a safety hazard at foreseeable levels of exposure. The agency agrees with the comment that the surfactants and other chemicals mentioned are used at low concentrations. The agency further agrees that, because of the washing of lakes during manufacture, these chemicals are unlikely to be present at significant levels in a lake that has been prepared under conditions of CGMP and that is otherwise in compliance with applicable regulations. Therefore, the agency is not proposing specifications for residues of these substances in lakes for drug and cosmetic use.

6. Other Impurities and Contaminants

The agency has tentatively concluded above that specifications to limit the levels of total heavy metals (except lead, arsenic, mercury, and soluble barium), soluble chlorides and sulfates, and residues of other chemicals are unnecessary to ensure the safety of lakes for drug and cosmetic use, as long as a general provision is included in the specifications for lakes to ensure that they are prepared in conformity with CGMP. Therefore, the agency is proposing to continue the requirement in existing § 82.5 that lakes be free from all impurities other than those named in the specifications, to the extent that such impurities can be avoided by CGMP.

C. Certification Requirement

As discussed in section IV.C. of this document, the agency has evaluated the necessity for the certification of lakes and has tentatively concluded that certification is necessary to protect the public health. The simplified procedure the agency is proposing for certification of lakes is described in section VI.B. of this document.

D. Provisions of Proposed Regulations

1. Proposed Section 74.1050 Lakes for Use in Drugs

The agency is proposing a new § 74.1050 to list lakes permanently for use in drugs as color additives subject to certification. Paragraphs (a)(1), (a)(2), and (a)(3) would designate the components permitted for use in preparing lakes for coloring drugs. These paragraphs would permit the use of one or more certified batches of one or more of the color additives FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Red No. 4, FD&C Red No. 40, D&C Blue No. 4, D&C Orange No. 4, D&C Orange No. 5, D&C Orange No. 10, D&C Red No. 6, D&C Red No. 7, D&C Red No. 21, D&C Red No. 22, D&C Red No. 27, D&C Red No. 28, D&C Red No. 31, D&C Red No. 33, D&C Red No. 34, and D&C Yellow No. 10 (see Table 1); one or more of the substrata alumina, aluminum benzoate, barium sulfate, calcium carbonate, kaolin, rosin, talc, titanium dioxide, and zinc oxide; and one or more precipitants that form the cation aluminum (Al^{+3}), barium (Ba^{+2}), calcium (Ca^{+2}), potassium (K^{+}), sodium (Na^{+}), strontium (Sr^{+2}), or zirconium (Zr^{+4}), and the anion chloride (Cl^{-}) or sulfate (So^{4-2}). Paragraph (a)(3) would require that the substrata (except alumina), or for aluminum benzoate, the components of the substrata, conform to the identity and purity requirements of the applicable color additive regulation or, if no such regulation exists, to the requirements of the USP 23d ed. (1995). The paragraph would require that alumina conform to the requirements of § 74.50(a)(3).

Proposed § 74.1050(a)(4) would limit the diluents used in color additive mixtures containing lakes to those diluents that are suitable and that are listed in § 73.1001 as diluents for drug use. This requirement is consistent with the existing requirements for mixtures of color additives for drug use and will ensure that color additive mixtures containing lakes are safe for drug use. As discussed in section III.C.2.b. of this document, the agency is proposing to amend § 73.1001 to permit additional diluents in color additive mixtures for drug use.

Proposed § 74.1050(b) would prescribe the following specifications for lakes for drug use: lead (not more than 20 ppm); arsenic (not more than 3 ppm); mercury (not more than 1 ppm); soluble barium (not more than 0.05 percent). It would also state that such lakes shall be free from impurities other than those named in the specifications, to the extent that such impurities may be avoided by CGMP.

Proposed § 74.1050(c)(1) would restrict the use of a lake to uses common to all of the straight colors in the lake. For example, use of a lake of the straight colors FD&C Red No. 4 and FD&C Blue No. 1 would be limited to externally applied drugs and cosmetics because of the limitations on the use of FD&C Red No. 4. Proposed § 74.1050(c)(2) would also specify that where regulations for the straight color impose quantitative limitations for the use of such straight color in drug products, the amount of such straight color in a lake shall be considered as a part of the total amount of such straight color permitted in a drug product.

Proposed § 74.1050(d) would identify each lake made as prescribed in § 74.1050(a) as a listed color and would prescribe the formation of its name from the names of the straight colors present in the lake (in descending order of predominance), followed by the names of the cations of the precipitants, and followed by the words ''Lake on _____ and _____'' (inserting the listed names of the substrata in descending order of predominance). For example, the name of a lake prepared by the extension of FD&C Yellow No. 5, FD&C Yellow No. 6 and D&C Orange No. 5 on alumina using aluminum chloride as the precipitant would be ''FD&C Yellow No. 5, FD&C Yellow No. 6 and D&C Orange No. 5 Aluminum Lake on Alumina''. The anion component of the precipitant would not be included in the name of the lake because this anion is removed during processing and is not a component of the finished lake.

Proposed § 74.1050(e)(1) would require that the label of the lake and of any mixtures prepared from it for coloring purposes conform to the requirements of § 70.25 of this chapter. Proposed § 74.1050(e)(2) would require that drug products that contain a lake of FD&C Yellow No. 5 comply with the label declaration requirements of § 74.1705(c)(2) and (c)(3). Proposed § 74.1050(e)(3) would require that drug products that contain a lake of FD&C Yellow No. 6 comply with the label declaration requirements of proposed § 74.1706(c)(2). These proposed labeling

provisions are discussed more fully in sections VI.C.2. and VI.C.3. of this document.

Proposed § 74.1050(f) would require that all batches of lakes be certified in accordance with proposed regulations in part 80.

2. Proposed § 74.2050 Lakes for Use in Cosmetics

The agency is proposing new § 74.2050 to list lakes permanently for use in cosmetics as color additives subject to certification. Proposed paragraph (a) would identify the components permitted for use in preparing lakes for coloring cosmetics by incorporating the identity provisions proposed in § 74.1050(a)(1), (a)(2), and (a)(3) for lakes for use in drugs, except that FD&C Blue No. 2 would not be permitted as a straight-color component in lakes for cosmetic use. Proposed § 74.2050(a) also would incorporate the specifications in proposed § 74.1050(b).

Proposed § 74.2050(b) would prescribe the same uses and restrictions for lakes for cosmetic use as proposed for lakes for drug use in § 74.1050(c).

Proposed § 74.2050(c) would identify each lake made as prescribed in § 74.2050(a) as a listed color and would prescribe the formation of its name in the same manner as proposed in § 74.1050(d).

Proposed § 74.2050(d)(1) would require that the label of the lake and of any mixtures prepared from it for coloring purposes conform to the requirements of § 70.25. Proposed § 74.2050(d)(2) would require the ingredient labeling of lakes in cosmetic products to comply with proposed § 701.3(c)(1)(i). These proposed labeling provisions are discussed more fully in sections VI.C.2. and VI.C.3. of this document.

Proposed § 74.2050(e) would require that all batches of lakes be certified in accordance with proposed regulations in part 80.

VI. Other Proposed Actions

A. Removal of Provisional Listings

1. Removal of 21 CFR Part 81

The agency is proposing to remove Part 81 *General Specifications and General Restrictions for Provisional Color Additives for Use in Foods, Drugs, and Cosmetics.* This part was originally issued in 1960 (25 FR 9759, October 12, 1960) to provide for the listing of commercially established color additives permitted for provisional use under the transitional provisions of the 1960 amendments, and to establish conditions for the continued provisional listing of these color additives pending completion of studies required to establish their safety for permanent listing.

Currently, only lakes are listed in § 81.1 *Provisional lists of color additives.* The final rule based on this proposal will remove these entries. When the final rule becomes effective, the section will no longer be necessary. The remaining three sections, § 81.10 *Termination of provisional listings of color additives;* § 81.30 *Cancellation of certificates;* and § 81.32 *Limitations of certificates,* concern past agency actions on provisionally listed color additives and are purely of historical interest, as the color additives referred to in these sections are no longer permitted for use in FDA-regulated products. In addition, after FDA completes action on this proposal and the final rule terminating all provisional color additive listings becomes effective, no further additions to part 81 will be possible. Therefore, the agency is proposing to remove the entire part.

2. Removal of 21 CFR Part 82

The agency is proposing to remove Part 82—*Listing of Certified Provisionally Listed Colors and Specifications.* The purpose of this part was to prescribe the identity, specifications, and uses of provisionally listed color additives. Currently, the regulations in this part apply only to lakes. When the final rule resulting from this proposal becomes effective, all remaining provisional listings in part 82 will terminate. Therefore, the agency is proposing to remove the entire part.

B. Certification Procedure for Lakes

1. Overview

The current requirements and procedures for batch certification of lakes are described in part 80. Under the provisions of § 80.21, a firm that has prepared or repacked a batch of lake submits a request for certification of the batch to FDA. The request provides the name, batch number, and batch weight of the lake or repack; information on storage pending certification; and the uses for which certification is requested. For a newly manufactured batch of lake, the request also provides the name, quantity, and (where applicable) the lot number of the straight color used, the identity of the precipitant used, the identity and quantity of the substratum used, and the identity (name and address) of the manufacturer of the lake. For a repack of a certified batch of lake, the request provides the original lot number, certified color content, and name and address of the source from which the repacker obtained the lake. (See section III.A.7. of this document for the proposed definition of ''repack.'') The request must be accompanied by the required certification fee, which varies according to the type of request and weight of the batch (§ 80.10), and a representative sample from the batch accompanied by any label or labeling intended for use with the batch (§ 80.22).

The agency evaluates the request and analyzes the sample to ensure that they meet the requirements of part 82, including identity, specifications, and uses of the lake. After evaluation of the information in the request and laboratory analysis of the sample, the agency determines whether the request meets the requirements for certification. For those requests that meet these requirements, the agency issues the requester a certificate (§ 80.31). The certificate states the name of the requester, the name of the color additive, the FDA certification lot number, the uses and restrictions that apply to the color additive, and the results of the agency's analyses of the batch. Upon receipt of the certificate, the requester then labels the batch with the certification lot number, the percent total color, uses and restrictions, and other labeling as required in § 70.25. The requester is also required to maintain the batch, both before and after certification, under conditions that ensure that the composition of the batch does not change and that the sample submitted to FDA for certification remains representative of the batch until the batch has been packaged and labeled as required by §§ 70.20 and 70.25 (§§ 80.37 and 80.38). The person to whom the certificate is issued is required to keep complete records showing the disposal of all color additive from the batch covered by the certificate until at least 2 years after disposal of the batch (§ 80.39).

The requirement for certification of lakes and repacks ensures that the agency can identify each firm that manufactures or repacks a lake. Under its inspectional authority, the agency can then inspect these establishments and determine compliance with labeling and storage requirements and verify the disposal of the batch. The regulations enable the agency to ensure the continued safety of lakes and other color additives after certification by establishing conditions (§ 80.32) under which a certificate will expire and the batch will be deemed to be uncertified. In addition, the agency can refuse certification service (§ 80.34) to firms that submit requests for certification but fail to comply with requirements designed to ensure the safety of certified

color additives, including recordkeeping and allowing inspection of the firm's color additive inventory and records.

This batch certification procedure provides the agency with an integrated system for ensuring the safety of lakes for use in foods, drugs, and cosmetics. For each batch of lake certified, the agency maintains, as records, the original request for certification and a copy of the certificate for the batch, which includes the results of agency analysis of the representative sample. The agency's analysis of the representative sample includes tests for total color, heavy metals, and impurities derived from the straight color used to prepare the lake.

As discussed in section IV.C. of this document, the agency has tentatively concluded that many requirements of the current batch certification system are necessary to ensure that lakes are safe for use in foods, drugs, and cosmetics, and thus to protect the public health. However, the agency also tentatively concludes that FDA analysis of a representative sample of the batch is not necessary in light of the other requirements for lakes being proposed. Therefore, the agency is proposing to establish a simplified procedure in § 80.31(b) for certification of batches of lakes and lake repacks. The agency notes that both new batches of lakes and repacks of previously certified batches of lakes would be subject to the new procedure. In subsequent discussion of the proposed certification requirements for lakes, the agency will address requirements for lakes generically and will distinguish between new batches and repacks only when it is necessary to identify specific requirements relating to only one type of batch. In the remainder of this document, the term ''batch of lake'' should be understood to encompass both new batches and repacks.

Under the proposed procedure, certification of a batch of lake would rely on the certificates for the batches of straight colors that are used in the lake, either directly to prepare the lake or indirectly as components of a certified batch of lake that is blended into the new batch. The certification of the batch would also rely on representations by the manufacturer or repacker that the batch complies with the requirements of parts 74 and 80.

The proposed procedure would require that a batch of lake meet the requirements of the proposed listing regulation for the lake in part 74, that the manufacturer of the lake be the same firm that was issued the certificates for all batches of straight color in the batch of lake, and that the firm complete the requirements of proposed § 80.33 for notifying the agency of the firm's claim to certification for the batch. The proposed procedure would also require that the firm submitting the notice maintain records of the composition and disposal of the batch, including the certificates for the straight colors used to make the batch. Repackers would be required to retain proof that the original batch of lake was certified, in lieu of the certificates for the batches of straight color used to prepare the lake. The manufacturer or repacker would also be required to retain a representative sample of the batch.

This proposed procedure would provide for routine agency review of only the information necessary to ensure the use of certified batches of straight color and to verify that the straight color in the lake did not degrade significantly during the laking process. Under this proposed procedure, the agency would not routinely monitor compliance with the remaining requirements for the preparation and repacking of lakes under the regulations in part 74. However, as noted above, the certification of a batch of lake would be based both on the agency's review of the critical factors in lake manufacturing and repacking and on the manufacturer's and repacker's representations of compliance with the remaining requirements. The agency would be able to verify these representations by inspecting the manufacturer's or repacker's records, and violations of the requirements for certification would be addressed under proposed §§ 80.32 and 80.34.

Under the proposed procedure, a manufacturer or repacker of a batch of lake would submit to FDA a notice claiming certification for the batch and providing the information and fee specified in proposed §§ 80.10(c) and 80.33. The notice would provide the same information about the batch that is currently provided in a request for certification under § 80.21(j), or generated by the agency as part of its evaluation of the certification request. However, the person submitting the notice would not be required to submit a representative sample of the batch for analysis by the agency. The agency would review the notice and, if the information in the notice was complete and appeared to comply with the requirements of parts 74 and 80, would issue an acceptance of the notice. Upon FDA's issuance of its acceptance of the notice, the batch covered by the notice would be a certified batch.

As noted above, the proposed certification procedure for batches of lakes and certified lake repacks would not require submission of a representative sample for agency analysis. Instead, the proposed new procedure would require that the manufacturer or repacker of the batch provide certain analyses and maintain certain records for agency inspection. Under the proposed procedure, the agency also would not issue a certificate for the batch. As noted above, the proposed certification procedure would rely on the certificates issued by the agency for the straight-color components of batches of lake and the representations of the manufacturer or repacker about the composition of the batch. Under this proposed procedure, certification of a batch of lake would be complete upon the agency's acceptance of the firm's notice claiming certification. This notice would provide information that would allow the agency to identify the certificates for the straight colors on which the certification of the lake relies and to ensure that the batch otherwise complies with the requirements of parts 74 and 80.

The agency is proposing to continue the application of the current storage and labeling requirements for batches pending certification and after certification (§§ 80.37 and 80.38) to batches of lakes certified under the proposed new procedure.

Amended § 80.39 would continue the application of the current recordkeeping requirements for certified color additives to lakes, including repacks, and would add recordkeeping requirements for lakes only to support the information and affirmations contained in the firm's notice to FDA.

Amended § 80.32 would provide for conditions under which the certification of a batch of lake would expire, and would add a provision to allow a certified color additive, including a lake, to be used in a batch of lake without losing its certification.

Amended § 80.34 would continue the agency's authority to refuse certification service to manufacturers and repackers of lakes who falsify records, obtain certification by fraud, or otherwise abuse the certification system.

The proposed certification procedure would provide a simplified system for assuring the safety of a certified batch of lake. For the reasons discussed in section VI.B.2.b. of this document, preparation of a lake would be limited to the firm issued the certificates for the straight colors used in the batch of lake. For each certified batch of lake, the agency would retain the original notice claiming certification for the batch and a copy of its response to the notice. The notice for each new certified batch of lake would contain the lot numbers for

the batches of straight colors used to prepare the batch of lake. This information would allow the agency to ensure that the batch of lake meets the requirements in part 74. The proposed requirement for submission of a premarket notice claiming certification would ensure that the agency could identify every firm that prepares or repacks certified batches of lakes. Under its inspectional authority, the agency could then inspect these establishments and their records to ensure compliance with the composition requirements of part 74 and the certification requirements of part 80, including the recordkeeping requirements of amended § 80.39. As part of a typical inspection, the agency might look at the facility, verify the records of the disposal of the batch, and check compliance with storage and labeling requirements.

The current batch certification procedure for lakes does not provide for certification of mixtures containing lakes. Color additive mixtures containing lakes are exempted from certification under § 80.35(b), subject to the conditions in that regulation. The agency is proposing to retain this exemption.

2. Certification Requirements

a. *Current provisions for batch certification.* The current requirements for batch certification of color additives in § 80.31 include references to parts 81 and 82. As discussed in section VI.A. of this document, the agency is proposing to delete parts 81 and 82 in this rulemaking. Therefore, the agency is proposing to amend § 80.31 to delete all references to parts 81 and 82.

Currently, § 80.31(a)(2) requires that a certified color additive conform to specifications and other conditions in parts 81 and 82. The section does not make any reference to specifications and other conditions in part 74, however. Because it appears that this omission was an oversight, the agency is proposing to amend § 80.31(a)(2) to add a reference to part 74. This action will clarify that permanently listed straight colors are subject, as a condition of certification, to the specifications and other conditions in part 74 of this chapter.

Currently, § 80.31(b) specifies the conditions under which the agency shall refuse to certify a batch and the procedures for contesting such refusal. The agency is proposing to modify this paragraph to cover the proposed changes in the procedure for certification of lakes. The agency is also proposing to redesignate this paragraph as paragraph (c) to allow the addition of the proposed new procedure in new paragraph (b).

b. *Proposed certification provisions for lakes.* The agency is proposing to add new § 80.31(b) to specify the conditions under which a batch of lake or certified lake repack is a certified batch. Proposed § 80.31(b) would require that a certified batch of lake or certified lake repack meet the specifications and any other conditions set forth in part 74 of this chapter. The agency tentatively concludes that this is an essential condition for certification because proposed §§ 74.50, 74.1050, and 74.2050 specify the conditions under which lakes are safe for use in foods, drugs, and cosmetics.

Proposed § 80.31(b) would also require, as a condition of certification for a batch of lake, that the firm preparing the batch be the same firm that was issued the certificate for each batch of straight color used in the lake. The agency tentatively concludes that this provision is a necessary condition for certification because, under the proposed procedure, certification of a batch of lake relies on the certificates issued for the batches of straight colors that were used to prepare the lake.

Under the proposed procedure, the agency would not issue a separate certificate for the batch of lake. Instead, the certificates for the straight colors in the lake would remain in effect provided that the lake was prepared in accordance with the regulations in part 74, including the requirement of preparation under conditions of CGMP such that the straight color does not significantly degrade. The agency recognizes that during the preparation of a lake, some change in the composition of the straight color inevitably occurs because the color goes from a water-soluble form in the straight color to a water-insoluble form in the lake. However, it is the responsibility of the manufacturer of the lake to prevent avoidable changes in the composition of the straight color so that the certificates for all straight colors used in the lake remain valid. The agency tentatively concludes that the responsibility for assuring the validity of the certificates of the straight colors in a lake should be retained by the firm issued the certificates.

The agency notes that a repacker of a certified lake would not be the same firm that was issued the certificates for the straight-color components of the lake. However, the handling of a lake during repacking is significantly less than during the preparation of the lake because no reprocessing occurs and no chemical reaction takes place; thus, the potential for change in composition is much less. Furthermore, a repack is derived from a single batch of lake, and the agency would keep on file all notices claiming certification for a batch of lake under § 80.31(b) and all agency acceptances of such notices. Therefore, the agency would have the necessary information on the certification of the original batch of lake to compare to the information submitted in a notice claiming certification for a repack of the batch.

Proposed § 80.31(b) would require that a firm that prepares or repacks a batch of lake comply with the notification requirements of § 80.33 as a condition of certification. Proposed § 80.33 would require that the firm submit and obtain FDA acceptance of a notice claiming certification of the batch. The proposed notice would provide FDA with the same information, except for the representative sample of the batch, that is currently provided by the request for certification of a batch of lake or generated by the agency when it analyzes the sample and evaluates the request for certification.

Proposed § 80.31(b) would also require that a firm that prepares or repacks a batch of lake comply with the recordkeeping requirements of § 80.39 as a condition of certification. Currently, § 80.39 requires that the person issued a certificate for a batch of color additive maintain records showing the disposal of all the color additive from the batch covered by the certificate. This section also specifies the types of records required to be kept and the required length of time for keeping the records, as well as requiring that such records be made available to agency representatives. This section further provides the agency access to check the correctness of the records. The agency is proposing to maintain the current recordkeeping requirements for lakes. The agency is also proposing to amend § 80.39 to require additional records that would apply to lakes only. These additional records would allow the agency to verify the information provided in the notice claiming certification. The proposed new recordkeeping requirements are essential to the success of the simplified certification procedure for lakes, as they would provide the means for the agency to verify that a batch of lake has been prepared, repacked, and maintained in compliance with safety requirements, and to trace any batches that are found to have problems.

The agency would review the notice claiming certification and, if the batch of lake covered by the notice appeared to comply with these requirements and the notice appeared to contain no

untrue statement of a material fact, would issue an acceptance of the notice. Upon issuance of the acceptance, the batch covered by the notice, subject to the terms, conditions and restrictions prescribed in part 74, would be a certified batch.

3. Notification Requirements

a. *General requirements.* An essential component of the agency's proposed certification procedure for lakes is the proposed requirement that a firm claiming certification for a batch of lake comply with the notification requirements in § 80.33. The proposed notice would be the primary vehicle for providing the agency with the information needed to verify that the batch is safe for use in foods, drugs, and cosmetics.

Proposed § 80.33 (a), (b), (c), and (d) would require that a notice claiming certification for a batch of lake be addressed to the Commissioner of Food and Drugs, be prepared in the format specified in § 80.33(i), be submitted in duplicate, and be signed by a responsible officer of the company (or, for a foreign manufacturer or repacker, by a responsible officer of the firm and by an agent of the firm who resides in the United States). Except for the format of the notice, these requirements are identical to the requirements for a request for certification of a batch of lake or repack under § 80.21.

Proposed § 80.33(e) would require that a notice claiming certification for a batch of lake show the name and address of the firm submitting the notice. This information is needed to issue a response to the notice and also to identify the location of the batch and the records supporting the notice.

Like existing § 80.21(f), proposed § 80.33(f) would require that the notice be accompanied by the fee prescribed in § 80.10 unless the firm has advanced a deposit to be used for prepayment of such fees. Currently, the fee for certification of lakes and lake repacks is based on the poundage of the color additive, with a minimum fee of $192.00 for a batch of lake and $30.00 for a repack. Under proposed § 80.10(c), the fee for a notice claiming certification for a batch of lake or lake repack would be $30.00 regardless of the size of the batch. This proposed fee is based on the agency's estimate that reviewing and responding to a notice claiming certification would require approximately 1 hour. The agency estimates that average total personnel costs for these activities would be approximately $25.00 per notice with an additional $5.00 per notice for recordkeeping and other overhead costs. The agency is proposing a flat fee rather than a fee based on the poundage of lake certified because the manufacturer of a lake has already paid a fee based on poundage for the certification of the straight colors used in the lake. The agency estimates that the resources required for the administrative handling, review, and response to a notice claiming certification for a new batch of lake or a lake repack would be essentially the same. Therefore, the agency is proposing the same fee for both types of notices.

Proposed § 80.33(g) would require that a copy of the label or labeling intended to be used with the batch accompany the notice. This proposed requirement is comparable to the current requirement (§ 80.22(c)(5)) that the sample submitted with the request for certification be accompanied by a copy of the label or labeling intended to be used with the batch. The agency notes, however, that under proposed § 80.33, no sample would be submitted with the notice.

Proposed § 80.33(h) would state that the name of the lake is derived as prescribed in part 74. This proposed provision is comparable to § 80.21(h), which cross-references the regulations that prescribe the naming of straight colors, mixtures, and repacks.

Under proposed § 80.33(j), the agency would respond to the notice claiming certification for a batch of lake within 5 working days of receipt. The agency's response would either accept or reject the notice, as discussed in section VI.B.3.d. of this document.

b. *Requirements for new batches of lakes.* Proposed § 80.33(i)(1) would prescribe the format and content of a notice claiming certification for a newly prepared batch of lake. The notice would be required to contain the name of the lake, as prescribed in §§ 74.50, 74.1050, or 74.2050; the batch number (manufacturer's number); the weight of the batch; conditions of storage pending certification; and proposed uses. This information is comparable to that currently required for an application for certification of a lake under § 80.21(j)(2).

Proposed § 80.33(i)(1) would also require that the notice state the total color content of the batch and the color content (as a percent of the batch) for each straight-color component of the lake. The total color content of a lake is essential to the identity of the lake, and necessary for the user of a lake to determine product formulation requirements and to ensure compliance with any quantitative limitations on the use of the straight-color component of a lake. Currently, in its routine certification analysis of the representative sample, the agency determines the total color content of a lake. This information is an essential part of the basis for the certificate issued by the agency. Under the proposed simplified certification procedure for lakes, the agency would not analyze a sample of the batch and determine the total color content. Rather, the manufacturer would provide this information in the notice, based on its analysis of the lake. These analyses would be part of the records that the manufacturer would be required to maintain for the batch of lake.

Proposed § 80.33(i)(1) would also require the notice to contain the following information for the components of the lake: the name, quantity used, and certification lot number of each batch of straight color used in the preparation of the lake; the name and quantity used of each precipitant or substratum ingredient in the lake, including the source of the chloride or sulfate anion; and, for each certified batch of lake blended into the batch, the name, quantity used, and certification lot number or FDA acceptance number (the number assigned to FDA's acceptance of the notice claiming certification). This information is comparable to that currently required for an application for certification of a lake under § 80.21(j)(2). Although § 80.21(j)(2) does not currently require information on certified batches of lakes that are blended into a new batch of lake, such information is important for describing the composition of a batch of lake and reflects a practice that is common in the industry. Such information is routinely included in current requests for certification of lakes under § 80.21.

In evaluating requests it has received for certification of batches of lakes, the agency has noted that, although the regulations for lakes in part 82 specify precipitants and substrata as distinct functional entities, the functions of ingredients that are added to the lake preparation for these purposes may overlap. Also, in some instances, acid is added to make a component water-soluble so that it can function as a precipitant in the laking process. Under proposed § 80.33(i)(1), the required information on ingredients of the lake in the notice claiming certification would encompass all ingredients that are either identified in §§ 74.50(a), 74.1050(a), or 74.2050(a) as components of lakes, or are added to form these components of lakes in situ. This information, together with the name of the lake, would provide the agency with the necessary information on the components of the lake and the ingredients used to form

these components in the preparation of the lake.

Proposed § 80.33(i)(1) would also require statements affirming that the batch meets the requirements of 21 CFR parts 74 and 80; that the records required by § 80.39, including a representative sample of the batch, are available for inspection by FDA; and that the firm submitting the notice is the manufacturer of the batch. These proposed affirmations are necessary to ensure that the batch of lake meets all the requirements of proposed § 80.31(b) and, therefore, that the batch is safe for use in foods, drugs, or cosmetics.

As discussed in section VI.B.1. of this document, the agency is proposing to provide for the certification of batches of lakes based on its review of the critical factors in lake manufacture and on the manufacturer's representations that the remaining requirements have been met. Under this proposed procedure, the agency would not routinely verify compliance with every requirement for the preparation and repacking of lakes in part 74; therefore, affirmations of compliance with these requirements from the manufacturer of each batch are necessary as a condition of certification.

c. *Requirements for repacks of certified lakes.* Proposed § 80.33(i)(2) would prescribe the format and content of a notice claiming certification for a repack of a previously certified batch of lake. The notice would be required to contain the name of the lake, as prescribed in proposed §§ 74.50, 74.1050, or 74.2050, and the following information for the original certified batch of lake that was repacked: FDA acceptance number for the manufacturer's notice claiming certification (or the certification lot number, if the batch was certified under the old procedure); total color content of the batch; color content for each straight color in the batch; and the manufacturer's name and place of business. Proposed § 80.33(i)(2) would also require the following information about the repacked batch of lake: The batch number, weight of batch, total color content, and the color content of each straight color in the batch, as well as conditions of storage pending certification and proposed uses. This information is comparable to that currently required for an application for certification of a repack under § 80.21(j)(3).

Proposed § 80.33(i)(2) would also require statements affirming that the batch meets the requirements of 21 CFR parts 74 and 80; that the records required by § 80.39, including a representative sample of the batch, are available for inspection by FDA; and that the firm submitting the notice is the repacker of the batch.

d. *Agency action on the notice.* Under proposed § 80.33(j), the agency would furnish a response to each notifier within 5 working days of receipt of the notice. The agency would review the notice and, if the information in the notice was complete and appeared to comply with the requirements of parts 74 and 80, would issue an acceptance of the notice. Upon issuance of the acceptance, the batch would be a certified batch. To facilitate identification of the batch, the acceptance document would be assigned a number.

If the information in the notice claiming certification was incomplete or did not appear to comply with the requirements of parts 74 and 80, the agency would issue a rejection of the notice. Proposed § 80.33(j)(2) would state that a batch of lake covered by a rejected notice has not complied with the requirements of § 80.31(b) and is not a certified batch. The proposed procedure would not provide for interim responses by the agency or for amendment of a notice by the submitter. The agency recognizes that a rejection of a notice may result from an oversight on the part of the submitter, such as the inadvertent omission of required information. If the deficiency in the notice was such that it could be corrected, the firm could submit a new notice that contained all the required information or otherwise corrected the deficiency. However, the resubmission would be considered a new notice. In addition, under proposed § 80.31(c), the notifier would also have the option to request a hearing on the rejection.

4. Recordkeeping Requirements

The current recordkeeping requirements for certified color additives are found in § 80.39 *Records of distribution.* This section requires that the person to whom a certificate is issued keep complete records showing the disposal of all the color additive from the batch covered by such certificate. The section also specifies the length of time the records must be kept (2 years after disposal of the batch) and permits FDA access to the facility to check the accuracy of these records. It also specifies that these records must be kept separately from all other records. The agency is proposing to maintain these recordkeeping requirements for certified batches of lakes by modifying the language of § 80.39 to conform to the proposed changes in the certification procedure for lakes.

The agency is also proposing to require in § 80.39(b) that a firm submitting a notice claiming certification for a batch of lake keep additional records that confirm the information submitted in the notice. Under proposed § 80.39(b)(1), a manufacturer or repacker of a batch of lake certified under § 80.31(b) would be required to retain records of all documents that the firm relied upon to establish the certified status of the batch of lake. For the manufacturer of a lake, such documents would include copies of the notice submitted to FDA claiming certification for the batch of lake, the FDA acceptance of the notice, the certificate for each batch of straight color used to prepare the batch of lake, the FDA acceptance (or, for batches certified before the effective date of this final rule, the certificate) for each batch of lake used as an ingredient in the batch of lake, and the manufacturer's specifications for the substrata used to prepare the batch of lake. For the repacker of a lake, such documents would include copies of the notice submitted to FDA claiming certification for the batch of lake, and the FDA acceptance of the notice.

These records would also include complete reports of any chemical analyses performed on the batch or its components, including records of analyses that show the total color content of the batch as a percentage and, if the batch contains more than one straight color, the color content of each straight-color component of the batch of lake. As noted above in section VI.B.3.b. of this document, an accurate statement of total color content is essential for identification and proper use of a lake. Complete records of the analyses would include a method description in sufficient detail to allow the analysis to be repeated, the experimental data, the final results and a clear description or calculations that show how the final results were obtained from the experimental data. The agency tentatively concludes that complete records of the analyses for total color in a batch of lake are necessary to allow the agency to verify the accuracy of the identity of the lake.

For new batches of lakes, proposed § 80.39 would require that, for each batch of lake that contains a barium salt, as permitted under §§ 74.1050 and 74.2050, the manufacturer maintain complete records of the analyses that show that the batch of lake conforms to the specification for soluble barium. Barium is a heavy metal whose safety in lakes is based on its insolubility (see section V.A.2.c. of this document). In lakes containing barium salts, soluble

barium is either deliberately introduced as a precipitant, or could form under the conditions of laking. Therefore, the agency tentatively concludes that analysis of the batch for soluble barium is necessary to ensure the safety of lakes that contain barium salts.

For new batches of lakes, the agency is proposing that the records for the batch would also include the manufacturer's specifications for substratum and precipitant ingredients used in the lake, as well as a copy of the certificate for each batch of straight color used to prepare the lake and a copy of the acceptance of the notice claiming certification (or the certificate, during the transition between the old and new procedures) for each batch of lake that was used as an ingredient in the lake. These additional records would allow the agency to verify the information and the affirmations about the identity and composition of the lake in the notice claiming certification.

Under proposed § 80.39(b)(2), the manufacturer or repacker of a batch of lake certified under proposed § 80.31(b) would be required to retain an 8-ounce sample of the batch. The requirements for taking, storing, and labeling this sample are provided in proposed § 80.22(b). The requirements are similar to those in existing § 80.22 for samples to accompany a request for certification. However, proposed § 80.22(b) also specifies when the sample is to be taken; storage conditions for the sample; and additional labeling to show the total color, the date the sample was taken, and (following FDA acceptance of the notice claiming certification) the FDA acceptance number.

The agency is proposing that the timeframes and conditions for agency access to these additional records, including the sample of the batch retained by the firm, be the same as currently specified in § 80.39 for records of distribution for certified color additives.

5. Treatment of Batches of Lakes Pending Certification and After Certification

Current § 80.37 *Treatment of batch pending certification* and § 80.38 *Treatment of batch after certification* contain requirements to ensure that the composition of a batch of color additive subject to certification does not change from the composition of the representative sample of the batch that was submitted to the agency and that formed the basis for the agency's issuance of the certificate for the batch; that the batch remains under control of the person requesting certification until it has been certified; and that the batch is clearly identified as the batch for which certification was requested or obtained. The proposed revision of these sections would maintain these requirements or comparable requirements for batches of lakes to be certified under § 80.31(b).

a. *Treatment of batches of lakes pending certification.* Section 80.37 specifies the storage and labeling requirements for a batch of color additive pending certification. The requirements of this section are triggered by the act of taking a representative sample from the batch of color additive for submission to FDA with the request for certification, and they continue until the requested certificate has been issued. The agency is proposing to amend § 80.37 to continue the requirements and conditions of this section for lakes subject to certification under proposed § 80.31(b). Specifically, the agency is proposing to amend the description of the sample in § 80.37 to include a sample taken and held as a record by the manufacturer or repacker of a batch of lake certifiable under proposed § 80.31(b). The agency is also proposing to amend § 80.37(b) to specify that the batch must be held under the control of the person requesting or claiming certification until certified. Finally, the agency is proposing to amend § 80.37(c) to specify that the batch must be marked in a manner such that there can be no question that the batch may not be used until the issuance of the certificate for the batch or, for lakes, the issuance of FDA's acceptance of the required notice claiming certification.

b. *Treatment of batches after certification.* Section 80.38 specifies the storage, labeling and use requirements, and limitations that apply to a batch of color additive after certification. The agency is proposing to amend § 80.38 to continue the requirements and conditions of this section for lakes under the proposed certification procedures in § 80.31(b). Specifically, the agency is proposing to amend § 80.38 to divide it into two subsections: (a) Labeling and (b) Storage. The agency is also proposing to establish two subparagraphs under § 80.38(a) to describe the labeling requirements for batches of color additives certified under § 80.31(a) and § 80.31(b), respectively. In both cases, the trigger for labeling would be notification from FDA that the batch is a certified batch. However, a batch certified under proposed § 80.31(b) would be identified by labeling it with the FDA acceptance number, rather than with the certified lot number. The agency is also proposing to amend § 80.38(b) to clarify that the person responsible for the storage and use of the batch after certification is the person requesting or claiming certification.

6. Color Additive Mixtures

Current § 80.35 refers to ''straight colors'' in describing the ingredients in color additive mixtures to be certified (§ 80.35(a)) and in color additive mixtures exempt from certification (§ 80.35(b)). Currently, the term ''straight color'' is defined to include lakes. As noted in section III.A.1. of this document, the agency is proposing to amend the definition of ''straight color'' to exclude lakes and to define a new term ''listed color'' that would include both straight colors and lakes. Therefore, the agency is proposing a conforming amendment to substitute the term ''listed color'' or ''listed colors'' for the term ''straight color'' or ''straight colors'' in § 80.35.

7. Enforcement Provisions

a. *Limitations of certification.* Current § 80.32 specifies conditions under which the certificate for a batch of color additive expires. The agency is proposing to adapt the provisions of § 80.32 to the proposed new procedure for certification of lakes.

As explained in section VI.B.1. of this document, under the proposed new certification procedure for lakes, the agency would not issue a certificate for a batch of lake. Instead, the certification of a batch of lake would rely on the certification of the straight colors used in the batch of lake, on the affirmations in the notice claiming certification, and on agency acceptance of the notice. The certification of a repacked batch of lake would rely on the certification of the original batch of lake rather than directly on the certification of the straightcolor components of the lake. The agency is proposing to amend § 80.32 to clarify that the certification of a batch of lake is inextricably linked to the certificates for the straight colors used to prepare the lake. As proposed, the expiration of the certificate for a batch of straight color would result in the expiration of the agency's acceptance of all notices claiming certification of batches of lakes made from that batch of straight color, including any repacks of such batches.

The agency is proposing to change the title of § 80.32 from ''Limitations of Certificates'' to ''Limitations of Certification'' to expand the application of § 80.32 to the proposed certification procedure for lakes, which would not result in the issuance of a certificate by the agency.

Current § 80.32(a) provides that a certificate that is obtained through fraud or misrepresentation of a material fact shall not be effective, and that any color additive from the batch covered by the fraudulently obtained certificate shall be considered to be from an uncertified batch. Proposed § 80.32(a) would continue the applicability of this provision to batches of lakes certified under the proposed new procedure by replacing the term ''certificate'' with the phrase ''certificate or acceptance of a notice claiming certification''. Proposed § 80.32(a) would also clarify that any lake prepared with the color additive covered by the fraudulently obtained certificate or acceptance would lose its certification.

Current § 80.32(b) provides that if, between the time a representative sample is taken from a batch of color additive and the time a certificate for the batch is received by the person to whom it is issued, the color additive becomes changed in composition, the certificate shall not be effective, and the changed color additive shall be considered to be from an uncertified batch. Proposed § 80.32(b) would continue the applicability of this provision to batches of lakes certified under the proposed new procedure by amending the description of the sample to include a sample retained by a firm claiming certification for a batch of lake and by replacing the word ''a certificate'' by ''a certificate or an acceptance of a notice claiming certification.'' The agency is also proposing to amend § 80.32(b) to state that if a certificate or acceptance of a notice claiming certification for a batch of color additive ceases to be effective, then any batch of lake prepared with such color additive is also an uncertified batch.

Current § 80.32(c) provides that if, at any time after a certificate is received by the person to whom it is issued, any color additive from the batch covered by the certificate becomes changed in composition, the certificate expires. Proposed § 80.32(c) would continue the applicability of this provision to batches of lakes certified under the proposed new procedure by replacing the term ''a certificate'' with the phrase ''a certificate or an acceptance of a notice claiming certification.'' The agency is also proposing to amend the second sentence in § 80.32(c) to indicate clearly that the expiration of a certificate or an acceptance of a notice claiming certification of a batch of color additive would cause any lake prepared with such color additive to be an uncertified batch.

To allow certain specified uses of the color additive, current § 80.32(c) provides three exceptions to the expiration of the certificate when a change in composition occurs. A change in composition does not cause the certificate to expire if the change in composition resulted solely from use of the color additive: (1) For coloring a food, drug, or cosmetic; (2) for the purpose of certifying a batch of a mixture in which the color additive was used as an ingredient; or (3) for use in preparing a batch of a mixture for which exemption from certification has been authorized. Proposed § 80.32(c) would add another exception to provide that a change in composition would not cause the certification of a color additive to expire if the change in composition resulted solely from use of the color additive as a component or ingredient in a batch of lake for which certification was claimed under § 80.31(b) of this chapter. This provision would allow the use of certified batches of straight color to prepare a lake, or the use of a portion of a certified batch of lake as an ingredient in another certified batch of lake.

As amended, § 80.32(c) would permit any changes in the straight-color components of a lake that would normally occur during lake manufacture under conditions consistent with CGMP. For example, if the straight color was a sodium salt (e.g. D&C Yellow No. 10), and the lake was prepared with aluminum cation, this provision would allow for the change in the cation associated with the straight color from sodium to aluminum. However, this provision could not be used to justify a claim for certification of a batch of lake containing a straight color that had degraded during preparation of the lake. Such a batch of lake would not meet the requirement in part 74 that lakes be free from impurities other than those named in the specifications, to the extent that such impurities may be avoided by CGMP. Therefore, the batch would not comply with the conditions of § 80.31(b) and could not be a certified batch.

Current § 80.32(d) provides that a certificate expires if the package in which the color additive was closed for shipment or delivery is opened. Current § 80.32(d)(1) through (d)(5) specify five exceptions to the expiration of the certificate. These exceptions allow a package of certified color additive to be opened and the color additive used (1) in coloring a food, drug, or cosmetic (subject to certain restrictions); (2) for the purpose of certifying a batch made by repacking the color additive; (3) for the purpose of certifying a batch of a mixture in which the color additive is used as an ingredient; (4) for the purpose of preparing a batch of a mixture for which exemption from certification has been authorized; and (5) when the package is reopened solely for repackaging by the person to whom the certificate was issued. Proposed § 80.32(d) would continue the applicability of these provisions to certified batches of lakes or certified repacks of such batches by replacing the term ''a certificate'' by the phrase ''a certificate or an acceptance of a notice claiming certification.''

Current §§ 80.32(e), (f), and (g) describe additional conditions under which a certificate ceases to be effective with respect to a package of color additive and under which the color additive is therefore considered to be from an uncertified batch. Proposed § 80.32(e), (f), and (g) would continue the applicability of these provisions to batches of lakes certified under the proposed new procedure by replacing the term ''a certificate'' by the phrase ''a certificate or an acceptance of a notice claiming certification.''

Current § 80.32(h) describes the consequences of revocation or amendment of the listing or specifications for a color additive. Section 80.32(h) states that on the date specified in the order effecting the revocation or amendment, all certificates for existing batches and portions of batches of the color additive issued under the revoked or amended regulations cease to be effective, and any such lots of the color additive are regarded as uncertified after the date specified unless a new certificate can be and is obtained in conformity with the new regulation. Proposed § 80.32(h) would continue the applicability of this provision to batches of lakes certified under the proposed new procedure by replacing the term ''a certificate'' by the phrase ''a certificate or an acceptance of a notice claiming certification.'' Proposed § 80.32(h) would also provide that any batch of lake prepared from a batch or portion of a batch of color additive that was certified under the revoked or amended regulations is also regarded as uncertified unless a new certificate is obtained.

b. *Authority to refuse certification.* Certification requirements are enforced through the provisions of § 80.34 *Authority to refuse certification service.* This section currently provides four conditions for refusing certification service to a firm requesting certification. Paragraph 80.34(a)(1) authorizes the agency to deny certification service to a firm that has ''obtained or attempted to obtain a certificate through fraud or misrepresentation of a material fact.''

The remaining three paragraphs (§ 80.34(a)(2), (a)(3), and (a)(4)) authorize the agency to deny certification service to a firm that violates the recordkeeping requirements of § 80.39 by falsifying the required records; failing to keep the records or to make them available to the agency; or by refusing to permit duly authorized FDA employees full access to inspect the manufacturing facilities, processes and formulae involved in the manufacture of color additives and of intermediates from which such color additives are derived. Proposed § 80.34 would continue the application of these provisions to firms certifying batches of lakes under the proposed new procedure by amending § 80.34 to replace the phrase ''a certificate'' with the phrase ''a certificate or acceptance of a notice claiming certification.'' Proposed § 80.34(a)(4) would also authorize FDA to examine processes and formulae for substrata, as substances from which color additives are derived.

C. Amendments to Other Regulations

1. Listings in Part 74

a. *Listings for FD&C Red No. 40 lakes.* Except for FD&C Red No. 40, all the straight colors used in lakes were provisionally listed in 1960. FD&C Red No. 40 was never provisionally listed and, when FD&C Red No. 40 was listed (permanently) in 1971 (food and drugs: 36 FR 23552, December 10, 1971) and 1975 (cosmetics: 39 FR 28278, August 6, 1974, and 39 FR 44198, December 23, 1974), the lakes of FD&C Red No. 40 were included, for convenience, in §§ 74.340, 74.1340, and 74.2340. These permanent listings for FD&C Red No. 40 lakes cross-reference the specifications and labeling requirements in the provisional listings for lakes. For consistency, the agency is proposing to move the current listings of lakes of FD&C Red No. 40 in §§ 74.340, 74.1340, and 74.2340 to §§ 74.50, 74.1050, and 74.2050, respectively, to conform the permanent listing of the lakes of FD&C Red No. 40 to the permanent listings for other lakes.

b. *Reference to lakes in listings for straight colors.* The proposed permanent listings for lakes (§§ 74.50, 74.1050, and 74.2050) would specify the straight colors that are permitted as components of a lake. The agency tentatively concludes that the regulations for the straight colors should specify that lakes made with the straight color must conform to the requirements for lakes (§§ 74.50, 75.1050, or 74.2050, as appropriate). Therefore, the agency is proposing to amend the listings in part 74, subpart A, for the straight colors used to prepare lakes for food use to specify that ''lakes made with (name of straight color) shall conform to the requirements of § 74.50''; to amend the listings in part 74, subpart B, for the straight colors used to prepare lakes for drug use to specify that ''lakes made with (name of straight color) shall conform to the requirements of § 74.1050''; and to amend the listings in part 74, subpart C, for the straight colors used to prepare lakes for cosmetic use to specify that ''lakes made with (name of straight color) shall conform to the requirements of § 74.2050.''

c. *Listings for eye-area use of lakes.* In 1994, the agency permanently listed the aluminum lakes on alumina of the straight colors FD&C Blue No. 1 and FD&C Red No. 40 (February 16, 1994, 59 FR 7635) and FD&C Yellow No. 5 (November 29, 1994, 59 FR 60893), for use in drugs and cosmetics intended for use in the area of the eye. Because § 81.1 specifically precludes use of provisionally listed lakes in eye-area products, these lakes were included in the permanent listings of the straight color. The agency tentatively concludes that it is appropriate to include the eye-area uses of lakes with the other permanently listed uses of lakes and is therefore proposing to move these eye-area uses from the permanent listings for the straight colors to §§ 74.1050 and 74.2050.

2. Color Additive Labeling

Currently, provisionally listed lakes are subject to the general labeling requirements for color additives in § 70.25. FDA is proposing to continue the applicability of these requirements to permanently listed lakes by including a provision in proposed §§ 74.50, 74.1050, and 74.2050 to prescribe that the label of a lake conform to the requirements of § 70.25.

To reflect the proposed deletion of the provisional listings for color additives, the agency is also proposing to amend § 70.25(a) by removing the reference to part 81. As a result of the proposed change in the definition of ''straight color'' and the proposed new definition of ''listed color,'' the agency is proposing to maintain the general labeling requirements for color additives by amending § 70.25(a)(1) and (a)(3) to replace the term ''straight color'' with the term ''listed color.'' As amended, § 70.25(a)(1) would require the label of a package of lake to include the name of the lake, as prescribed in part 74 (§§ 74.50, 74.1050, or 74.2050).

As a result of the proposed new certification procedure for batches of lakes, the agency is also proposing to amend § 70.25(a)(3), which requires that the label of certified colors that are subject to a tolerance (quantitative limitation on use) bear directions to prevent products to which the color may be added from exceeding the tolerance. As amended, § 70.25(a)(3) would provide that, where regulations impose a tolerance for a general or specific use of a straight color, the amount of a straight color present in a lake would be included in the total amount of the straight color.

In addition, the agency is proposing to amend § 70.25(d) *Special labeling for color additives not exempt from certification* to establish separate labeling requirements for color additives subject to the certification procedures of § 80.31(a) and lakes subject to the certification procedures of § 80.31(b). Proposed § 70.25(d)(1) would apply to color additives subject to certification under § 80.31(a) and would incorporate the provisions of current § 70.25(d). Proposed § 70.25(d)(2) would prescribe special labeling requirements for lakes subject to certification procedures under § 80.31(b). The proposed paragraph would require that the labeling for such lakes include the total color content of the lake, the amount of color contributed by each straight-color component of the lake, and FDA's acceptance number for the notice claiming certification of the batch. The information on the total color content and content of each straight color in the lake would enable the user of the lake to comply with any quantitative limitations on the use of the straight-color component of a lake. This information would also assist the user in the formulation of products using the lake. The inclusion of the FDA acceptance number for the notice claiming certification for the batch would facilitate agency verification of the records and other information for the batch.

3. Product Labeling

a. *Food ingredient labeling.* i. *Statutory authority.* Currently, lakes are provisionally listed colors subject to certification. Therefore, under section 403(i) of the act (21 U.S.C. 343), as amended by the Nutrition Labeling and Education Act of 1990 (Pub. L. 101–535) (the NLEA), lakes must be listed as ingredients on the label of food products that contain them. Before the NLEA was enacted, the act provided that color additives added to food need not be declared individually by their common or usual names but could be designated by the collective term ''colorings.'' In 1990, the NLEA amended section 403(i) of the act to exempt from label

declaration only colors not required to be certified. To implement amended section 403(i), the agency revised its labeling regulations in § 101.22 by adding new paragraph (k), which became effective on May 8, 1993. Under § 101.22(k)(1), the lake of a color additive subject to certification must be individually identified on the food label. Because all lakes for food use are made from straight colors subject to certification and are themselves certified color additives, the presence of a lake in a food product must always be individually identified on the label of the product under § 101.22(k)(1). The agency is now proposing to list lakes permanently as color additives subject to certification. Therefore, in accordance with section 403(i) of the act (21 U.S.C. 343(i)), the agency is proposing to retain the requirement that lakes be declared on the food label under their individual names rather than as ''colorings.''

Section 721(b)(3) of the act (21 U.S.C. 379e(b)(3)) provides that regulations for the listing of a color additive ''shall, to the extent deemed necessary * * * to assure the safety of the use or uses for which a particular color additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to * * * directions or other labeling or packaging requirements for such additive).'' The straight colors FD&C Yellow No. 5 and FD&C Yellow No. 6 have been reported to cause hypersensitivity in some individuals. Declaration of the lakes of FD&C Yellow No. 5 and FD&C Yellow No. 6 on the label of foods that contain them will provide the means for consumers who are sensitive to these color additives to identify the foods that contain them and thereby avoid suffering a reaction. Therefore, the agency tentatively concludes that such a label declaration requirement is necessary.

Label declaration of the straight color FD&C Yellow No. 5 is required under § 74.705 for all foods that contain this color additive, including butter, cheese, and ice cream (foods exempted under section 403(k) of the act (21 U.S.C. 343(k)) from the requirement to declare the presence of certified color additives). In the Federal Register of July 21, 1995 (60 FR 37611), the agency published a proposal to require declaration of FD&C Yellow No. 6 on the labels of butter, cheese, and ice cream (hereinafter referred to as the July 1995 proposal). Declaration of FD&C Yellow No. 6 in other foods is already required under § 101.22(k)(1). The agency notes that both its original proposal to require the labeling of FD&C Yellow No. 5 in foods and ingested drugs (42 FR 6835, February 4, 1977) and the pending proposal to require the labeling of FD&C Yellow No. 6 in butter, cheese, and ice cream refer to the need for label declaration of the presence of the color additive in food for humans—whether added as a straight color, a mixture, or a lake—to enable persons intolerant to the color additive to minimize exposure to it. Therefore, the agency tentatively concludes that the lakes of FD&C Yellow No. 5 and FD&C Yellow No. 6 should be subject to the same label declaration requirements for foods as the straight colors. Accordingly, this proposal modifies the July 1995 proposal to include lakes.

Proposed § 74.50(e)(2) would require that the label of food products for human use that contain a lake declare the presence of the lake in accordance with § 101.22(k) of this chapter. Proposed § 74.50(e)(3) would require that the labels of butter, cheese, and ice cream that contain a lake of FD&C Yellow No. 5 or FD&C Yellow No. 6 declare such lake in the list of ingredients.

ii. *Format.* Currently, § 101.22(k)(1) provides for the declaration of certified color additives, including lakes, in the ingredient listing on the food label and cites part 74 or 82 as the source of the name of such color additive. In this rulemaking, the agency is proposing to list lakes permanently in part 74 and to remove parts 81 and 82. Therefore, the agency is proposing to remove the reference to part 82 as a source of the name for a certified color additive for declaration on the food label.

Section 101.22(k)(1) states that it is not necessary to include the ''FD&C'' prefix or the term ''No.'' in the declaration of a color additive on the food label, but that the term ''Lake'' must be included in the declaration of a lake. However, the example given in § 101.22(k)(1) (''Blue 1 Lake'') to illustrate the declaration of a lake does not include the identity of the precipitant cation, although the precipitant cation is part of the listed name of the lake under current § 82.51. In addition, in this rulemaking, the agency is proposing in § 74.50 to include the substratum as well as the precipitant cation in the listed name of a lake.

The agency tentatively concludes that the current abbreviated nomenclature (e.g., Blue 1 Lake) for food ingredient labeling is still appropriate and that the inclusion of the identity of the precipitant cation and substratum in the name of the lake on the food label is unnecessary and may be confusing to consumers. Inclusion of these components of lakes as part of the name of the lake in the ingredient list would greatly lengthen the name of the lake on the food label without providing any additional information about the color additive, since the agency is proposing to permit only the aluminum cation and the substratum alumina in lakes for food use.

As discussed in section IV.A.1.d. of this document, the agency is also proposing in new § 74.50 to allow the use of more than one straight color in a lake. Accordingly, the agency is proposing to amend § 101.22(k)(1) to require that all straight colors used to prepare a lake be included in the name of the lake. Amended § 101.22(k)(1) would also specify that it is not necessary to include the name of the precipitant cation or the substratum in the name of a lake when listing it as an ingredient in a food product. Thus, a lake would be identified on a food label by a name consisting of the names of the straight colors (in descending order of predominance) present in the lake (without the ''FD&C'' designation or the term ''No.'') followed by the word ''Lake.'' For example, a lake that contains 10 percent FD&C Yellow No. 5, 5 percent FD&C Blue No. 1, the aluminum cation, and alumina substratum would be declared on the food label as ''Yellow 5 and Blue 1 Lake.''

b. *Cosmetic ingredient labeling.* Currently, § 701.3 requires that the label of each package of a cosmetic bear a declaration of the name of each ingredient in descending order of predominance. Section 701.3(c) also designates, in order of priority, the sources from which the names of cosmetic ingredients are to be derived for the purpose of declaration of ingredients. Under § 701.3(c)(1), if FDA has established a name for the ingredient in § 701.30, that name is used. However, § 701.3(c)(1) does not cite the color additive regulations as the preferred source for names of color additives. The agency is proposing to correct this oversight by amending § 701.3(c) to include the color additive listings in parts 73 and 74 as the preferred source of names for the declaration of ingredients on the cosmetic label.

Currently, under § 701.3(c)(2) (21 CFR 701.3(c)(2)), a lake is declared on the cosmetic label by the name under which it is listed in the CTFA Cosmetic Ingredient Dictionary, 2d ed. (1977). This name is the same as the listed name of the color additive, which, under §§ 82.51, 82.1051, and 82.2051, is formed from the name of the straight color, the name of the precipitant

cation, and the word ''lake.'' As discussed in previous sections of this document, the agency is proposing in § 74.2050(c) to change the listed name of a lake to include the name of the substrata used in the lake, and is also proposing to allow the use of more than one straight color to make a lake. The agency recognizes that these proposed changes would result in a long listed name for a lake. As with food labels, the agency is concerned that the additional information that such a name on a cosmetic label would provide to consumers would be overshadowed by consumer confusion about the identity and composition of the color additive.

Unlike lakes added to food (which, under the proposed regulation, would be permitted to contain only one cation precipitant (aluminum) and one substratum (alumina)), however, lakes added to cosmetics would continue to contain a range of possible cation precipitants and substrata. The straight color and the substrata are the principal components of the lake by weight, making up over 95 percent of the total weight of the lake. Currently, the name of a lake provides only the identity of the straight color and the precipitant. The complete name of a lake would provide additional information to consumers about the substrata present in lakes. On the other hand, the space available for ingredient declaration on a cosmetic label is limited, and under the proposed new nomenclature that would be required by § 74.2050, the name of a lake would occupy a significantly greater amount of space than currently. Furthermore, the amount of space on the label that would be allocated to declaring the presence of a lake would give undue prominence to the lake as an ingredient and overshadow the other ingredients of the cosmetic product, although lakes are not necessarily more important to the consumer.

Therefore, the agency tentatively concludes that the abbreviated nomenclature permitted for declaring lakes as ingredients on the food label under § 101.22(k) should be permitted for cosmetic labels as well. The agency believes that the abbreviated name would provide consumers with more understandable information about the identity of the color additive because it would clearly identify the ingredient as a color additive and highlight the color component of the lake, which is its primary characterizing feature from the consumer's point of view. The agency tentatively finds that adopting uniform nomenclature for color additives, including lakes, on food and cosmetic ingredient labels would assist consumers in identifying these ingredients as color additives. Therefore, the agency tentatively concludes that the extension of abbreviated nomenclature for ingredient labeling of lakes to cosmetics as well as foods will provide maximum benefit to consumers.

For consistency, the agency also tentatively concludes that this abbreviated nomenclature for cosmetic ingredient labeling should apply to all certified color additives, not just to lakes. Currently, straight colors are declared on the cosmetic label by the listed name of the straight color (e.g., FD&C Blue No. 2). However, as discussed above, under § 101.22(k) the agency permits the use of abbreviated names for identifying straight colors in the ingredient statement on the food label. The agency tentatively concludes that the abbreviated name now being used on the food label (the listed name without the prefix ''FD&C'' or ''D&C,'' and without the term ''No.'') would meet the purpose of ingredient declaration on the cosmetic label to prevent consumer deception and to facilitate value comparisons (38 FR 28912, October 17, 1973).

However, for cosmetics, the prefix ''Ext.'' would still be required as part of the abbreviated name to uniquely identify different color additives. For example, D&C Yellow No. 7 (21 CFR 74.1707 and 74.2707) and Ext. D&C Yellow No. 7 (21 CFR 74.1707a and 74.2707a) are different chemical compounds, although they are both listed as color additives for use in externally applied drug and cosmetic products. Under the proposed abbreviated nomenclature, Ext. D&C Yellow No. 7 would be declared as Ext. Yellow 7, whereas D&C Yellow No. 7 would be declared as Yellow 7.

Adopting this abbreviated nomenclature for ingredient declaration of certified colors on cosmetic labels would eliminate the current inconsistency between the nomenclature used to identify certified colors on food labels and the nomenclature used on cosmetic labels, as well as any resulting consumer confusion. Therefore, the agency is further proposing to adopt as an option, for the purpose of declaring certified colors as ingredients on the labels of cosmetics, the same abbreviated nomenclature currently permitted under § 101.22(k) for declaring certified colors on the food label, except that the ''Ext.'' prefix must be included where applicable. For example, the color additive D&C Red No. 28 could be declared on the cosmetic label as ''Red 28,'' and a lake containing 10 percent FD&C Yellow No. 5, 5 percent D&C Red No. 28, the precipitant cations aluminum and calcium, and 50 percent barium sulfate and 35 percent rosin, could be declared on the cosmetic label as ''Yellow 5 and Red 28 Lake.'' The requirement that the prefix ''Ext.'' be included on cosmetic labels would not create an inconsistency with the nomenclature for food labels because, by definition, ''Ext.'' color additives are for external use and cannot be used in foods.

To accomplish the changes discussed above, the agency is proposing to amend § 701.3(c) by establishing new paragraphs (c)(1)(i) and (c)(1)(ii). Proposed paragraph (c)(1)(ii) would incorporate the existing citation to § 701.30 as a source of names. Proposed paragraph § 701.30(c)(1)(i) would identify the color additive regulations in parts 73 and 74 as the preferred source of names for color additives. This proposed paragraph would further state that for color additives listed in part 74 it is not necessary to include the prefix ''FD&C'' or ''D&C'' or the term ''No.'' in the ingredient declaration, but that the prefix ''Ext.'' shall be included in the declaration. For lakes, it would also not be necessary to include the identity of precipitant cations or substrata, but the term ''Lake'' would have to be included in the name.

c. *Labeling of drug products.* Under §§ 201.20 (a) and (b) (21 CFR 201.20 (a) and (b)) and § 74.1705(c), certain over-the-counter and prescription drug products intended for human use must declare the presence of FD&C Yellow No. 5 as a color additive. The regulations specify that the labeling for these drug products shall bear a statement such as ''Contains FD&C Yellow No. 5 (tartrazine) as a color additive'' or ''Contains color additives including FD&C Yellow No. 5 (tartrazine),'' and prescribe a more detailed warning that must be included in the ''Precautions'' section of the labeling.

Under the July 1995 proposal, the labels of certain over-the-counter and prescription drug products would be required to declare the presence of FD&C Yellow No. 6 as a color additive. The agency had previously published a final rule adopting the same requirement for such drug products (51 FR 41765, November 19, 1986), but subsequently, in compliance with a stipulation for the dismissal of a lawsuit challenging the 1986 final rule, the agency published a notice in the Federal Register of December 6, 1988 (53 FR 49138), announcing that the requirement would not be enforced pending a reproposal of the action.

The provisional listings of the lakes of FD&C Yellow No. 5 (§ 82.705) and FD&C Yellow No. 6 (§ 82.706) do not contain any reference to the declaration of these lakes in drug products. However, FDA's proposal to require the labeling of FD&C Yellow No. 5 in foods and ingested drugs (42 FR 6835, February 4, 1977) explicitly states that ''a label declaration of the presence of FD&C Yellow No. 5 in food for humans, whether added as the straight color, a mixture, or a lake, would enable persons intolerant to FD&C Yellow No. 5 to minimize exposure to the color.'' The July 1995 proposal contains almost identical language in the foods section of the proposal (60 FR 37611 at 37613 to 37614). Although these proposals were silent as to whether the labeling requirement would encompass all forms (straight color, mixture, or lake) of the color additive when added to drugs, the safety issue necessitating such labeling in drugs is the same as for foods. Therefore, the agency tentatively concludes that the presence of FD&C Yellow No. 5 should be declared as prescribed by § 74.1705 (c)(2) and (c)(3) and by § 201.20 (a) and (b) when a lake of FD&C Yellow No. 5 is used in these products, and that the presence of FD&C Yellow No. 6 should be declared as prescribed by proposed §§ 74.1706(c)(2) and 201.20(c) when a lake of FD&C Yellow No. 6 is used. Accordingly, this proposal modifies the July 1995 proposal to include lakes of FD&C Yellow No. 5 and FD&C Yellow No. 6. The agency notes that the declaration of FD&C Yellow No. 5 and FD&C Yellow No. 6 in these drug products is intended as a warning statement about the presence of these color additives, not as an ingredient declaration.

To minimize confusion, the agency is proposing that the declaration for the presence of a lake of FD&C Yellow No. 5 in drug products should be the same as that required for the straight color in §§ 74.1705(c) and 201.20. Therefore, the agency is proposing to require in § 74.1050(e)(2) that drugs that contain a lake of FD&C Yellow No. 5 be labeled in accordance with § 74.1705 (c)(2) and (c)(3). Similarly, the agency is proposing to require in § 74.1050(e)(3) that drugs that contain a lake of FD&C Yellow No. 6 be labeled in accordance with proposed § 74.1706(c)(2). The agency is also proposing to amend § 201.20 to state that a drug product that contains a lake of FD&C Yellow No. 5 or a lake of FD&C Yellow No. 6 is subject to the same labeling requirements as a drug product that contains the straight color. Finally, the agency is proposing to amend § 74.1705 (c)(2) and (c)(3) to clarify that drugs made with a lake of FD&C Yellow No. 5 are subject to the same label declaration requirements as drugs made with the straight color, and to modify proposed § 74.1706(c)(2) to clarify that drugs made with a lake of FD&C Yellow No. 6 are subject to the same label declaration requirements as drugs made with the straight color.

Under the current regulations, certain drug products that are also cosmetics, such as antibacterial mouthwashes and fluoride toothpastes, need not comply with the label declaration requirements for FD&C Yellow No. 5 in §§ 74.1705(c) and 201.20, provided that they comply with the ingredient labeling provisions for cosmetics in § 701.3. The pending July 1995 proposal for declaration of FD&C Yellow No. 6 in ingested drugs contains the same proviso. The agency is proposing to allow the labeling of such drug/cosmetic products that contain lakes of FD&C Yellow No. 5 or FD&C Yellow No. 6 to use the abbreviated nomenclature for ingredient declaration of lakes in proposed § 701.3(c)(1), which is discussed in section VI.C.3.b. of this document.

4. Other Amendments

As a result of the proposed change in the definition of ''straight color'' and the proposed new definition of ''listed color,'' the agency is also proposing to amend §§ 70.20, 73.1, and 73.1001 to replace the term ''straight color'' with the term ''listed color.''

As a result of the deletion of the provisional listings (parts 81 and 82), the agency is also proposing to amend § 178.3297(d) by removing the references to parts 81 and 82.

VII. Summary of Information Requested

To protect the confidentiality of the requested identity and process information, interested parties may submit such information, as well as reference samples of rosin products, directly to the Office of Cosmetics and Colors (address above).

A. In Situ Manufacturing Processes

As discussed in section V.A.2. of this document, the agency is aware that some substrata, including aluminum benzoate, alumina, barium sulfate (blanc fixe), and gloss white, may be currently prepared in situ during the manufacture of lakes. The agency is proposing conditions for the in situ preparation of alumina and aluminum benzoate as substrata and is requesting, as comments on this proposal, information on appropriate methods of preparation and ingredient specifications for barium sulfate produced in situ. If such comments are received, the agency will consider modifying the proposal to permit the in situ preparation of barium sulfate as a substratum.

B. Identity and Specifications for Rosin

As discussed in section V.A.2.k. of this document, the agency is requesting, as comments on this proposal, information (e.g., a manufacturer's product specification sheet or analytical data sheet) about identity and specifications for any type of rosin that does not meet the identity and specifications proposed in this document, but that is currently used as the substratum ''rosin'' under §§ 82.1051 or 82.2051. The agency is also requesting a 5-pound reference sample of each type of rosin identified in a comment. Comments should identify the specific type(s) of rosins used by the lake manufacturer and describe any treatment of the rosin prior to incorporation in a lake. Furthermore, the agency requests data concerning the dermal safety of any rosin intended for use as a diluent in color additives for externally applied drug use.

If the agency receives satisfactory information for additional types of rosin, the agency will expand the definition of rosin in its final action on this rulemaking to provide for the use of the additional products as substrata in lakes for drug or cosmetic use. In addition, to alleviate the concerns raised by literature reports of allergic reactions and dermal irritation caused by some forms of free rosin, the agency is requesting information on the safety of rosin as a diluent in color additive mixtures used in externally applied drugs. If the requested data are received and they demonstrate that rosin used as a diluent in externally applied drugs is safe, the agency will consider listing rosin for such use in the final rule.

C. Anions in Precipitants

As discussed above, the agency is proposing to allow only the anions chloride (Cl^{-1}) and sulfate (SO_4^{-2}) for use as components of precipitants. However, because the provisional listing regulations did not specify the anions that could be used in lakes, the agency is requesting comments on the use of other anions in the preparation of lakes for food, drug, or cosmetic use. This information should include data to document the current use of such anions in preparing lakes and to demonstrate their safety for such use. If the agency receives information to confirm the current safe use of anions other than chloride and sulfate in lakes, the agency will consider listing these anions in the final rule.

VIII. Effective Date

Section 701(e) of the act (21 U.S.C. 371(e)) allows 30 days for the filing of objections to a final rule listing a color additive and states that such a final rule may not become effective until the period for filing objections is over. Thus, the earliest possible effective date for a final rule listing a color additive is 31 days after publication. FDA typically sets a longer effective date for changes in labeling requirements.

In accordance with section 701(e) of the act, the agency is proposing that the final rule resulting from this proposal become effective 31 days following its publication, except for the proposed provisions of §§ 201.20, 74.1050(e), 74.1705(c), and 74.1706(c)(2) concerning declaration of lakes of FD&C Yellow No. 5 and FD&C Yellow No. 6 on the labels of certain drug products, and the proposed provisions of §§ 74.50(e)(3) and 74.706(d)(2) concerning declaration of lakes of FD&C Yellow No. 6 on the labels of butter, cheese, and ice cream. FDA is proposing that these provisions, which are part of the rulemaking initiated by the July 1995 proposal (as modified by this proposal), become effective when the final rule resulting from that proposal takes effect.

Although this proposal contains changes in the ingredient labeling provisions applicable to cosmetics, the proposed abbreviated nomenclature for declaration of lakes as ingredients in these products is optional, and manufacturers may continue to use the old labeling nomenclature if they wish. Therefore, FDA tentatively concludes that the amendments to the labeling regulations for lakes in cosmetics do not necessitate a delay in the effective date of the final rule.

IX. Inspection of Documents

The documents that FDA considered and relied upon in developing this proposal are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (address above). As provided in § 71.15 (21 CFR 71.15), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

X. Environmental Impact

The agency has determined under 21 CFR 25.24(b)(3) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XI. Paperwork Reduction Act

This proposed rule contains collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). Therefore, in accordance with 44 U.S.C. 3506(c)(2)(B) and 5 CFR part 1320, FDA is providing below the title, description, and respondent descriptions for the collections of information contained in this proposal along with an estimate of the resulting annual collection of information burden. Included in the estimate is the time needed to review instructions, to gather the required information, and to disclose the information.

FDA invites comments on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques, where appropriate, or other forms of information technology.

Title: Certification and Labeling Requirements for Color Additive Lakes.

Description: Section 721(c) of the act requires the certification of color additives where a certification requirement is necessary in the interest of the public health. Currently, lakes are subject to certification under §§ 80.21 and 80.31 and recordkeeping as required in § 80.39. The proposed rule would establish a new simplified procedure for certification of batches of lakes. Under § 80.33 of the proposed rule, the manufacturer or repacker of a lake would submit a notice claiming certification, in lieu of a request for certification. The notice would contain information about the ingredients and chemical composition of the batch. The manufacturer or repacker would be required to keep records, including a sample taken from the batch, to document the information in the notice. After certification, the manufacturer or repacker would be required to keep records of the disposition of the batch. The proposal would also require that these records be made available to FDA upon request. Because most of the records that would be required by the proposed rule are already kept in the usual course of business, the agency believes that the proposed provisions will add only a minor additional record retention burden for firms subject to the proposed provisions.

Section 721(b)(3) of the act provides that a color additive regulation shall prescribe the conditions under which the additive may be safely employed for use in foods, drugs, or cosmetics, including any labeling or packaging requirements necessary to ensure the safety of the additive. The presence of FD&C Yellow No. 5 or FD&C Yellow No. 6 in food has been reported to cause allergic-type reactions. To ensure that consumers who are sensitive to these color additives will be able to identify and avoid them, the agency is proposing to require in § 74.50(e)(3) that lakes of FD&C Yellow No. 5 and FD&C Yellow No. 6 that are used as ingredients in butter, cheese, and ice cream be declared on the labels of these foods. (Declaration of these lakes in all foods is already required both by statute and regulation.) However, because the agency is unaware of any current use of lakes of FD&C Yellow No. 5 or FD&C Yellow No. 6 in butter, cheese, or ice cream, the agency tentatively concludes that no burden would result from this proposed change.

Proposed § 701.3(c)(1)(i) changes the reference for the names under which color additives, including lakes, are declared on the cosmetic label, and provides for the optional use of abbreviated nomenclature for the declaration of color additives as ingredients on the cosmetic label. Proposed § 701.3(c)(1)(i) would also allow continued use of the current nomenclature, however. The agency does not anticipate that cosmetic manufacturers will change their labels immediately to take advantage of the abbreviated nomenclature; rather, the agency expects that manufacturers will start using the abbreviated nomenclature when they institute a label change for some other reason. Therefore, the agency tentatively concludes that proposed § 701.3(c)(1)(i) would introduce no startup costs or other burden.

To avoid double-counting, certain labeling provisions in this proposal have not been included in the burden estimate because they merely cross-reference labeling requirements contained in other regulations. Accordingly, proposed §§ 74.50(e)(1) and (e)(2), 74.1050(e), and 74.2050(d) do

not appear in the burden estimate table. Provisions that merely continue existing labeling requirements, such as proposed § 101.22(k)(1), also have not been included in the burden estimate for this proposal.

Other proposed labeling changes do not constitute collections of information because they provide for disclosure of information supplied by FDA. Proposed §§ 201.20, 74.1705(c)(2) and (c)(3), and 74.1706(c)(2) would require disclosure of the presence of FD&C Yellow No. 5 and FD&C Yellow No. 6 on the labels and in the labeling of certain drug products. The proposed regulations specify the wording of the required disclosures. Also, proposed § 70.25(d)(2) would require disclosure, on the package label of the lake, of the number assigned by FDA to its acceptance of the notice claiming certification for the batch of lake. These labeling requirements provide for ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' and are, therefore, exempt from OMB review under 5 CFR 1320.3(c)(2). Finally, some proposed requirements have been excluded from the burden estimate because the agency tentatively concludes that the resources necessary to comply with these requirements would be expended by businesses in the normal course of their activities and that the reporting, recordkeeping, or disclosure activities required by the proposed regulation are, thus, usual and customary (5 CFR 1320.3(b)(2)). For example, the information on percent total color and percent color from each straight color used in a batch of lake that must appear on the package label of the lake under proposed § 70.25(d)(2)(i) and (ii) is needed by the purchaser of the lake to properly formulate the purchaser's food, drug, or cosmetic product. Therefore, as a matter of business necessity, a manufacturer or repacker would obtain and disclose this information to clients, regardless of FDA requirements.

Description of Respondents: Businesses, including small businesses.

ESTIMATED ANNUAL REPORTING BURDEN

CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating and Maintenance Costs
21 CFR 74.50(e)(3)	0	0	0	0	0	0
21 CFR 80.33	20	80	1,600	0.25	400	$48,000
21 CFR 701.3(c)(1)(i)	0	0	0	0	0	0
Totals					400	48,000

ESTIMATED ANNUAL RECORDKEEPING BURDEN

CFR Section	Number of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
21 CFR 80.22	20	1	20	2.65	53
21 CFR 80.39	20	1	20	37.35	747
Totals				40	800

The agency expects that the number of respondents and the annual burden hours will not change significantly over succeeding years because it believes that the use of lakes in foods, drugs, and cosmetics will remain constant. There are no anticipated capital or startup costs associated with the proposed information collection requirements.

The agency has submitted copies of the proposed rule to OMB for review of the portions of the proposal that are within the ambit of the Paperwork Reduction Act of 1995. Interested persons are requested to send comments regarding information collection by April 3, 1996, but not later than May 3, 1996, to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, rm. 10235, Washington, DC 20503, ATTN: Desk Officer for FDA.

XII. Comments

As noted in section XI. of this document, interested parties may, on or before May 3, 1996, submit to the Office of Information and Regulatory Affairs, OMB (address above) written comments regarding the collections of information contained in this proposal. For other issues in the proposed rule, interested persons may, on or before June 3, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number of the rulemaking or rulemakings to which the comment is relevant. Comments on modifications to the July 1995 proposal regarding label declaration of FD&C Yellow No. 6 should be identified with both docket numbers found in brackets in the heading of this document; comments on other aspects of this proposal should be identified with docket number 79N–0043 only. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In addition, interested persons may, on or before June 3, 1996, submit to the Office of Cosmetics and Colors (address above) written comments containing process information relating to the identity and current use of substrata (including rosin) in lakes, and samples of such substrata. Written comments regarding the use of anions other than chloride and sulfate in precipitants may also be submitted to this address. Two copies of each comment and one 5-pound sample are to be submitted, and each submission is to be identified with the docket number (79N–0043) found in

brackets in the heading of this document.

XIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Kubo, Y., T. Iijima, ''Dye Elution from Aluminum Lake Synthetic Food Colors (VI) Brilliant Blue FCF Lakes,'' *Shikisai*, 60(1): 2–13, 1987.

2. Kubo, Y., M. Shirai, T. Iijima, ''Dye Elution from Aluminum Lake Synthetic Food Colors (VII) Lakes Produced by One-Step Method,'' *Shikisai*, 60(2):83–93, 1987.

3. Kubo, Y., H. Kawaguchi, ''Dye Elution from Aluminum Lake Synthetic Food Colors (V) Indigo Carmine Lakes,'' *Shikisai*, 59(11):663–669, 1986.

4. U.S. Patent 2,418,416 to Locke, R. C., Salem, NJ assignor to E.I. du Pont de Nemours and Co., Wilmington, DE, ''Manufacture of Azo Lakes,'' April 1, 1947.

5. U.S. Patent 2,478,768 to Locke, R. C., Salem, NJ assignor to E.I. du Pont de Nemours and Co., Wilmington, DE, ''Manufacture of Azo Lakes,'' August 9, 1949.

6. Clark, G. R., ''Report on Pure Dye, Impurities, and Substrata in Pigments,'' *Journal of the Association of Official Agricultural Chemists*, 28(4):938–941, 1942.

7. Clark, G. R., ''Report on Lakes and Pigments,'' *Journal of the Association of Official Agricultural Chemists*, 24(4):904–906, 1941.

8. Holtzman, H., ''The Hydrous Oxides of Aluminum and Color Lake Formation,'' agency internal progress report, 1942.

9. Zuckerman, S., ''Color in Cosmetics: *Cosmetics, Science and Technology*,'' edited by E. Sagarin, Interscience Publishers, New York, NY, pp. 539–572, 1974.

10. United States Department of Agriculture, Food Inspection Decision 76, July 13, 1907.

11. United States Department of Agriculture, ''Certification of Coal-Tar Colors Begun by Food and Drug Administration,'' information for the press, May 11, 1939.

12. Faulkner, E. B., ''Coping with International Color Regulations,'' *Cosmetics & Toiletries*, 107:45–49, 1992.

13. Memorandum dated June 27, 1988, from the Additives Evaluation Branch, FDA, to the Division of Food and Color Additives, FDA.

14. Memoranda dated July 13, 1994, and August 22, 1994, from Research Chemist, Office of Cosmetics and Colors, FDA (HFS-128), to Aydin Örstan, FDA (HFS–217).

15. Memorandum dated December 3, 1986, from the Division of Food and Color Additives, FDA, to the Division of Colors and Cosmetics, FDA.

16. *Color Index*, 3d ed., vol. 4, Society of Dyers and Colourists, Bradford, Yorkshire, England, pp. 4003, 4009–4011, 4013, 4379, 4417, 4435, 4593–4594, 1971.

17. Marmion, D. M., *Handbook of U.S. Colorants for Foods, Drugs, and Cosmetics*, 2d ed., John Wiley and Sons, New York, NY, pp. 48, 64–89, 1984.

18. Food and Drug Administration, ''Report on the Certification of Color Additives, Foreign and Domestic Manufacturers, fiscal year 1995.''

19. Color Additive Master File No. 9, entry nos. 550, 550A, and 550-addendum 1, dated September 3, 1986, October 8, 1986, and June 3, 1987.

20. Memoranda from the Division of Colors and Cosmetics, FDA, to the Division of Food and Color Additives, FDA, dated October 2, 1986, November 21, 1986, and October 7, 1987.

21. Food and Drug Administration, Office of Cosmetics and Colors, ''Intermediates and Subsidiary Colors in FD&C Blue No. 2 Straight Color and Lake,'' September 14, 1995.

22. Lykens, D. N., ''Thermal Stability of FD&C Lake Pigments,'' *Plastics Compounding*, pp. 35 to 40, November/December, 1986.

23. Memorandum from the Food and Color Additives Review Section, FDA, to the Direct Additives Branch, FDA, dated March 19, 1991.

24. Memorandum from the Additives Evaluation Branch, FDA, to the Direct Additives Branch, FDA, dated April 17, 1991.

25. Committee on GRAS List Survey—Phase III, ''The 1977 Survey of Industry on the Use of Food Additives,'' vol. 1, National Academy of Sciences, Washington, DC, pp. 1175 to 1192, 1979.

26. King, J., ''Method for Determination of Color Stability in Laking; The Results of Experiments with the Method of Establishing the Stability of Color in Laking for FD&C Red No. 4 and D&C Orange No. 4,'' January 28, 1980.

27. Food and Drug Administration, ''Report of FY–95 Certification Results for Batches of D&C Lakes of D&C Orange No. 5, D&C Red Nos. 21, 22, 27 and 28,'' December 1, 1995.

28. Food and Drug Administration, ''Report of FY–95 Certification Results for Batches of D&C Yellow No. 10 Lakes Prepared from Certified Batches of Straight Color,'' December 1, 1995.

29. The Cosmetic, Toiletry, and Fragrance Association, edited by Wenninger, J. A., and G. N. McEwen, ''International Cosmetic Ingredient Dictionary, 5th ed.,'', vol. 1, Washington, DC, p. 640, 1993.

30. Hercules, Product Data Sheet no. 7248, for Dresinate Dry Powder Soaps.

List of Subjects

21 CFR Part 70

Color additives, Cosmetics, Drugs, Labeling, Packaging and containers.

21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

21 CFR Part 74

Color additives, Cosmetics, Drugs, Incorporation by reference.

21 CFR Part 80

Color additives, Cosmetics, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 81

Color additives, Cosmetics, Drugs.

21 CFR Part 82

Color additives, Cosmetics, Drugs.

21 CFR Part 101

Food Labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 178

Food additives, Food packaging.

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 701

Cosmetics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the transitional provisions of the Color Additive Amendments of 1960, and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Associate Commissioner for Regulatory Affairs, it is proposed that 21 CFR parts 70, 73, 74, 80, 81, 82, 101, 178, 201 and 701 be amended as follows:

PART 70—COLOR ADDITIVES

1. The authority citation for 21 CFR part 70 continues to read as follows:

Authority: Secs. 201, 401, 402, 403, 409, 501, 512, 601, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 360b, 361, 371, 379e).

2. Section 70.3 is amended by revising paragraphs (j), (k), (l), and (n), and by adding new paragraphs (w) and (x) to read as follows:

§ 70.3 Definitions.

* * * * *

(j) The term *straight color* means a color additive listed in parts 73 or 74 of this chapter, but does not include color additive mixtures or lakes.

(k) The term *mixture* means a color additive made by mixing two or more listed colors, or one or more listed colors and one or more diluents, without an accompanying chemical reaction.

(l) The term *lake* means a color additive made by extending one or more straight colors on one or more substrata by adsorption, coprecipitation, or chemical combination, but does not include mixtures.

* * * * *

(n) The term *substratum* means the substance on which the straight color in a lake is extended.

* * * * *

(w) The term *listed color* means a color additive listed in parts 73 or 74 of this chapter and includes lakes.

(x) The term *repack* means all or a portion of a batch of certified color additive that has been sealed in accordance with § 70.20 and labeled in accordance with § 70.25, but has been reopened solely for repackaging without further processing, or relabeled for shipment or delivery, by a person other than the person to whom the certificate or acceptance of a notice claiming certification was issued.

3. Section 70.20 is amended by revising the section heading and first sentence to read as follows:

§ 70.20 Packaging requirements for listed colors and mixtures (other than hair dyes).

Listed colors and mixtures shall be packaged in containers which prevent changes in composition. * * *

* * * * *

4. Section 70.25 is amended in paragraph (a), introductory text, by removing from the first sentence ''80, and 81'' and adding in its place ''and 80''; in paragraph (a)(1) by removing the words ''straight color'' and adding in their place the words ''listed color''; in paragraph (a)(3) by removing the words ''straight color'' and adding in their place the words ''listed color'' the two times they appear and by adding a new sentence at the end of the paragraph; and by revising paragraph (d) to read as follows:

§ 70.25 Labeling requirements for color additives (other than hair dyes).

(a) * * *

(3) * * * The amount of such straight color in a lake shall be considered part of the total amount of such straight color.

* * * * *

(d) *Special labeling for color additives not exempt from certification.* (1) Color additives subject to the certification procedures of § 80.31(a) of this chapter shall in addition include in the labeling the lot number assigned by the Color Certification Branch, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration, except that in the case of any mixture for household use which contains not more than 15 percent of pure color and which is in packages containing not more than 3 ounces there appears on the label, a code number which the manufacturer has identified with the lot number by giving to the Food and Drug Administration written notice that such code number will be used in lieu of the lot number.

(2) Lakes subject to the certification procedures of § 80.31(b) of this chapter shall in addition include in the labeling:

(i) The total color content of the lake;

(ii) The amount of color contributed by each straight-color component of the lake; and

(iii) The FDA acceptance number assigned to the firm's notice claiming certification for the batch.

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

5. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: Secs. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e).

§ 73.1 [Amended]

6. Section 73.1 *Diluents in color additive mixtures for food use exempt from certification* is amended in the introductory text by removing the words ''straight color'' and adding in their place the words ''listed color''.

7. Section 73.1001 is amended in the first sentence of the introductory text by removing the words ''straight color'' and adding in their place the words ''listed color'', and in the table in paragraph (a)(1) by alphabetically adding four new entries to read as follows:

§ 73.1001 Diluents in color additive mixtures for drug use exempt from certification.

* * * * *

(a) * * *

(1) * * *

Substances	Definitions and specifications	Restrictions
* *	* * * * *	*
Aluminum benzoate	As set forth in § 74.1050(a)(3)(ii) of this chapter	
Barium sulfate	As set forth in § 74.1050(a)(3)(iii) of this chapter	
* *	* * * * *	*
Kaolin	As set forth in § 74.1050(a)(3)(v) of this chapter	
* *	* * * * *	*
Rosin	As set forth in § 74.1050(a)(3)(vi) of this chapter	For use only in ingested drugs.
* *	* * * * *	*

* * * * *

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

8. The authority citation for 21 CFR part 74 continues to read as follows:

Authority: Secs. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 721 of the Federal Food, Drug, and Cosmetic Act.

(21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e)

9. Section 74.50 is added to subpart A to read as follows:

§ 74.50 Lakes for use in foods.

(a) *Identity.* (1) Lakes listed in this section are color additives made by extending one or more certified batches of one or more straight colors listed in paragraph (a)(2) of this section on a substratum of alumina that conforms to the requirements of paragraph (a)(3) of this section using one or more precipitants that form aluminum (Al^{+3}) cation and chloride (Cl^{-1}) or sulfate (SO_4^{-2}) anion.

(2) Lakes listed in this section may contain one or more of the following straight colors:

(i) FD&C Blue No. 1;

(ii) FD&C Blue No. 2;

(iii) FD&C Green No. 3;

(iv) FD&C Red No. 40;

(v) FD&C Yellow No. 5; and

(vi) FD&C Yellow No. 6.

(3) Lakes listed in this section shall contain the substratum alumina, which may either conform to the requirements for alumina under § 73.1010(a)(1) and (b) of this chapter, or may be a suspension in water of precipitated aluminum hydroxide that is formed from aluminum sulfate that meets the requirements of the Food Chemicals

Codex, 2d. ed., 1972, pp. 39–40, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, and sodium carbonate or sodium hydroxide that meets the specifications of the Food Chemicals Codex, 3d. ed., 1981, p. 280 (sodium carbonate) or p. 287 (sodium hydroxide), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(4) Color additive mixtures for food use (including dietary supplements) made with lakes listed in this section may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring foods. Such mixtures shall be used in accordance with paragraph (c) of this section.

(b) *Specifications.* Lakes listed in this section shall conform to the following specifications and shall be free from impurities other than those named, to the extent that such other impurities may be avoided by current good manufacturing practice:

(1) Lead (as Pb), not more than 10 parts per million;

(2) Arsenic (as As), not more than 3 parts per million; and

(3) Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* Lakes listed in this section may be safely used for coloring foods generally (including dietary supplements) in amounts consistent with current good manufacturing practice, except that:

(1) They may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards; and

(2) Any restriction on the use of a straight color shall also apply to the use of a lake of such straight color. If a lake is prepared using a single straight color, the lake may be used in the same manner as permitted for the straight color. If a lake is prepared using more than one straight color, its use shall be restricted to those uses common to all of the component straight colors.

(d) *Identification.* Each lake made as prescribed in paragraph (a) of this section shall be considered to be a listed color and to be listed therein under the name that is formed as follows:

(1) The listed names of the straight colors present in the lake (in descending order of predominance);

(2) The name of the cation precipitant ''Aluminum,'' followed by the words ''Lake on Alumina.'' (For example, the name of a lake prepared by the extension of FD&C Yellow No. 5 and FD&C Blue No. 1 on alumina using aluminum chloride as a precipitant is ''FD&C Yellow No. 5 and FD&C Blue No. 1 Aluminum Lake on Alumina.'')

(e) *Labeling.* (1) The label of each lake listed in this section and any mixtures prepared from them that are intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(2) Foods for human use that contain lakes listed in this section shall declare the presence of such lakes in accordance with § 101.22(k)(1) of this chapter.

(3) Butter, cheese, and cream that contain a lake of FD&C Yellow No. 5 or FD&C Yellow No. 6 shall be labeled in accordance with § 101.22(k)(1) of this chapter.

(f) *Certification.* All batches of lakes listed in this section shall be certified in accordance with regulations in part 80 of this chapter.

10. Section 74.101 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.101 FD&C Blue No. 1.

(a) * * *

(3) Lakes made with FD&C Blue No. 1 shall conform to the requirements of § 74.50.

* * * * *

11. Section 74.102 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.102 FD&C Blue No. 2.

(a) * * *

(3) Lakes made with FD&C Blue No. 2 shall conform to the requirements of § 74.50.

* * * * *

12. Section 74.203 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.203 FD&C Green No. 3.

(a) * * *

(3) Lakes made with FD&C Green No. 3 shall conform to the requirements of § 74.50.

* * * * *

13. Section 74.340 is amended by revising paragraph (a)(3); in paragraph (d) by removing the words ''lakes or''; and in paragraph (e) by removing the words ''and lakes thereof'', to read as follows:

§ 74.340 FD&C Red No. 40.

(a) * * *

(3) Lakes made with FD&C Red No. 40 shall conform to the requirements of § 74.50.

* * * * *

14. Section 74.705 is amended by revising paragraph (a)(3) to read as follows:

§ 74.705 FD&C Yellow No. 5.

(a) * * *

(3) Lakes made with FD&C Yellow No. 5 shall conform to the requirements of § 74.50.

* * * * *

15. Section 74.706 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.706 FD&C Yellow No. 6.

(a) * * *

(3) Lakes made with FD&C Yellow No. 6 shall conform to the requirements of § 74.50.

* * * * *

16. Section 74.1050 is added to subpart B to read as follows:

§ 74.1050 Lakes for use in drugs.

(a) *Identity.* (1) Lakes listed in this section are color additives made by extending one or more certified batches of one or more straight colors specified in paragraph (a)(2) of this section on one or more substrata specified in paragraph (a)(3) of this section, using one or more precipitants that form aluminum (Al^{+3}), barium (Ba^{+2}), calcium (Ca^{+2}), potassium (K^{+1}), sodium (Na^{+1}), strontium (Sr^{+2}), or zirconium (Zr^{+4}) cation, and chloride (Cl^{-1}) or sulfate (SO_4^{-2}) anion.

(2) Lakes listed in this section may contain one or more of the following straight colors:

(i) FD&C Blue No. 1;
(ii) FD&C Blue No. 2;
(iii) FD&C Green No. 3;
(iv) FD&C Yellow No. 5;
(v) FD&C Yellow No. 6;
(vi) FD&C Red No. 4;
(vii) FD&C Red No. 40;
(viii) D&C Blue No. 4;
(ix) D&C Orange No. 4;
(x) D&C Orange No. 5;
(xi) D&C Orange No. 10;
(xii) D&C Red No. 6;
(xiii) D&C Red No. 7;
(xiv) D&C Red No. 21;
(xv) D&C Red No. 22;
(xvi) D&C Red No. 27;
(xvii) D&C Red No. 28;
(xviii) D&C Red No. 31;
(xix) D&C Red No. 33;
(xx) D&C Red No. 34; and
(xxi) D&C Yellow No. 10.

(3) Lakes listed in this section may contain one or more of the following substrata:

(i) Alumina that conforms to the requirements of § 74.50(a)(3) of this chapter; and

(ii) Aluminum benzoate that is prepared from aluminum chloride or aluminum sulfate that conforms to the requirements of the United States Pharmacopeia, 23d ed. (1995), p. 64 (aluminum chloride) or p. 68 (aluminum sulfate), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, and benzoic acid that conforms to the requirements of the United States Pharmacopeia, 23d ed. (1995), pp. 176 and 177, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the United States Pharmacopoeial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(iii) Barium sulfate that conforms to the requirements of the United States Pharmacopeia, 23d ed. (1995), pp. 165 and 166, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a)(3)(ii) of this section.

(iv) Calcium carbonate that conforms to the requirements of § 73.1070(a)(1) and (b) of this chapter.

(v) Kaolin that conforms to the requirements of the United States Pharmacopeia, 23d ed. (1995), p. 863, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a)(3)(ii) of this section.

(vi) Rosin, which is the pale, cream-colored sodium soap of the residue left after distilling off the volatile oil from the oleoresin obtained from *Pinus palustris* and other species of *Pinus*, and which conforms to the following specifications:

(A) Solids, not less than 95 percent;

(B) Acid number, not greater than 7.5; and

(C) Free alkali, not greater than 2.5 percent.

(vii) Talc that conforms to the requirements of § 73.1550(a)(1) and (b) of this chapter.

(viii) Titanium dioxide that conforms to the requirements of § 73.575 (a)(1) and (b) of this chapter.

(ix) Zinc oxide that conforms to the requirements of § 73.1991(a)(1) and (b) of this chapter.

(4) Color additive mixtures for drug use made with lakes listed in this section may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs. Such mixtures shall be used in accordance with paragraph (c) of this section.

(b) *Specifications.* Lakes listed in this section shall conform to the following specifications and shall be free from impurities other than those named, to the extent that such other impurities may be avoided by current good manufacturing practice:

(1) Lead (as Pb), not more than 20 parts per million;

(2) Arsenic (as As), not more than 3 parts per million;

(3) Mercury (as Hg), not more than 1 part per million; and

(4) For a lake that contains a barium salt, soluble barium (in dilute HCl) as $BaCl_2$, not more than 0.05 percent.

(c) *Uses and restrictions.* Lakes listed in this section may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice, except that:

(1) Any restriction on the use of a straight color shall also apply to the use of a lake of such straight color. If a lake is prepared using a single straight color, the lake may be used in the same manner as permitted for the straight color. If a lake is prepared using more than one straight color, its use shall be restricted to those uses common to all of the component straight colors. (For example, a lake produced using two straight colors, one listed for use in coloring drugs generally and one listed for use in coloring externally applied drugs only, may be used only for coloring externally applied drugs.)

(2) Where regulations impose quantitative limitations for a general or specific use of a straight color, the amount of such straight color in a lake shall be considered part of the total amount of such straight color in a drug product.

(3) The aluminum lakes on alumina of FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5, prepared in accordance with the requirements of § 74.50, may be safely used for coloring drugs intended for use in the area of the eye, in amounts consistent with current good manufacturing practice. Use of these lakes in the area of the eye is subject to the limitations in § 70.5 (b) and (c) of this chapter and does not include use in articles intended for use in injections or as a surgical suture in the area of the eye.

(d) *Identification.* Each lake made as prescribed in paragraph (a) of this section shall be considered to be a listed color and to be listed therein under the name that is formed as follows:

(1) The listed names of the straight colors present in the lake (in descending order of predominance);

(2) The names of the cations of the precipitants, followed by the words ''Lake on _____'';

(3) The names of the substrata (in descending order of predominance). (For example: The name of a lake prepared by the extension of FD&C Red No. 40 and D&C Orange No. 5 on alumina and titanium dioxide using aluminum chloride and calcium chloride as precipitants is ''FD&C Red No. 40 and D&C Orange No. 5 Aluminum/Calcium Lake on Alumina and Titanium Dioxide.'')

(e) *Labeling.* (1) The label of each lake listed in this section and any mixtures prepared from them that are intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(2) Drugs that contain a lake of FD&C Yellow No. 5 shall be labeled in accordance with § 74.1705 (c)(2) and (c)(3).

(3) Drugs that contain a lake of FD&C Yellow No. 6 shall be labeled in accordance with § 74.1706(c)(2).

(f) *Certification.* All batches of lakes listed in this section shall be certified in accordance with regulations in part 80 of this chapter.

17. Section 74.1101 is amended by adding a new paragraph (a)(4), by removing paragraphs (b)(2) and (c)(2) and redesignating paragraph (b)(1) and (c)(1) as paragraphs (b) and (c), respectively, to read as follows:

§ 74.1101 FD&C Blue No. 1.

(a) * * *

(4) Lakes made with FD&C Blue No. 1 shall conform to the requirements of § 74.1050.

* * * * *

18. Section 74.1102 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.1102 FD&C Blue No. 2.

(a) * * *

(3) Lakes made with FD&C Blue No. 2 shall conform to the requirements of § 74.1050.

* * * * *

19. Section 74.1104 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.1104 FD&C Blue No. 4.

(a) * * *

(3) Lakes made with FD&C Blue No. 4 shall conform to the requirements of § 74.1050.

* * * * *

20. Section 74.1203 is amended by adding a new paragraph (a)(3) to read as follows:

§ 74.1203 FD&C Green No. 3.

(a) * * *

(3) Lakes made with FD&C Green No. 3 shall conform to the requirements of § 74.1050.

* * * * *

21. Section 74.1254 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.1254 D&C Orange No. 4.

(a) * * *

(3) Lakes made with D&C Orange No. 4 shall conform to the requirements of § 74.1050.

* * * * *

22. Section 74.1255 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.1255 D&C Orange No. 5.

(a) * * *

(3) Lakes made with D&C Orange No. 5 shall conform to the requirements of § 74.1050.

* * * * *

23. Section 74.1260 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.1260 D&C Orange No. 10.

(a) * * *

(3) Lakes made with D&C Orange No. 10 shall conform to the requirements of § 74.1050.

* * * * *

24. Section 74.1304 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.1304 FD&C Red No. 4.

(a) * * *

(3) Lakes made with FD&C Red No. 4 shall conform to the requirements of § 74.1050.

* * * * *

25. Section 74.1306 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.1306 D&C Red No. 6.

(a) * * *

(3) Lakes made with D&C Red No. 6 shall conform to the requirements of § 74.1050.

* * * * *

26. Section 74.1307 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.1307 D&C Red No. 7.

(a) * * *

(3) Lakes made with D&C Red No. 7 shall conform to the requirements of § 74.1050.

* * * * *

27. Section 74.1321 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.1321 D&C Red No. 21.

(a) * * *

(3) Lakes made with D&C Red No. 21 shall conform to the requirements of § 74.1050.

* * * * *

28. Section 74.1322 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.1322 D&C Red No. 22.

(a) * * *

(3) Lakes made with D&C Red No. 22 shall conform to the requirements of § 74.1050.

* * * * *

29. Section 74.1327 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.1327 D&C Red No. 27.

(a) * * *

(3) Lakes made with D&C Red No. 27 shall conform to the requirements of § 74.1050.

* * * * *

30. Section 74.1328 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.1328 D&C Red No. 28.

(a) * * *

(3) Lakes made with D&C Red No. 28 shall conform to the requirements of § 74.1050.

* * * * *

31. Section 74.1331 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.1331 D&C Red No. 31.

(a) * * *

(3) Lakes made with D&C Red No. 31 shall conform to the requirements of § 74.1050.

* * * * *

32. Section 74.1333 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.1333 D&C Red No. 33.

(a) * * *

(3) Lakes made with D&C Red No. 33 shall conform to the requirements of § 74.1050.

* * * * *

33. Section 74.1334 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.1334 D&C Red No. 34.

(a) * * *

(3) Lakes made with D&C Red No. 34 shall conform to the requirements of § 74.1050.

* * * * *

34. Section 74.1340 is amended by revising paragraph (a)(3); by removing paragraph (b)(2); by redesignating paragraph (b)(1) as paragraph (b); by amending newly redesignated paragraph (b) by removing the phrase ''and FD&C Red No. 40 Aluminum Lake''; by amending paragraph (c) by removing the phrase ''lakes or''; and by amending paragraph (d) by removing the phrase ''and lakes thereof'' to read as follows:

§ 74.1340 FD&C Red No. 40.

(a) * * *

(3) Lakes made with FD&C Red No. 40 shall conform to the requirements of § 74.1050.

* * * * *

35. Section 74.1705 is amended by revising paragraph (a)(2); by removing paragraph (b)(2); by redesignating paragraph (b)(1) as paragraph (b); and by removing in the first sentence of paragraph (c)(2) and paragraph (c)(3), the phrase ''containing FD&C Yellow No. 5'' and adding in its place the phrase ''containing FD&C Yellow No. 5 or a lake of FD&C Yellow No. 5''.

§ 74.1705 FD&C Yellow No. 5.

(a) * * *

(2) Lakes made with FD&C Yellow No. 5 shall conform to the requirements of § 74.1050.

* * * * *

36–37. Section 74.1706 is amended by adding new paragraphs (a)(3) and (c)(2) to read as follows:

§ 74.1706 FD&C Yellow No. 6.

(a) * * *

(3) Lakes made with FD&C Yellow No. 6 shall conform to the requirements of § 74.1050.

* * * * *

(c) * * *

(2) The label of over-the-counter and prescription drug products intended for human use and administered orally, nasally, rectally, or vaginally containing FD&C Yellow No. 6, or a lake of FD&C Yellow No. 6, shall specifically declare the presence of FD&C Yellow No. 6 by listing the color additive using the name FD&C Yellow No. 6. The labels of certain drug products subject to this labeling requirement that are also cosmetics, such as antibacterial mouthwashes and fluoride toothpastes, need not comply with this requirement provided they comply with the requirements of § 701.3 of this chapter.

38. Section 74.1710 is amended by adding new paragraph (a)(3) to read as follows:

§ 74.1710 D&C Yellow No. 10.

(a) * * *

(3) Lakes made with D&C Yellow No. 10 shall conform to the requirements of § 74.1050.

* * * * *

39. Section 74.2050 is added to subpart C to read as follows:

§ 74.2050 Lakes for use in cosmetics.

(a) *Identity and specifications.* Lakes listed in this section shall conform in identity and specifications to the requirements of § 74.1050(a)(1), (a)(2), (a)(3), and (b), except that the straight color FD&C Blue No. 2 shall not be a component of such lakes.

(b) *Uses and restrictions.* Lakes listed in this section may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice, except that:

(1) Any restriction on the use of a straight color shall also apply to the use of a lake of such straight color. If a lake is prepared using a single straight color, the lake may be used in the same manner as permitted for the straight color. If a lake is prepared using more than one straight color, its use shall be restricted to those uses common to all of the component straight colors. (For example, a lake produced using two straight colors, one listed for use in coloring cosmetics generally and one listed for use in coloring externally applied cosmetics only, may be used only for coloring externally applied cosmetics.)

(2) Where regulations impose quantitative limitations for a general or specific use of a straight color, the amount of such straight color in a lake shall be considered a part of the total amount of such straight color in a cosmetic product.

(3) The aluminum lakes on alumina of FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5, prepared in accordance with the requirements of § 74.50, may be safely used for coloring cosmetics intended for use in the area of the eye, in amounts consistent with current good manufacturing practice. Use of these lakes in the area of the eye is subject to the limitations in § 70.5(b) and (c) of this chapter, and does not include use in articles intended for use in injections or as a surgical suture in the area of the eye.

(c) *Identification.* Each lake made as prescribed in paragraph (a) of this section shall be considered to be a listed color and to be listed therein under the name that is formed as prescribed in § 74.1050(d).

(d) *Labeling.* (1) The label of each lake listed in this section and any mixtures prepared from that are intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(2) Cosmetics that contain lakes listed in this section shall declare the presence of such lakes in accordance with § 701.3(c)(1)(i) of this chapter.

(e) *Certification.* All batches of lakes listed in this section shall be certified in accordance with regulations in part 80 of this chapter.

40. Section 74.2101 is amended by removing paragraphs (b)(2) and (c)(2); by redesignating paragraphs (a), (b)(1), and (c)(1) as paragraphs (a)(1), (b), and (c), respectively; and by adding new paragraph (a)(2) to read as follows:

§ 74.2101 FD&C Blue No. 1.

(a) * * *

(2) Lakes made with FD&C Blue No. 1 shall conform to the requirements of § 74.2050.

* * * * *

41. Section 74.2104 is amended by redesignating paragraph (a) as paragraph (a)(1) and by adding new paragraph (a)(2) to read as follows:

§ 74.2104 D&C Blue No. 4.

(a) * * *

(2) Lakes made with D&C Blue No. 4 shall conform to the requirements of § 74.2050.

* * * * *

42. Section 74.2203 is amended by redesignating paragraph (a) as paragraph (a)(1) and by adding new paragraph (a)(2) to read as follows:

§ 74.2203 FD&C Green No. 3.

(a) * * *

(2) Lakes made with FD&C Green No. 3 shall conform to the requirements of § 74.2050.

* * * * *

43. Section 74.2254 is amended by redesignating paragraph (a) as paragraph (a)(1) and by adding new paragraph (a)(2) to read as follows:

§ 74.2254 D&C Orange No. 4.

(a) * * *

(2) Lakes made with D&C Orange No. 4 shall conform to the requirements of § 74.2050.

* * * * *

44. Section 74.2255 is amended by redesignating paragraph (a) as paragraph (a)(1) and by adding new paragraph (a)(2) to read as follows:

§ 74.2255 D&C Orange No. 5.

(a) * * *

(2) Lakes made with D&C Orange No. 5 shall conform to the requirements of § 74.2050.

* * * * *

45. Section 74.2260 is amended by redesignating paragraph (a) as paragraph (a)(1) and adding new paragraph (a)(2) to read as follows:

§ 74.2260 D&C Orange No. 10.

(a) * * *

(2) Lakes made with D&C Orange No. 10 shall conform to the requirements of § 74.2050.

* * * * *

46. Section 74.2304 is amended by redesignating paragraph (a) as paragraph (a)(1) and by adding new paragraph (a)(2) to read as follows:

§ 74.2304 FD&C Red No. 4.

(a) * * *

(2) Lakes made with FD&C Red No. 4 shall conform to the requirements of § 74.2050.

* * * * *

47. Section 74.2306 is amended by redesignating paragraph (a) as paragraph (a)(1) and by adding new paragraph (a)(2) to read as follows:

§ 74.2306 D&C Red No. 6.

(a) * * *

(2) Lakes made with D&C Red No. 6 shall conform to the requirements of § 74.2050.

* * * * *

48. Section 74.2307 is amended by redesignating paragraph (a) as paragraph (a)(1) and by adding new paragraph (a)(2) to read as follows:

§ 74.2307 D&C Red No. 7.

(a) * * *

(2) Lakes made with D&C Red No. 7 shall conform to the requirements of § 74.2050.

* * * * *

49. Section 74.2321 is amended by redesignating paragraph (a) as paragraph (a)(1) and by adding new paragraph (a)(2) to read as follows:

§ 74.2321 D&C Red No. 21.

(a) * * *

(2) Lakes made with D&C Red No. 21 shall conform to the requirements of § 74.2050.

* * * * *

50. Section 74.2322 is amended by redesignating paragraph (a) as paragraph (a)(1) and by adding new paragraph (a)(2) to read as follows:

§ 74.2322 D&C Red No. 22.

(a) * * *

(2) Lakes made with D&C Red No. 22 shall conform to the requirements of § 74.2050.

* * * * *

51. Section 74.2327 is amended by redesignating paragraph (a) as paragraph (a)(1) and by adding new paragraph (a)(2) to read as follows:

§ 74.2327 D&C Red No. 27.

(a) * * *

(2) Lakes made with D&C Red No. 27 shall conform to the requirements of § 74.2050.

* * * * *

52. Section 74.2328 is amended by redesignating paragraph (a) as paragraph (a)(1) and by adding new paragraph (a)(2) to read as follows:

§ 74.2328 D&C Red No. 28.

(a) * * *

(2) Lakes made with D&C Red No. 28 shall conform to the requirements of § 74.2050.

* * * * *

53. Section 74.2331 is amended by redesignating paragraph (a) as paragraph (a)(1) and by adding new paragraph (a)(2) to read as follows:

§ 74.2331 D&C Red No. 31.

(a) * * *

(2) Lakes made with D&C Red No. 31 shall conform to the requirements of § 74.2050.

* * * * *

54. Section 74.2333 is amended by redesignating paragraph (a) as paragraph (a)(1) and by adding new paragraph (a)(2) to read as follows:

§ 74.2333 D&C Red No. 33.

(a) * * *

(2) Lakes made with D&C Red No. 33 shall conform to the requirements of § 74.2050.

* * * * *

55. Section 74.2334 is amended by redesignating paragraph (a) as paragraph (a)(1) and by adding new paragraph (a)(2) to read as follows:

§ 74.2334 D&C Red No. 34.

(a) * * *

(2) Lakes made with D&C Red No. 34 shall conform to the requirements of § 74.2050.

* * * * *

56. Section 74.2340 is amended by revising paragraph (a)(2); by removing in the introductory text of paragraph (b) the phrase ''except that only FD&C Red No. 40 and FD&C Red No. 40 Aluminum Lake may be safely used in coloring'' and adding in its place the word ''including'', in paragaph (b)(2) by removing the words ''additives'' and ''their'' and adding in their place the words ''additive'' and ''its'', respectively, to read as follows:

§ 74.2340 FD&C Red No. 40.

(a) * * *

(2) Lakes made with FD&C Red No. 40 shall conform to the requirements of § 74.2050.

* * * * *

57. Section 74.2705 is amended by redesignating paragraph (a) as paragraph (a)(1) and by adding new paragraph (a)(2), by removing paragraph (b)(2) and (c)(2) and redesignating paragraphs (b)(1) and (c)(1) as paragraphs (b) and (c), respectively, to read as follows:

§ 74.2705 FD&C Yellow No. 5.

(a) * * *

(2) Lakes made with FD&C Yellow No. 5 shall conform to the requirements of § 74.2050.

* * * * *

58–59. Section 74.2706 is amended by redesignating paragraph (a) as paragraph(a)(1) and by adding new paragraph (a)(2) to read as follows:

§ 74.2706 FD&C Yellow No. 6.

(a) * * *

(2) Lakes made with FD&C Yellow No. 6 shall conform to the requirements of § 74.2050.

* * * * *

60. Section 74.2710 is amended by redesignating paragraph (a) as paragraph(a)(1) and by adding a new paragraph (a)(2) to read as follows:

§ 74.2710 D&C Yellow No. 10.

(a) * * *

(2) Lakes made with D&C Yellow No. 10 shall conform to the requirements of § 74.2050.

* * * * *

PART 80—COLOR ADDITIVE CERTIFICATION

61. The authority citation for 21 CFR Part 80 continues to read as follows:

Authority: Secs. 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371, 379e).

62. Section 80.10 is amended in paragraph (a) by revising the paragraph heading and by removing the phrase ''and (j)(2)''; in paragraph (b), introductory text, by revising the paragraph heading and by removing ''§ 80.21(j)(3) and (j)(4)'' and adding in its place ''§ 80.21(j)(2) and (j)(3)''; by redesignating paragraphs (c), (d), (e), and (f) as paragraphs (d), (e), (f), and (g), respectively, by amending newly redesignated paragraph (d) by removing the phrase ''(a) and (b)'' and adding in its place the phrase ''(a), (b), and (c)'', and by adding new paragraph (c) to read as follows:

§ 80.10 Fees for certification services.

(a) *Fees for straight colors.* * * *

* * * * *

(b) *Fees for repacks of certified straight colors and color additive mixtures.* * * *

* * * * *

(c) *Fees for lakes and repacks of certified lakes.* The fee for the services provided under the regulations in this part in the case of each notice claiming certification submitted in accordance with § 80.33 shall be $30.00.

* * * * *

63. Section 80.21 is amended in paragraph (g)(1) by removing the phrase ''and lakes''; by amending paragraph (g)(2) by adding the words ''of straight colors'' at the end of the sentence; by revising paragraph (h)(1); by removing paragraph (h)(2) and redesignating paragraphs (h)(3) and (h)(4) as paragraphs (h)(2) and (h)(3), respectively; by revising newly redesignated paragraph (h)(3); by amending paragraph (j), introductory text, by removing the words ''a lake,'' and by removing the phrase ''previously certified color additive'' and adding in its place the phrase ''previously certified straight color''; by removing paragraph (j)(2) and redesignating paragraphs (j)(3) and (j)(4) as paragraphs (j)(2) and (j)(3), respectively; and by revising the paragraph heading of newly designated paragraph (j)(2) to read as follows:

§ 80.21 Request for certification.

* * * * *

(h) * * *

(1) The name of a straight color shall be the name of the color additive as listed in part 74 of this chapter.

* * * * *

(3) The name of a repack shall be the name described in paragraph (h)(1) or (h)(2) of this section, whichever is applicable.

* * * * *

(j) * * *

(2) *Request for certification of a repack of a batch of certified straight color.* * * *

* * * * *

64. Section 80.22 is revised to read as follows:

§ 80.22 Samples to accompany requests for certification or to be held as records.

(a) *Straight colors and their mixtures and repacks.* A sample of a batch of color additive which is to accompany a request for certification shall:

(1) Be taken only after such batch has been so thoroughly mixed as to be of uniform composition throughout;

(2) Be held under the control of the person requesting certification until certified; and

(3) Be labeled to show:

(i) The name of the color additive;

(ii) The manufacturer's batch number;

(iii) The quantity of such batch;

(iv) The name and post office address of the person requesting certification of such batch; and

(v) Be accompanied by any label or labeling intended to be used.

(b) *Lakes and their repacks.* A sample of a batch of lake that is to be held by a firm claiming certification for the batch shall:

(1) Be taken prior to submission of the notice claiming certification;

(2) Be taken only after such batch has been so thoroughly mixed as to be of uniform composition throughout;

(3) Be sealed and stored in such a manner as to prevent change in composition;

(4) Be held by the firm claiming certification for the batch, as required by § 80.39(b)(3); and

(5) Be labeled to show:

(i) The name of the lake;

(ii) The percent total color for the batch and, if the batch contains more than one straight color, the percent color in the batch for each straight color;

(iii) The firm's batch number and the date the sample was taken;

(iv) The quantity of the batch;

(v) The name and place of business of the firm claiming certification for the batch;

(vi) A copy of any label or labeling intended to be used with the batch; and

(vii) After receipt of an acceptance of the notice claiming certification for the batch, FDA's acceptance number.

65. Section 80.31 is amended in paragraph (a) by adding a new heading; by removing in paragraph (a)(2) in the phrase ''parts 81 and 82'' and adding in its place ''part 74'', by removing in paragraph (a)(3) the phrase ''81, and 82'', by revising paragraph (b), and by adding new paragraph (c) to read as follows:

§ 80.31 Certification.

(a) *Straight colors and their mixtures and repacks.* * * *

* * * * *

(b) *Lakes and their repacks.* If the Commissioner determines, after such investigations as the Commissioner considers to be necessary, that:

(1) A notice submitted in accordance with § 80.33 appears to contain no untrue statement of a material fact;

(2) Such lake conforms to the specifications and any other conditions set forth therefor in part 74 of this chapter;

(3) The manufacturer of the lake is the firm that was issued the certificate for each batch of straight color used in the lake;

(4) The manufacturer or repacker of the batch has complied with the notification requirements in § 80.33 and the recordkeeping requirements in § 80.39; and

(5) The batch covered by such notice otherwise appears to comply with the regulations in this chapter, the Commissioner shall issue to the firm that submitted the notice, an acceptance showing the acceptance number assigned to such notice. Upon issuance of such an acceptance, the batch covered by the notice, subject to the terms, conditions and restrictions prescribed by part 74 of this chapter, is a certified batch.

(c) If the Commissioner determines, after such investigation as the Commissioner considers to be necessary, that a request submitted in accordance with § 80.21, or the batch of color additive covered by such request, does not comply with the requirements prescribed by paragraph (a) of this section for the issuance of a certificate, or that a notice submitted in accordance with § 80.33, or the batch of lake covered by such notice, does not comply with the requirements prescribed by paragraph (b) of this section for the issuance of an acceptance of the notice, the Commissioner shall refuse to certify such batch and shall give notice thereof to the person who submitted such request, or such notice, stating the Commissioner's reasons for refusal. Any person who contests such refusal shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

66. Section 80.32 is amended by revising the section heading and paragraphs (a), (b), (c), and the introductory text of paragraph (d); in paragraphs (e), (f), introductory text, and (g) by adding the words ''or an acceptance of a notice claiming certification'' after the words ''A certificate''; and in paragraph (h) by revising the first sentence to read as follows:

§ 80.32 Limitations of certification.

(a) If a certificate or an acceptance of a notice claiming certification is obtained through fraud or misrepresentation of a material fact, such certificate or acceptance shall not be effective, and a color additive from the batch on which such certificate or acceptance was issued, or from any batch of lake prepared with such color additive, shall be considered to be from a batch that has not been certified in accordance with the regulations in this part. Whenever the Commissioner learns that any certificate or acceptance of a notice claiming certification has been obtained through fraud or material misrepresentation, the Commissioner shall notify the holder of the certificate or acceptance that it is of no effect.

(b) If, between the time a sample of color additive accompanying a request for certification or retained by a firm that has submitted a notice claiming certification is taken from a batch of color additive and the time a certificate or an acceptance of the notice claiming certification for such batch is received by the person to whom such certificate or acceptance is issued, any such color additive becomes changed in composition, such certificate or such acceptance shall not be effective with respect to such changed color additive, and such changed color additive, and any lake prepared with such color additive, shall be considered to be from a batch that has not been certified in accordance with the regulations in this part.

(c) If, at any time after a certificate or an acceptance of a notice claiming certification is received by the person to whom it is issued, any color additive from the batch covered by such certificate or acceptance becomes changed in composition, such certificate or acceptance shall expire with respect to such changed color additive. After such expiration, such color additive and any lake prepared with such color additive shall be considered to be from a batch that has not been certified in accordance with this part; except that such color additive or lake shall not be so considered when used for coloring a food, drug, or cosmetic, or for the purpose of certifying a batch of a mixture in which such color additive was used as an ingredient, or for use in preparing a batch of a mixture for which exemption from certification has been authorized, or for use in preparing a batch of lake for which certification is claimed under § 80.31(b), if such change resulted solely from such use.

(d) A certificate or an acceptance of a notice claiming certification shall expire with respect to any color additive covered thereby if the package in which such color additive was closed for shipment or delivery is opened. After such expiration such color additive shall be considered to be from a batch that has not been certified, except that such color additive shall not be so considered when the package is opened;

* * * * *

(h) When the listing or the specifications for a color additive are revoked or amended, the final order effecting the revocation or amendment may specify, in addition to its own effective date, a date on which all previous certificates or acceptances of

notices claiming certification for existing batches and portions of batches of such a color additive issued under the revoked or amended regulations shall cease to be effective; and any such lots or batches of the color additive, and any batches of lake prepared from such lots or batches, shall be regarded as uncertified after the date specified unless a new certificate or, for a lake, a new acceptance of a notice claiming certification, can be and is obtained in conformance with the new regulations.

* * *

67. New § 80.33 is added to subpart B to read as follows:

§ 80.33 Notice claiming certification for a batch of lake.

A notice claiming certification for a batch of lake or lake repack shall:

(a) Be addressed to the Commissioner of Food and Drugs;

(b) Be prepared in the manner set forth in paragraph (i) of this section;

(c) Be submitted in duplicate;

(d) Be signed by a responsible officer of the firm submitting the notice. In the case of a foreign company, the notice must be signed by a responsible officer of such firm, and by an agent of the firm who resides in the United States;

(e) Show the name and place of business (street address, city, State, and zip code) of the firm submitting the notice;

(f) Be accompanied by the fee prescribed in § 80.10 unless the firm has established an advanced deposit to be used for prepayment of such fees. In no case shall the Commissioner consider a notice claiming certification for a batch of lake or lake repack if the fee accompanying such notice is less than that required by § 80.10 or if such fee exceeds the amount held in the advance deposit account of the firm submitting such notice; and

(g) Be accompanied by any label or labeling intended to be used with the batch.

(h) The name of a lake shall be the name derived in the manner described in part 74 of this chapter.

(i) The form for submission of the notice shall be one of the following, depending on whether the color additive is a new batch of lake or a repack of a previously certified batch of lake:

(1) *Notice claiming certification for a new batch of lake.*

Date _____

Division of Programs and Enforcement Policy (HFS–105), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby give notice that we claim certification for a batch of lake.

Name of lake _____

Batch number _____

Batch weighs _____ pounds (or kilograms)

Total color _____ percent of batch

For each straight color used:

Color content _____ percent of batch.

How stored pending certification _____

_____

_____

(State conditions of storage, with kind and size of containers, location, etc.)

For use in _____

_____

_____

(State proposed uses)

Ingredients of batch

Name of each straight color used _____

_____

For each straight color used:

Certified Lot number _____

Quantity used _____ pounds (or kilograms)

For each precipitant or substratum ingredient used:

Name of ingredient used _____

Quantity used _____ pounds (or kilograms)

If any previously certified batches of lake have been used, provide the following information for each such batch.

Name of lake _____

FDA acceptance number (or certified lot number) _____

Quantity used _____ pounds (or kilograms), Required fee, § 30.00 (drawn to the order of Food and Drug Administration.)

This batch of lake was manufactured by the undersigned firm and meets the requirements of 21 CFR parts 74 and 80. The records required by 21 CFR 80.39, including a representative sample of the batch, are available for FDA inspection at the undersigned firm.

(Signed) _____

By _____

(Title)

(2) *Notice claiming certification for a repack of a batch of certified lake.*

Date _____

Division of Programs and Enforcement Policy (HFS–105), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby give notice that we claim certification for a batch of lake repack.

Name of lake _____

Original batch:

FDA acceptance number (or certified lot number) _____

Total color _____ percent of batch

For each straight color used:

Color content _____ percent of batch.

This lake obtained from (provide name and place of business of manufacturer of the lake)

Batch number _____

Batch weighs _____ pounds (or kilograms)

Repacked batch:

Total color _____ percent of batch

For each straight color used:

Color content _____ percent of batch.

How stored pending certification _____

_____

_____

(State conditions of storage, with kind and size of containers, location, etc.)

Certified for use in _____

_____

_____

_____

(State proposed uses)

Required fee, $30.00 (drawn to the order of Food and Drug Administration).

This batch of lake was repacked by the undersigned firm and meets the requirements of 21 CFR parts 74 and 80. The records required by 21 CFR 80.39, including a representative sample of the batch, are available for FDA inspection at the undersigned firm.

(Signed) _____

By _____

(j) The Food and Drug Administration will furnish a response to each notifier within 5 working days of receipt of the notice. The response will either:

(1) Accept the notice claiming certification; or

(2) Reject the notice claiming certification, in which case the batch of lake covered by the notice has not complied with the requirements of § 80.31(b) of this chapter and is not a certified batch.

§ 80.34 [Amended]

68. Section 80.34 *Authority to refuse certification service* is amended in paragraph (a)(1) by removing the phrase ''a certificate'' and adding in its place the phrase ''a certificate or an acceptance of a notice claiming certification''; and in paragraph (a)(4) by removing the phrase ''color additives and intermediates'' and adding in its place ''color additives, intermediates and substrata''.

§ 80.35 [Amended]

69. Section 80.35 *Color additive mixtures; certification and exemption from certification* is amended in paragraphs (a) and (b) by removing the words ''straight colors'' and adding in their place the words ''listed colors''; and in paragraph (b) by removing the words ''straight color'' and adding in their place the words ''listed color'' the three times they appear.

70. Section 80.37 is revised to read as follows:

§ 80.37 Treatment of batch pending certification.

Immediately after the sample is taken that (for a batch of color additive subject to certification under § 80.31(a)) is to accompany a request for certification of the batch or (for a batch of lake subject to certification under § 80.31(b)) is to be

retained by the firm preparing or repacking the batch, the batch shall be:

(a) Stored in containers of such kind as to prevent change in composition.

(b) Held under the control of the person requesting or claiming certification until certified.

(c) Marked, by labeling or otherwise, in a manner such that there can be no question as to the identity of the batch and no question that it is not to be used until the requested certificate or acceptance of the notice claiming certification has been issued.

71. Section 80.38 is revised to read as follows:

§ 80.38 Treatment of batch after certification.

(a) *Labeling.* (1) Immediately upon notification that a batch of color additive has been certified under § 80.31(a), the person requesting certification thereof shall identify such batch, by labeling, with the certified lot number.

(2) Immediately upon notification that the notice submitted in accordance with § 80.33 has been accepted, the firm claiming certification for the batch shall identify such batch, by labeling, with the FDA acceptance number.

(b) *Storage.* The person requesting or claiming certification shall maintain storage in such manner as to prevent change in composition until such batch has been packaged and labeled as required by §§ 70.20 and 70.25 of this chapter, except that the person requesting or claiming certification may use such color additive for the purpose of coloring a food, drug, or cosmetic.

72. Section 80.39 is revised to read as follows:

§ 80.39 Records.

(a) *Records of distribution.* (1) The person to whom a certificate is issued or the firm to which FDA issues an acceptance of a notice claiming certification shall keep complete records showing the disposal of all the color additive from the batch covered by such certificate or such acceptance. These records shall show:

(i) Each quantity used by such person or firm from such batch and the date and kind of such use.

(ii) The date and quantity of each shipment or delivery from such batch, and the name and post office address of the person to whom such shipment or delivery was made.

(2) Upon the request of any officer or employee of the Food and Drug Administration or of any other officer or employee acting on behalf of the Secretary of Health and Human Services, such person or such firm, at all reasonable hours until at least 2 years after disposal of all such color additive, shall make the records required by paragraph (a)(1) of this section available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such color additive on hand and otherwise to check the correctness of such records.

(b) *Certification records for lakes.* (1) The manufacturer or repacker of a lake certified under § 80.31(b) shall keep complete records showing that the batch of lake covered by the notice claiming certificaion is in compliance with parts 74 and 80 of this chapter.

(i) For both manufacturers and repackers, these records shall include:

(A) A copy of the notice claiming certification for the batch;

(B) A copy of FDA's acceptance of the notice; and

(C) Complete reports of all chemical analyses performed on the batch. Such analyses shall include, for each batch, analyses that establish the percent total color for the batch and, if the batch contains more than one straight color, the percent color for each straight color in the batch.

(ii) For manufacturers only, the records shall also include:

(A) A copy of the certificate for each batch of straight color used to prepare the batch of lake;

(B) For each certified batch of lake that was used as an ingredient, a copy of FDA's acceptance of the notice claiming certification for the batch, or if certified before (date of publication of the final rule), a copy of the certificate for the batch;

(C) Manufacturer specifications for substratum and precipitant ingredients used in the preparation of the batch; and

(D) For each batch that contains a barium salt as provided in §§ 74.1050 and 74.2050 of this chapter, analyses that show that the batch meets the specification for soluble barium in § 74.1050(b) of this chapter.

(2) A firm claiming certification for a batch of lake under § 80.31(b) shall retain an 8-ounce sample of the batch as required by § 80.22(b); however, such sample need not be submitted to FDA.

(3) Upon the request of any officer or employee of the Food and Drug Administration or of any other officer or employee acting on behalf of the Secretary of Health and Human Services, such firm, at all reasonable hours until at least 2 years after disposal of all such color additive, shall make the records and the sample required by paragraphs (b)(1) through (b)(3) of this section available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such color additive on hand and otherwise to check the correctness of such records.

(c) The records required to be kept by paragraphs (a) and (b) of this section shall be kept separately from all other records.

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

73. The authority citation for 21 CFR part 81 continues to read as follows:

Authority: Secs. 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371, 379e).

PART 81—[REMOVED]

74. Part 81 is removed.

PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

75. The authority citation for 21 CFR part 82 continues to read as follows:

Authority: Secs. 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371, 376, 379e).

PART 82—[REMOVED]

76. Part 82 is removed.

PART 101—FOOD LABELING

77. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

78. Section 101.22 is amended in paragraph (k)(1) by revising the first sentence and by removing the phrase ''or part 82'' in the second sentence to read as follows:

§ 101.22 Foods; labeling of spices, flavorings, colorings and chemical preservatives.

* * * * *

(k) * * *

(1) A color additive, including a lake, subject to certification under section 721(c) of the act shall be declared by the name of the color additive listed in the applicable regulation in part 74 of this chapter, except that it is not necessary to include the ''FD&C'' prefix or the term ''No.'' in the declaration, and for lakes it is also not necessary to identify the aluminum cation or alumina substratum, but the term ''Lake'' shall be

included in the declaration (e.g., Blue 1 Lake). * * *

* * * * *

PART 178—INDIRECT FOOD ADDITIVES; ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

79. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

§ 178.3297 [Amended]

80. Section 178.3297 *Colorants for polymers* is amended in paragraph (d) by removing the phrase ‘‘, 81, and 82’’.

PART 201—LABELING

81. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 201, 301, 501, 502, 503, 505, 506, 507, 508, 510 512, 530–542, 701, 704, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360, 360b, 360gg-360ss, 371, 374, 379e); secs 215, 301, 351, 361 of the Public Health Service Act (42 U.S.C. 216, 241, 262, 264).

§ 201.20 [Amended]

82. Section 201.20 *Declaration of presence of FD&C Yellow No. 5 and/or FD&C Yellow No. 6 in certain drugs for human use* is amended in paragraph (a) by adding the words ‘‘or a lake of FD&C Yellow No. 5’’ before the words ‘‘as a color additive using the names’’, in paragraph (b) by adding the words ‘‘or a lake of FD&C Yellow No. 5’’ before the words ‘‘that are administered’’, and in paragraph (c) by adding the words ‘‘or a lake of FD&C Yellow No. 6’’ before the words ‘‘shall specifically’’.

PART 701—COSMETIC LABELING

83. The authority citation for 21 CFR part 701 continues to read as follows:

Authority: Secs. 201, 502, 601, 602, 603, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 352, 361, 362, 363, 371, 374); secs. 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1454, 1455).

84. Section 701.3 is amended by redesignating paragraph (c)(1) as paragraph (c)(1)(ii) and by adding new paragraph (c)(1)(i) to read as follows:

§ 701.3 Designation of ingredients.

* * * * *

(c) * * *

(1)(i) For color additives, the name of the color additive listed in the applicable regulation in part 73 or 74 of this chapter, except that it is not necessary to include the ‘‘FD&C’’ or ‘‘D&C’’ prefix or the term ‘‘No.’’ in the declaration, but the prefix ‘‘Ext.’’ shall be included in the declaration. (For example, Ext. D&C Yellow No. 7 may be declared as Ext. Yellow 7.) For lakes, it is also not necessary to identify the cation precipitants or the substrata, but the term ‘‘Lake’’ shall be included in the declaration. (For example, the name of a lake prepared by the extension of FD&C Red No. 40 and D&C Yellow No. 10 on alumina and titanium dioxide using aluminum chloride and calcium chloride precipitants is ‘‘Red 40 and Yellow 10 Lake.’’).

* * * * *

Dated: February 16, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–4584 Filed 2–29–96; 8:45 am]

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Monday
March 4, 1996

Part IV

Department of the Treasury

Fiscal Service

31 CFR Part 357

Regulations Governing Book-Entry Treasury Bonds, Notes, and Bills; Proposed Rule

DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Part 357

[Department of the Treasury Circular, Public Debt Series, No. 2–86]

Regulations Governing Book-Entry Treasury Bonds, Notes, and Bills

AGENCY: Bureau of the Public Debt, Fiscal Service, Treasury.

ACTION: Proposed rule.

SUMMARY: Treasury is proposing regulations that will govern Treasury bonds, notes, and bills (marketable Treasury securities) in book-entry form held in the commercial book-entry system. The rules incorporate recent and significant changes in commercial and property law addressing the holdings of securities through financial intermediaries. The proposed rules would replace existing Treasury regulations that contain outdated legal concepts.

DATES: Comments must be submitted on or before May 3, 1996.

ADDRESSES: Send comments to the Office of the Chief Counsel, Bureau of the Public Debt, Room 503, E Street Building, Washington, DC 20239–0001. Comments received will be available for public inspection and copying at the Treasury Department Library, Room 5030, Main Treasury Building, 1500 Pennsylvania Avenue, NW, Washington, DC 20220.

FOR FURTHER INFORMATION CONTACT: Walter T. Eccard, Chief Counsel (202) 219–3320, or Cynthia E. Reese, Deputy Chief Counsel, (202) 219–3320.

SUPPLEMENTARY INFORMATION:

I. Introduction

Treasury is reproposing rules for the Treasury/Reserve Automated Debt Entry System (''TRADES''). The adoption of TRADES is the culmination of a 27-year Treasury process of moving from issuing securities only in definitive (physical/certificated/paper) form to issuing marketable securities exclusively in book-entry form.

Some numbers help put the scope of this process in perspective. In 1967, the year before Treasury issued its first book-entry security, there were $211 billion of marketable Treasury securities outstanding—all in definitive form. As of December 31, 1995, there were approximately $3.3 trillion of marketable Treasury securities outstanding (not counting Treasury securities held by various government trust funds), 99.7% of which were in book-entry form.

Treasury had considered the potential benefits of converting from definitive securities to securities in book-entry form at various times since as early as 1940. In 1964, following substantial losses of definitive securities, Treasury and the Federal Reserve Banks began a four-year study of the practical and legal aspects of initiating a book-entry system.

As a culmination of this study, the first Treasury book-entry securities regulations were issued effective January 1, 1968.[1] Securities converted to book-entry form pursuant to these regulations consisted of marketable Treasury securities held by Federal Reserve Banks that were either held as collateral pledges to the United States or represented proprietary holdings of member banks. The Federal Reserve Banks, which already acted as Treasury's fiscal agent with respect to transactions in definitive U.S. securities, began to act in that capacity with respect to Treasury's book-entry securities as well.

During the following year, the then applicable regulations were revised to extend the book-entry system to Treasury securities held by the Federal Reserve Banks that were pledged to third parties, such as courts or other public officials, for the performance of certain obligations or to secure deposits of public funds. The book-entry conversion authority initiated in 1968 and 1969 allowed the Federal Reserve Banks to reduce both the increasing volume of definitive securities stored in their vaults and the risk of loss. Studies were undertaken at that time to determine the feasibility of expanding the system to include other Treasury securities not initially eligible for the Treasury book-entry system.

In 1971, Treasury regulations were further revised to allow for all marketable Treasury securities to be held in book-entry form.[2] The regulations permitted member banks to place in book-entry form securities held for customers, including those of dealers. Pursuant to these regulations, holding marketable Treasury securities in book-entry form was optional and book-entry securities could be converted to definitive form.

Issuance of these regulations was significant in several respects. They were a key factor in averting a crisis in the government securities market. At that time, banks, brokers and dealers were being threatened with cancellation of insurance coverage because of large losses resulting from the theft of definitive securities. The dramatic increase in thefts and losses of government securities during the late 1960's ($30 million in 1969 and again in 1970) required Treasury to obtain new legislation and implement new claims procedures to grant relief to claimants through replacement of lost or stolen securities prior to maturity.[3] At the close of fiscal year 1971, about $230 billion of marketable Treasury securities were outstanding and about $125 billion of that amount was in book-entry form.

This initial success led to Treasury's decision to expand its efforts to move toward a complete book-entry system. A Treasury and Federal Reserve Bank task force was formed in 1976 to plan for the expansion of the book-entry system for issuing Treasury securities. The goal of the task force was to eliminate the issuance of definitive securities in all new marketable Treasury offerings, with an overall purpose of reducing paperwork, protecting against loss, theft, and counterfeiting, and reducing printing costs. The task force planned for a timed phase-out of the issuance of all definitive securities, beginning in late 1976.

In December 1976, with the promulgation of new regulations,[4] Treasury took the first step towards an exclusive book-entry environment by offering Treasury bills only in that form, phasing in this change for the various bill maturities. A 52-week bill issue in December 1976 became the first offering of securities exclusively in book-entry form. Use of book entry was expanded to include 26-week bills in June 1977 and 13-week bills in September 1977.

Also, beginning in December 1976, Treasury, for the first time, began to provide book-entry accounts for investors who did not choose to hold their book-entry securities accounts at financial institutions or dealers. As of September 30, 1977, Treasury maintained 6,690 book-entry accounts holding a total $182 million of Treasury bills. These accounts were the predecessor to the current TREASURY DIRECT system,[5] which was established in 1986. Treasury notes and bonds were issued in book-entry only form beginning in August 1986, upon implementation of the TREASURY

[1] 32 FR 15672 (November 14, 1967).

[2] 35 FR 20001 (December 31, 1970) and 36 FR 6749 (April 18, 1971).

[3] Pub. L. No. 92–19, May 27, 1971, 85 Stat. 74.

[4] 41 FR 5335 (December 6, 1976).

[5] TREASURY DIRECT is a system in which persons purchasing or already owning marketable Treasury securities may hold such securities directly with the Treasury in book-entry accounts maintained in their names. As of December 31, 1995, there were 922,397 accounts holding $85.3 billion of marketable Treasury book-entry securities.

DIRECT system pursuant to new Treasury regulations.[6]

With the issuance of these regulations, all original issues of marketable Treasury securities (bills, notes, and bonds) were required to be in book-entry form. Book-entry holdings in Treasury securities have increased dramatically since that time. The following chart illustrates this rapid increase.

TOTAL MARKETABLE SECURITIES OUTSTANDING [7]

Year	Percent in book-entry
June 1965	0
August 1976	82
August 1982	95.6
August 1986	97.2
December 1995	99.7

[7] Exclusive of securities held in various government trust funds.

Adoption of the TRADES regulations, to govern the commercial book-entry system counterpart to TREASURY DIRECT, will mark a major step in the evolution of Treasury's full book-entry securities project by providing a clearer legal framework for all commercially-maintained marketable Treasury book-entry securities.

II. Legal Development

As Treasury began to issue securities in book-entry form, it confronted a legal landscape that did not provide a framework for describing how such securities should be treated. As described by Professor James Rogers, the reporter for the drafting committee that produced Revised Article 8, Investment Securities of the Uniform Commercial Code (UCC), adopted by the American Law Institute (''ALI'') and the National Conference of Commissioners on Uniform State Laws (''NCCUSL'') in 1994 (''Revised Article 8''), the version of Article 8 in effect in the late 1960s and early 1970s ''* * * was based on the assumption that possession and delivery of physical certificates are the key elements in the securities holding system.'' [8] Those assumptions, however, did not fit the commercial reality of marketable Treasury book-entry securities.

As noted above, beginning in 1968, Treasury began to promulgate regulations for its marketable securities held in book-entry form. These regulations provided, for the first time, a legal framework for treating marketable book-entry securities issued by Treasury. These regulations, particularly those adopted in 1971, contained several important innovations. First, they described transfers of interests in securities by means other than by moving paper certificates.[9] As currently set forth in the regulations,[10] a transfer of a marketable Treasury book-entry security occurs when a Federal Reserve Bank makes an entry in its records. Second, the regulations implicitly acknowledged that interests in marketable Treasury book-entry securities held in the commercial book-entry system were held in a tiered system.[11]

Specifically, the regulations developed by Treasury had rules for transfers both at the level of institutions having accounts at a Federal Reserve Bank and rules for transfers at custodial levels below that level. These were significant innovations.

The regulations developed by Treasury to describe the nature of a book-entry security, however, also deemed such security to be the equivalent of a bearer-definitive security. This bearer-definitive security fiction, as it came to be known, had the advantage of simplicity. It was also, at the time of its adoption, a useful concept that allowed for the application of existing law at a time when holding securities in book-entry form was a new development. Ultimately, however, the bearer- definitive fiction proved to be unsatisfactory because the attempt to graft the rules of certificated securities onto book-entry securities left too many questions unanswered.[12] This uncertainty poses risks in the event of systemic failure.[13] TRADES is designed to ameliorate these risks.

In 1978 the existing UCC Article 8 was amended and, as part of that process, there was an attempt to provide some guidance on the treatment of book-entry securities. That attempt did not provide sufficient guidance for a tiered system of ownership such as the one that exists for Treasury securities because the rules of that version of Article 8 ''were based on the assumption that changes in ownership of securities would be effected by delivery of physical certificates or by registration of transfer on the books of the issuer.'' [14] In the Treasury system that assumption was not correct. A second level of confusion was created because the Treasury regulations continued to rely on the bearer-definitive fiction but referenced state law (which for most states included the 1978 revision to Article 8). Thus, there was lack of clarity as to how the 1978 amendments to Article 8 and the bearer-definitive fiction interacted and how interests at levels below a Federal Reserve Bank were to be treated.[15]

By 1984 Treasury had concluded that it needed to change its existing book-entry regulations. Several events buttressed that conclusion. As described above, the outstanding amount of marketable Treasury book-entry securities increased dramatically. In 1984 representatives of a number of financial institutions brought to Treasury's attention the need for certainty in the market and raised a number of questions about the existing regulations that they believed undermined that certainty. With the growth of the size of the Treasury market came an increase in the need for, and the use of, short-term financing techniques, such as repurchase transactions, structured to be low risk. In order to preserve the liquidity of this most liquid of markets, it was critical that participants be able to settle their transactions quickly with a high degree of certainty.

Disruptions in the market caused by the failure of some government securities broker-dealers further

[6] 31 CFR Part 357, Subpart C.

[8] James Steven Rogers, Boston College Law School, Reporter, Drafting Committee to Revise U.C.C. Article 8 Investment Securities, Prefatory Note, page 1, U.C.C. Article 8 (1994 official text with comments), hereinafter ''Prefatory Note.''

[9] UCC § 8–320, added in 1962, provided for transfers within a central depository system by the making of appropriate entries on the books of a clearing corporation. Unlike the Treasury regulatory formulation, this UCC provision originally contemplated the deposit of paper certificates with the depository.

[10] 31 CFR 306.118(a).

[11] The Federal Reserve Banks maintain book-entry security accounts for depository institutions and other entities such as government and international agencies and certain foreign central banks. In their book-entry accounts at the Federal Reserve, the depository institutions may maintain their own security holdings and holdings for customers, which may include other depository institutions, dealers, brokers, institutional investors and individuals. In turn, the depository institutions' customers may maintain accounts for their customers. This creates a tiered chain of custodial relationships. Thus, there frequently are multiple levels between the issuer of the security and the ultimate holder of the beneficial interest in that security.

[12] These uncertainties are well described in Charles W. Mooney, Jr., ''Beyond Negotiability: A New Model for Transfer and Pledge of Interests in Securities Controlled by Intermediaries,'' 12 Cardozo L. Rev. 305 (1990) (hereinafter ''Beyond Negotiability'').

[13] ''What led to the revision of Revised Article 8 is not intermediary risk itself, that is, the risk that customers of a failed intermediary might suffer loss, but *systemic risk*, that is, the risk that a failure of one security firm might cause others to fail.'' Rogers, *supra*, memorandum accompanying U.C.C. Revised Article 8, (1994 official text with comments), ''Revised U.C.C. Article 8—Why it's Needed—What it Does.''

[14] Rogers, *supra*, U.C.C. Revised Article 8, Prefatory Note, page 4.

[15] Mooney, Beyond Negotiability, *supra*, pp. 345–350.

underscored the need for certainty in the minds of market participants. Events post-1984, such as the 1987 market break and the failure of Drexel Burnham, Lambert validated the concern that lack of certainty, given the magnitude of the dollars involved, posed serious systemic risks—both to the market for Treasury securities and all financial markets.[16] More recently, there has been reaffirmation of the importance of certainty for transactions involving book-entry securities. In a March 3, 1995 speech, Alan Greenspan, Chairman of the Board of Governors of the Federal Reserve System, stated, ''* * * my experience with financial crises has convinced me that the greatest threat to the liquidity of our financial markets is the potential for disturbance to the clearance and settlement process for financial transactions.'' He went on to note, ''The most important set of concerns relates to the legal and institutional foundations of book entry settlement systems.'' [17]

III. Previous Trades Proposals

In 1985 Treasury began the process of revising its book-entry security regulations. Treasury recognized early on that the process would be quite complicated.

For reasons already explained, the first decision made in the initial proposal of the TRADES regulations [18] was to eliminate the bearer-definitive fiction. This proposed elimination, however, presented two major difficulties in determining what should replace the bearer-definitive fiction. First, state law was not uniform. In 1986 all states had not adopted the 1978 version of UCC Article 8. Because of this lack of uniformity, Treasury determined that for purposes of clarity and certainty, the basic mechanical rules for transfer and pledge of marketable Treasury book-entry securities needed to be set out in the Federal regulations.

The second difficulty was that the provisions in the 1978 version of Article 8 could not be used as a model for the TRADES rules without significant modifications to fit the Treasury book-entry system. As a consequence, although this first proposal was based on provisions of the 1978 version of Article 8, there were some significant modifications. Treasury's goal was to clarify the rules for marketable Treasury book-entry securities to the extent possible without causing unnecessary changes in market practice.

The most problematic issue raised in the March 1986 proposal, however, was the resolution of competing claims to interests in the same securities when held through intermediaries (''book-entry custodians,'' now referred to as ''Securities Intermediaries''). In other words, under some circumstances (particularly in scenarios involving failures of intermediaries), more than one person (e.g., owner or secured creditor) could claim entitlement to a Treasury security. How should such disputes be sorted out? After considering several different alternatives to deal with this issue, all of which had some disadvantages, the initial proposal of TRADES left the resolution of questions involving competing claims to state law.

Comments on the first TRADES proposal were wide-ranging in their content and helpful. Most of the detailed comments dealt with the issue of competing claims and urged some form of bona fide purchaser rule (providing that an innocent purchaser would take a security free of prior adverse claims) and some form of a priority clearing lien for entities that perform the critical function of extending credit as a part of a clearing function in the government securities market. These and other new areas suggested by commenters were added to the second regulatory proposal published in November 1986.[19]

Another difficult issue that was raised in the TRADES rulemaking was the interaction between Federal and State law and the extent to which the Federal regulations should preempt State law. The opinions of the commentators on this point varied. The preamble to the second TRADES proposal in November, 1986 noted that:

> * * * With respect to book-entry securities, there is not an accepted body of principles [uniform state laws] that operates to provide predictable results * * * Even where such rules [the 1978 UCC Article 8] have been adopted, some of the litigation arising from recent failures of government securities dealers suggests that important legal issues are yet to be resolved that stem from some of the concepts and relationships that arise where interests in securities are transferred without the transfer of a certificate.[19a]

Because of the difficulties in drawing lines between coverage of Federal and State law, the November 1986 proposal adopted an approach of complete preemption of State law. Like the first TRADES proposal, the second proposal generated a large volume of detailed and helpful comments.

Another significant development that had an impact on the TRADES rulemaking was the passage, at about the time the November 1986 proposal was issued, of the Government Securities Act of 1986 (''GSA'').[19b] The GSA granted Treasury rulemaking authority over the government securities market, including custodial holding of government securities. It also required the registration of government securities brokers and dealers for the first time and imposed a regulatory framework that had not previously existed for those entities. Treasury exercised its authority by promulgating rules in July 1987 in the areas of financial responsibility, protection of investor securities and balances, recordkeeping, and reporting and audit. In addition, the GSA rules imposed, for the first time, standards for the safeguarding and use of government securities by depository institutions that hold such obligations in custody for the account of customers. This new regulatory framework addressed many of the practices that had been involved in dealer failures and increased customer protection for securities held in the commercial book-entry system. It also provided, for the first time, comprehensive Federal regulation of the custody practices for government securities.

In the next few years, other groups also explored many of the same issues raised in the proposed TRADES regulations. In 1988, in response to concerns raised about securities clearance and settlement as a result of the stock market break of 1987, the American Bar Association established an Advisory Committee on Settlement of Market Transactions. In addition, the Market Transactions Advisory Committee was established by the Securities and Exchange Commission under the Market Reform Act of 1990. Finally, and most significantly, a major effort to revise existing Article 8 commenced in 1991.

Under the aegis of the ALI and NCCUSL, a group of scholars and

[16] As set forth in the May 1988 Interim Report of the Working Group on Financial Markets, ''the laws of the various states do not have uniform requirements for * * * transfers and pledges of certificated and uncertificated stocks * * * investors, market professionals and their lenders should have a single, clear set of rules for the transfer and pledge of securities similar to those being developed by the United States Treasury.'' The working group consisted of the chairpersons of the Board of Governors of the Federal Reserve System, the Securities and Exchange Commission and the Commodity Futures Trading Commission and the Department of the Treasury Under Secretary for Finance.

[17] Remarks by Alan Greenspan at the Financial Markets Conference of the Federal Reserve Bank of Atlanta, Coral Gables, Florida, March 3, 1995.

[18] 51 FR 8846 (March 14, 1986).

[19] 51 FR 43027 (November 28, 1986).

[19a] 51 FR 43029 (November 28, 1986).

[19b] Pub. L. No. 99–571, October 28, 1986, 100 Stat. 3208.

practitioners began work on a multi-year process that by 1994 produced Revised UCC Article 8. The importance of their work cannot be overstated. Representatives of Treasury, the Federal Reserve Banks and the Federal Reserve Board participated in virtually all of their drafting sessions. It soon became obvious that the drafters of Revised Article 8 were dealing with many of the issues that Treasury had considered in its earlier versions of TRADES, including the difficult questions involving the resolution of competing claims. While Treasury continued to work on TRADES and produced a third draft in 1992, Treasury ultimately concluded that it made sense to wait for work to be completed on Revised Article 8 so that Treasury would have the benefit of their final product.[19c] Treasury believes that decision was prudent.

The many difficult issues resolved by the drafters of Revised Article 8 have been of significant benefit to Treasury as it has worked on this proposal for TRADES. Based on its participation in the many drafting sessions that produced Revised Article 8, and after a detailed study, Treasury has concluded that Revised Article 8 represents a major advance in commercial law. For the first time, there is a comprehensive set of rules to govern the modern book-entry systems. Treasury agrees with Professor Rogers when he notes that, ''The present version of Article 8 [the 1978 version], which is based on legal concepts adopted to the paper-based systems of the past, is not adequate to that task in the modern world of computerized recordkeeping and global securities trading.'' [20] Accordingly, as set forth in detail below, Treasury has concluded that it is appropriate to rely on Revised Article 8 in a significant way in this proposal for TRADES.[21]

IV. Comparison of Trades and Treasury Direct

A person can hold interests in marketable Treasury book-entry securities either in TRADES [22] or TREASURY DIRECT. The following summarizes the major differences between the two systems.

As previously described, persons holding marketable Treasury book-entry securities in TRADES hold their interests in such securities in a tiered system of ownership accounts. In TRADES, Treasury, through its fiscal agents, the Federal Reserve Banks, knows the identity only of Participants (persons with a direct account relationship with a Federal Reserve Bank). While Participants may be beneficial owners of interests in marketable Treasury book-entry securities, there are many beneficial owners of such interests that are not Participants. Such beneficial owners hold their interests through one or more Securities Intermediaries such as banks, brokerage firms or securities clearing organizations.

The rights of non-Participant beneficial owners can be exercised only through Securities Intermediaries. Neither Treasury nor the Federal Reserve Banks have any obligations to a non-Participant beneficial owner of an interest in a marketable Treasury book-entry security. Two examples illustrate this principle. First, Federal Reserve Banks, as Treasury's fiscal agents, will act only on instructions of the Participant in whose Securities Account the marketable Treasury book-entry security is maintained in recording transfers of an interest in a marketable Treasury book-entry security. A beneficial owner of such an interest that is a non-Participant has no ability to direct a transfer on the books of a Federal Reserve Bank. Second, Treasury discharges its payment obligation with respect to a marketable Treasury book entry security when payment is credited to a Participant's account or paid in accordance with such Participant's instructions. Neither Treasury nor a Federal Reserve Bank has any payment obligation to a non-Participant beneficial owner of an interest in a marketable Treasury book-entry security. A non-Participant beneficial owner receives its payment when its Securities Intermediary credits such owner's account.

Persons holding marketable Treasury book-entry securities in TREASURY DIRECT, on the other hand, hold their securities accounts on records maintained by Treasury through its fiscal agents, the Federal Reserve Banks. The primary characteristic of TREASURY DIRECT is a direct account relationship between the beneficial owner of a marketable Treasury book-entry security and Treasury. In TREASURY DIRECT, Treasury discharges its payment obligation when payment is credited to the depository institution specified by the beneficial owner of the marketable Treasury book-entry security. Unlike TRADES, TREASURY DIRECT does not provide a mechanism for the exchange of cash in a sales transaction, nor are pledges of marketable Treasury book-entry securities generally recognized. Accordingly, TREASURY DIRECT is suited for persons who plan to hold their Treasury securities until maturity, and provides an alternative for investors who are concerned about holding securities through intermediaries and who do not wish to hold their interests in Treasury securities indirectly in TRADES.

V. Scope of Proposed Regulation

Just as the scope of Revised Article 8 is limited,[23] the scope of this regulation is limited. It is not a comprehensive codification of the law governing securities, transactions in securities or the law of contracts for the purchase or sale of securities. Similarly, it is not a codification of all laws that could affect a person's interest in a marketable Treasury book-entry security. For example, state laws regarding divorce or intestate succession could well affect which persons have rights in the interest in a marketable Treasury book-entry security. This regulation does not displace such laws—with the sole exception that such laws cannot affect either Treasury or the Federal Reserve Banks.

VI. Section by Section Analysis

A. Dual Book-Entry Systems

Section 357.0 sets forth that Treasury provides two systems for maintaining marketable Treasury book-entry securities—TRADES and TREASURY DIRECT. Subpart A of Part 357 of 31 CFR contains general information about TRADES and TREASURY DIRECT. Subpart B will contain the TRADES

[19c] The third TRADES proposal was published in April 1992 (57 FR 12244, April 9, 1992). In response to the comments on the second proposal, Treasury reexamined and articulated the Federal interest in the regulations. That interest was described as ''to provide that degree of certainty in the law that is needed by participants in the Government securities market to facilitate transactions in book-entry securities and to assure the continued liquidity and efficiency of the market.'' In that proposal, the extent of Federal preemption was cut back from the prior proposal, and some areas that had been included in prior proposals (e.g., warranties) were left to state law. The 1992 proposal retained provisions dealing with competing claims, while recognizing that the examination of legal principles in this area was continuing. The overall content of the rules, however, was not significantly different from the prior two proposals. Commenters to this third proposal urged Treasury to suspend its efforts and await the completion of the Revised Article 8 project. On November 12, 1993, Treasury agreed to that suggestion. (58 FR 59972, November 12, 1993).

[20] Letter from James Rogers, Reporter, Drafting Committee to Revise U.C.C. Article 8, to James Wong, Chief Consultant, (California) Senate Judiciary Committee (April 10, 1995).

[21] Copies of Article 8 are available upon request from the Bureau of the Public Debt's Public Affairs Officer, (202) 219–3302.

[22] In TRADES a person's interest in a marketable Treasury book-entry security is a Security Entitlement. See the discussion at VI.D.4. below.

[23] Prefatory Note at 12.

regulations. Subpart C contains the TREASURY DIRECT regulations. Subpart D contains miscellaneous provisions. Thus, in its totality, Part 357 sets forth in one place the complete set of governing rules for marketable Treasury securities issued in book-entry form.

B. Effective Date

Section 357.1 establishes the effective date for TRADES. Treasury contemplates that TRADES will apply to outstanding securities currently governed by 31 CFR Part 306, Subpart O. Conforming changes to Part 306 will be made with the publication of TRADES in final form. Consistent with the approach set forth in Revised Article 8 (see § 8–603 and the official comment thereto), on and after the effective date these regulations will apply to all transactions, including transactions commenced prior to the effective date.

Treasury proposes that the effective date for TRADES will be 90 days following the publication of TRADES in final form in the Federal Register. While TRADES is based in large part on Revised Article 8 that has received widespread attention in the financial community and already has been adopted in 13 states,[24] Treasury is proposing that TRADES will become effective 90 days following publication of the final TRADES rule to ensure a smooth transition to TRADES. Such an effective date, when combined with TRADES being published in proposed form with a 60-day comment period, should provide sufficient time for an orderly transition to the new TRADES rules. Treasury specifically seeks comments on whether the proposed effective date of TRADES is sufficient to permit an orderly transition.

C. Definitions

Section 357.2 contains definitions for use in Subparts B and C. While most of the definitions are straightforward, four terms—Participant, Entitlement Holder, Security Entitlement and Securities Intermediary—are critical to an understanding of the proposed TRADES regulations.

1. Participant

A Participant is a person that has an account relationship in its name with a Federal Reserve Bank. Accordingly, the Federal Reserve Bank and Treasury know both the identity of the persons maintaining these accounts and the marketable Treasury book-entry securities held in these accounts.

2. Securities Intermediary

Securities Intermediaries are persons (other than individuals, except as described below) that are in the business of holding interests in marketable Treasury book-entry securities for others. Participants can be, and usually are, Securities Intermediaries. In addition, entities such as clearing corporations, banks, brokers and dealers can be Securities Intermediaries in a single chain of ownership of a Treasury security. An individual, unless registered as a broker or dealer under the federal securities laws, cannot be a Securities Intermediary. As an illustration of a possible chain of ownership, in the following chart, the Federal Reserve Bank, Participant and Broker-Dealer are all Securities Intermediaries.

Treasury

Federal Reserve Bank

Participant

Broker-Dealer

Individual Holder

3. Entitlement Holder

An Entitlement Holder is any person for whom a Securities Intermediary holds an interest in a marketable Treasury book-entry security. In the above example Individual Holder, Broker-dealer and Participant are all Entitlement Holders. Thus, a person can be both a Securities Intermediary and an Entitlement Holder.

4. Security Entitlement

A Security Entitlement is the interest that an Entitlement Holder has in a marketable Treasury book-entry security. In the example, Participant, Broker-Dealer and Individual Holder all hold Security Entitlements. The rights and property interests associated with a Security Entitlement of a Participant held on the books of a Federal Reserve Bank (''Participant's Security Entitlement'') are, however, different from the rights and property interests associated with other Security Entitlements. As provided in Section 357.10(a), Federal law defines the scope and nature of a Participant's Security Entitlement. While TRADES is based in large part on Revised Article 8, the meaning of Security Entitlement under federal law is different than under Revised Article 8. For example, Participants have a direct claim against the United States for interest and principal even though, under state law, an Entitlement Holder would only have a claim against its Securities Intermediary for such payment. To the extent not inconsistent with this regulation, the scope and nature of a Security Entitlement of an Entitlement Holder below the level of a Participant (Broker-dealer and Individual Holder in the example above), is defined by applicable state law, as determined pursuant to Section 357.11.

D. Law Governing the United States and Reserve Banks

Section 357.10(a) provides that the rights and obligations of the United States and the Federal Reserve Banks (with one exception detailed below), with respect to both the TRADES system and marketable Treasury book-entry securities maintained in TRADES are governed solely and exclusively by Federal law. Thus, claims against the United States and Federal Reserve Banks of both Participants and all other persons with an interest (or claiming an interest) in a marketable Treasury book-entry security maintained in TRADES are governed by Federal law. Federal law is defined to include TRADES, the offering circulars pursuant to which the Treasury securities are sold, the offering announcements and Federal Reserve Bank Operating Circulars. Prior to March 1, 1993, the terms of each offering of marketable Treasury securities, except for Treasury bills, were set forth in an offering circular published in the Federal Register.[25] Since March 1, 1993, all marketable Treasury book-entry securities have been offered pursuant to a uniform offering circular set forth at 31 CFR Part 356.

While TRADES is based in large measure on Revised Article 8, a fundamental principle of these regulations (and a divergence from Revised Article 8) is that the obligations of the issuer (the United States) and the Federal Reserve Banks, as well as all claims with respect to TRADES or a marketable Treasury book-entry security against Treasury or a Federal Reserve Bank, are governed solely by Federal law. Thus, for example, those parts of Revised Article 8 that detail obligations of issuers (or their agents) of securities are not applicable to either the United States or Federal Reserve Banks. In addition, neither the United States nor Federal Reserve Banks have any obligations to persons holding their interests in a marketable Treasury book-entry security at levels below the level

[24] As of January 1, 1996, those states are: Arizona, Arkansas, Idaho, Illinois, Indiana, Louisiana, Minnesota, Nebraska, Oklahoma, Oregon, Texas, Washington and West Virginia.

[25] Treasury bills were issued pursuant to one master offering circular (31 CFR Part 349, removed, and replaced by 31 CFR Part 356) effective March 1, 1993. (58 FR 412)

of a Participant or to any other person claiming an interest in a marketable Treasury book-entry security (with the limited exception set out in Section 357.12(c)(1)). Thus, there are no derivative rights against either the United States or the Federal Reserve Banks.

Section 357.10(b) sets forth the law applicable with respect to security interests granted to Federal Reserve Banks. There are three possible ways that such security interests are granted. First, security interests granted to a Federal Reserve Bank by a Participant in which such Bank does not mark its books are governed by the law of the state in which the head office of the Federal Reserve Bank is located. If the state in which the head office of a Federal Reserve Bank is located has not adopted Revised Article 8, the law of such jurisdiction is deemed to include Revised Article 8. (See discussion of federal pre-emption below). Second, if a Federal Reserve Bank does not mark its books, a security interest granted by a non-Participant is governed by the law specified in the agreement with a Federal Reserve Bank. Third, if a Participant or non-Participant grants a Federal Reserve Bank a security interest and the Federal Reserve Bank marks its books, Section 357.12(c)(1) governs.

For purposes of applying the state law specified in Section 357.10(b), Federal Reserve Banks are treated as clearing corporations. As a result, security interests granted under Section 357.12(c)(2) in favor of a Federal Reserve Bank have the same priority as security interests granted to other clearing corporations under state law.

E. Law Governing Other Interests

1. Law Governing the Rights and Obligation of Participants and Third Parties

Section 357.11 is a choice of law rule. The substantive matters subject to this choice of law rule are set forth in Section 357.11(a). The matters set forth in Section 357.11(a) are meant to be coextensive with those matters covered by Revised Article 8 with respect to a person's interest in a marketable Treasury book-entry security (other than those related to a person's relationship to Treasury or a Federal Reserve Bank which are governed solely by federal law). For purposes of this choice of law rules, both Participants and Federal Reserve Banks are Securities Intermediaries.

Section 357.11(b) adopts Revised Article 8's choice of law rule. Section 357.11(c) sets forth a special choice of law rule with respect to security interests perfected by filing. Generally, the law applicable to the Securities Intermediary will govern matters involving an interest in a book-entry security held through that intermediary. This approach is not followed with respect to security interests created by filing. In those cases, the law applicable to the debtor is the governing law. Since filing systems are based on the location of the debtor, this approach should reduce uncertainty and preserve the normal practice of searching records based on the debtor's location.[26]

Section 357.11(d) provides for the application of Revised Article 8 if the choice of law analysis required by Section 357.11(b) results in the choice of the law of a jurisdiction that has not yet adopted Revised Article 8. This section also provides that, for purposes of applying state law, the Federal Reserve Banks are clearing corporations and Participants' interests in book-entry securities are Security Entitlements.

2. Limited Scope of Federal Preemption

As noted above, in an earlier TRADES proposal Treasury contemplated adopting a comprehensive regulation governing the rights of all persons in marketable Treasury book-entry securities held in TRADES. Such an approach was proposed because Treasury believed that a uniform rule was necessary to preserve the efficiency and liquidity of the market for Treasury securities—the most liquid and efficient market in the world. Treasury believed then, and believes now, that the material rights of a holder in the United States of an interest in a Treasury security should not vary solely by virtue of such holder's geographic location or the location of the financial institution through which it holds its interest in Treasury securities. In light of Revised Article 8, Treasury has determined that it is possible to achieve this uniformity without developing an independent system of Federal commercial law.[27] The questions inherent in a tiered system of ownership have been analyzed, and, in Treasury's view, satisfactorily addressed by Revised Article 8.

As of the date of this release, 13 states have adopted Revised Article 8 and Treasury understands that it will soon be adopted in additional states. As with all uniform laws, the adoption process takes several years. In order to assure uniformity, in light of the unavoidable delays in the state-by-state adoption process of Revised Article 8, Treasury is proposing a limited form of preemption. As provided in both Sections 357.10(c) and 357.11(d), if the choice of law rules set forth in TRADES would lead to the application of the law of a state that has not yet adopted Revised Article 8, TRADES will apply Revised Article 8 (with conforming and miscellaneous amendments to other Articles) in the form approved by the ALI and NCCUSL. Treasury expects that these provisions will be operative only during the state-by state adoption process and would plan to amend TRADES to delete reference to these provisions once the adoption process has been completed.

While Revised Article 8 is defined to mean the official text of Article 8 as approved by the ALI and NCCUSL, Treasury recognizes that states may make minor changes in that text when adopting Article 8. Treasury has concluded that minor changes should not prevent Revised Article 8, as adopted by a state, from being the appropriate law. In other words, if a state passes a version of Article 8 that is substantially identical to Revised Article 8, reference to Revised Article 8 (as defined) would no longer be required. This approach represents a significantly reduced form of preemption of state law from former versions of TRADES and preserves Treasury's preeminent interest in a uniform system of rules applicable to all holders of interests in marketable Treasury book-entry securities.

F. Obtaining an Interest in a Book-Entry Security

1. Creation of a Participant's Security Entitlement

A Participant's interest in a marketable Treasury book-entry security is a Securities Entitlement. Section 357.12(a) provides that a Participant's Securities Entitlement is created when a Federal Reserve Bank indicates by book entry that a Book-entry Security has been credited to a Participant's Securities Account. Instead of the concept of initial credit and transfer of a marketable Treasury book-entry security, as set forth in the existing regulations, this proposal focuses on the creation of a Participant's Securities Entitlement and, in this way, is similar to Section 8–501 of Revised Article 8.

The regulation focuses on the creation of a Participant's Security Entitlement because Security Entitlement is the term used to describe the Participant's interest in a marketable Treasury book-

[26] The substantive effect of filing is limited and applies only in states which have adopted Revised Article 8. Since the effect of filing is a unique state law matter, in this one area, Treasury has determined that possible lack of uniformity does not justify altering state law.

[27] As noted previously, the substantive scope of this regulation is limited.

entry security. Once a Participant obtains that interest, the regulation sets forth what that interest is. Thus, as provided in Section 357.10, federal law describes a Participant's rights against the United States and the Federal Reserve Bank where it maintains its Securities Account. To the extent not inconsistent with Section 357.10, Section 357.11 describes the applicable law to determine Participants' rights and obligations with respect to all other persons. Under these regulations, Participants can still transfer their interests in a marketable Treasury book-entry security as they do today—by issuing a Transfer Message to the Federal Reserve Bank where they hold such interest. Transfer of interests between Participants can occur by a Participant holding such interest issuing a Transfer Message. As a result of such message, the Federal Reserve Bank will make a book entry in favor of the receiving Participant (thereby creating a Security Entitlement in favor of such Participant) and also will make a book entry deleting the initiator Participant's interest in such marketable Treasury book-entry security (thereby eliminating that Participant's Security Entitlement). In addition, if authorized under applicable state law, Participants may enter into agreements with other Participants that, as to the Participants, constitute a transfer. Such action is without effect to either the United States or a Federal Reserve Bank.

2. Creation and Priority of a Security Interest

Security Interests of the United States.

Section 357.12(b) provides that a security interest in favor of the United States has priority over the interests of any other person in a marketable Treasury book-entry security. The United States obtains security interests in Treasury securities as collateral to secure funds in a variety of situations such as Treasury Tax and Loan accounts; government agency funds or funds under the control of the Federal Courts held at financial institutions; and securities pledged in lieu of surety by contractors and others. The priority provided the United States in these situations is consistent with existing law.

In addition, Federal Reserve Banks do recognize on their books and records security interests in favor of the United States. In that situation, the Federal Reserve Bank will not transfer the security without the permission of the United States. This section provides that a Federal Reserve Bank may rely exclusively on the directions of an authorized representative of the United States to transfer a security and is protected in so relying.

Security Interests on the Books of a Reserve Bank

In a limited number of situations, Federal Reserve Banks will agree to record a security interest on their books. It is important to note that there is no obligation for either Treasury or a Federal Reserve Bank to agree to record a security interest on the books of a Federal Reserve Bank. If they do so, the security interest is perfected when the Federal Reserve Bank records a security interest on its books. In addition, the security interest has priority over all other interests in the marketable Treasury book-entry security except an interest of the United States.

Other Security Interests

As provided in Section 357.12(c)(2), Participants can create security interests in any manner authorized by applicable state law.[28] The perfection and priority of such interests shall be governed by such applicable law. In applying such law, when a Participant grants a Federal Reserve Bank a security interest, the Federal Reserve Bank is treated as a clearing corporation.

If a person perfects a security interest pursuant to Section 357.12(c)(2) obligations of the Treasury and the Federal Reserve Banks with respect to that security interest are limited. Specifically, unless special arrangements are agreed to by the United States or a Federal Reserve Bank pursuant to Section 357.12(c)(1), neither the Federal Reserve Bank nor the United States will recognize the interests of any person other than the person in whose securities account the interest in a marketable Treasury book-entry security is maintained. This does not mean that such a security interest is invalid. Rather, it means that the creditor's recourse will be solely against the debtor Participant or other third party.

G. Rights and Obligations of Treasury and the Reserve Banks

1. Adverse Claims

Section 357.13(a) sets forth the general rule that, except as provided in Section 357.12(c)(1), Treasury and the Federal Reserve Banks will recognize only the interest of a Participant in a marketable Treasury book-entry security in whose Securities Account such interest is maintained.

As noted previously, marketable Treasury book-entry securities maintained in TRADES are held in a tiered system of ownership. The records of a Federal Reserve Bank reflect only the ownership at the top tier. Institutions maintaining a Securities Account with a Federal Reserve Bank frequently will hold interests in marketable Treasury book-entry securities for their customers (which can include broker-dealers and other Securities Intermediaries) and in certain cases those customers will hold interests in securities for their customers. Accordingly, neither Treasury nor a Federal Reserve Bank will know the identity or recognize a claim of a Participant's customer if that customer were to present it to Treasury or a Federal Reserve Bank.

In addition, except as provided in Section 357.12(c)(1), neither the Treasury nor a Federal Reserve Bank will recognize the claims of any other person asserting a claim in a marketable Treasury book-entry security. Persons at levels below the Participant level must present their claims to their Securities Intermediary.

2. Payment Obligations

Section 357.13(b) contains a corollary to the rule set forth in Section 357.13(a). This section provides that Treasury discharges its payment responsibility with respect to a security that it has issued when a Federal Reserve Bank credits the funds account of a Participant with amounts due on that security or makes payment in such other manner specified by the Participant. This is consistent with existing law and the first TRADES proposal.[29] In Revised Article 8, the issuer discharges its obligations when it makes payment to an owner registered on its books. Under common commercial practice, the registered owner in the indirect system may be a clearing corporation or the clearing corporation's nominee. Unlike Revised Article 8, even though Federal Reserve Banks are deemed to be clearing corporations, Treasury remains liable until payment is made to a Participant. Section 357.13(b)(2) establishes the mechanism of how marketable Treasury book-entry securities are paid at maturity. This paragraph makes clear that such payment takes place automatically and that, unlike with physical certificates, there is no act of presentment required by the Participant.

H. Authority of Reserve Banks

Section 357.14 provides that Federal Reserve Banks are authorized, as fiscal agents of Treasury, to operate the

[28] If the state has not yet adopted Revised Article 8, applicable state law would be Revised Article 8.

[29] 51 FR 8846, 8848 (March 14, 1986).

commercial book-entry system for Treasury.

I. Notices

Section 357.44 contains a revised version of a provision that appeared in earlier TRADES proposals. Similar to the rule in Revised Article 8 (see § 8–112), it provides where certain legal process should be directed. While providing instructions on where notice should be directed, it makes clear that the regulations do not establish whether a Federal Reserve Bank is required to honor any such order or notice.

VII. Procedural Requirements

This proposed rule does not meet the criteria for a ''significant regulatory action'' pursuant to Executive Order 12866.

Although this proposed rule is being issued in proposed form to secure the benefit of public comment, the notice and public comment procedures requirements of the Administrative Procedure Act are inapplicable, pursuant to 5 U.S.C. 553(a)(2).

As no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) do not apply.

There are no collections of information contained in this proposed rule. Therefore, the Paperwork Reduction Act does not apply.

List of Subjects in 31 CFR Part 357

Bonds, Electronic funds transfer, Federal Reserve System, Government securities, Securities.

For the reasons set forth in the preamble, Title 31, Chapter II, Subchapter B, Part 357 is proposed to be amended as follows:

PART 357—[AMENDED]

1. The authority citation for Part 357 continues to read as follows:

Authority: 31 U.S.C. Chapter 31; 5 U.S.C. 301; 12 U.S.C. 391.

2–3. Sections 357.0 and 357.1 are added to read as follows:

§ 357.0 Dual book-entry systems.

(a) Treasury securities shall be maintained in either of the following two book-entry systems:

(1) *Treasury/Reserve Automated Debt Entry System (TRADES).* A Treasury security is maintained in TRADES if it is credited by a Federal Reserve Bank to a Participant's Securities Account. See Subpart B for rules pertaining to TRADES.

(2) *TREASURY DIRECT Book-entry Securities System (TREASURY DIRECT).* A Treasury security is maintained in TREASURY DIRECT if it is credited to a TREASURY DIRECT account as described in Section 357.20 of this Part. Such accounts may be accessed by investors in accordance with Subpart C through any Federal Reserve Bank or the Bureau of the Public Debt. *See* Subpart C for rules pertaining to TREASURY DIRECT.

(b) A Treasury security eligible to be maintained in TREASURY DIRECT under the terms of its offering circular or pursuant to notice published by the Secretary may be transferred to or from an account in TRADES from or to an account in TREASURY DIRECT in accordance with Section 357.22(a).

§ 357.1 Effective date.

Subpart B of this Part, and other changes made to this Part with the publication of Subpart B in final form, are effective on and after [insert date 90 calendar days after the date of publication in final form]. Subpart C and other provisions in this Part published in final form on May 16, 1986, or as amended prior to [insert date 90 calendar days after the date of publication in final form] (related to TREASURY DIRECT) remain in effect.

§ 357.3 [Redesignated and § 357.2; amended]

4. Section 357.3 is redesignated § 357.2, the introductory text of the section is designated as paragraph (a) introductory text, the definition of *security interest and pledge* is removed, the definition of *TRADES* is revised, the remaining definitions are added in alphabetical order, and a new paragraph (b) is added to read as follows:

§ 357.2 Definitions.

(a) * * *

* * * * *

Book-entry Security means, in Subpart B, a Treasury Security maintained in TRADES and, in Subpart C, a Treasury Security maintained in TREASURY DIRECT.

* * * * *

Entitlement Holder means a Person to whose account an interest in a Book-entry Security is credited on the records of a Securities Intermediary.

* * * * *

Federal Reserve Bank Operating Circular means the uniform publication issued by each Federal Reserve Bank that sets forth the terms and conditions under which the Reserve Bank maintains Book-entry Securities accounts and transfers Book-entry Securities.

* * * * *

Funds Account means a reserve and/or clearing account at a Federal Reserve Bank to which debits or credits are posted for transfers against payment, book-entry securities transaction fees, or principal and interest payments.

* * * * *

Issue means a group of securities, as defined in this section, that is identified by the same CUSIP (*C*ommittee on *U*niform *S*ecurities *I*dentification *P*ractices) number.

* * * * *

Participant means a Person that maintains a Participant's Securities Account with a Federal Reserve Bank.

Participant's Securities Account means an account in the name of a Participant at a Federal Reserve Bank to which Book-entry Securities held for a Participant are or may be credited.

Person means and includes an individual, corporation, company, governmental entity, association, firm, partnership, trust, estate, and any other similar organization, but does not mean or include the United States or a Federal Reserve Bank.

* * * * *

Revised Article 8 means Uniform Commercial Code, Revised Article 8, Investment Securities (with Conforming and Miscellaneous Amendments to Articles 1, 4, 5, 9, and 10) 1994 Official Text, as set forth in Appendix B of this part.

Securities Intermediary means:

(1) A Person that is registered as a ''clearing agency'' under the federal securities laws; a Federal Reserve Bank; any other person that provides clearance or settlement services with respect to a Book-entry Security that would require it to register as a clearing agency under the federal securities laws but for an exclusion or exemption from the registration requirement, if its activities as a clearing corporation, including promulgation of rules, are subject to regulation by a federal or state governmental authority; or

(2) A Person (other than an individual, unless such individual is registered as a broker or dealer under the federal securities laws) including a bank or broker, that in the ordinary course of its business maintains securities accounts for others and is acting in that capacity.

Security means a bill, note, or bond, each as defined in this section. It also means any other obligation issued by the Department that, by the terms of the applicable offering circular or announcement, is made subject to this Part. Solely for purposes of this Part, it also means:

(1) the interest and principal components of a security eligible for Separate Trading of Registered Interest

and Principal of Securities (''STRIPS''), if such security has been divided into such components as authorized by the express terms of the offering circular under which the security was issued and the components are maintained separately on the books of one or more Federal Reserve Banks; and

(2) the interest coupons that have been converted to book-entry form under the Treasury's Coupons Under Book-Entry Safekeeping Program (''CUBES''), pursuant to agreement and the regulations in 31 CFR Part 358.

Security Entitlement means the rights and property interest of an Entitlement Holder with respect to a Book-entry Security.

* * * * *

TRADES is the Treasury/Reserve Automated Debt Entry System, also referred to as the commercial book-entry system.

* * * * *

Transfer Message means an instruction of a Participant to a Federal Reserve Bank to effect a transfer of a Book-entry Security maintained in TRADES, as set forth in Federal Reserve Bank Operating Circulars.

* * * * *

(b) Unless the context requires otherwise, terms not defined in this section have the meanings as set forth in Revised Article 8.

5. Subpart B, consisting of Sections 357.10 through 357.14, is added to read as follows:

Subpart B—Treasury/Reserve Automated Debt Entry System (TRADES)

357.10 Law governing rights and obligations of United States and Federal Reserve Banks; rights of any Person against United States and Federal Reserve Banks.
357.11 Law governing other interests.
157.12 Creation of Participant's Security Entitlement; security interests.
357.13 Obligations of United States; no adverse claims.
357.14 Authority of Federal Reserve Banks.

Subpart B—Treasury/Reserve Automated Debt Entry System (TRADES)

§ 357.10 Law governing rights and obligations of United States and Federal Reserve Banks; rights of any Person against United States and Federal Reserve Banks.

(a) Except as provided in paragraph (b) of this section, the rights and obligations of the United States and the Federal Reserve Banks with respect to: a Book-entry Security or Security Entitlement and the operation of the Treasury book-entry system; and the rights of any Person, including a Participant, against the United States and the Federal Reserve Banks with respect to: a Book-entry Security or Security Entitlement and the operation of the Treasury book-entry system; are governed solely by Treasury regulations, including the regulations of this Part, the applicable offering circular (which is 31 CFR Part 356, in the case of securities issued on and after March 1, 1993), the announcement of the offering, and Federal Reserve Bank Operating Circulars.

(b) A security interest granted to a Federal Reserve Bank, in the manner described in Section 357.12(c)(2), is governed by the law (not including the conflict-of-law rules) of the jurisdiction where the head office of the Federal Reserve Bank maintaining the Participant's Securities Account is located. For purposes of the application of such law, the Federal Reserve Bank shall be deemed a clearing corporation. A security interest granted to a Federal Reserve Bank by a Person that is not a Participant, is governed by the law specified in the agreement between the Federal Reserve Bank and the non-Participant.

(c) If the jurisdiction specified in paragraph (b) of this section is a State or territory or possession of the United States that has not adopted Revised Article 8, then the law specified in paragraph (b) shall be Revised Article 8.

§ 357.11 Law governing other interests.

(a) To the extent not inconsistent with these regulations, the law (not including the conflict-of-law rules) of a Securities Intermediary's jurisdiction governs:

(1) the acquisition of a Security Entitlement from the Securities Intermediary;

(2) the rights and duties of the Securities Intermediary and Entitlement Holder arising out of a Security Entitlement;

(3) whether the Securities Intermediary owes any duties to an adverse claimant to a Security Entitlement;

(4) whether an adverse claim can be asserted against a Person who acquires a Security Entitlement from the Securities Intermediary or a Person who purchases a Security Entitlement or interest therein from an Entitlement Holder; and

(5) except as otherwise provided in paragraph (c), the perfection, effect of perfection or non-perfection and priority of a security interest in a Security Entitlement.

(b) The following rules determine a ''Securities Intermediary's jurisdiction'' for purposes of this section:

(1) If an agreement between the Securities Intermediary and its Entitlement Holder specifies that it is governed by the law of a particular jurisdiction, that jurisdiction is the Securities Intermediary's jurisdiction.

(2) If an agreement between the Securities Intermediary and its Entitlement Holder does not specify the governing law as provided in paragraph (b)(1), but expressly specifies that the securities account is maintained at an office in a particular jurisdiction, that jurisdiction is the Securities Intermediary's jurisdiction.

(3) If an agreement between the Securities Intermediary and its Entitlement Holder does not specify a jurisdiction as provided in paragraph (b)(1) or (b)(2), the Securities Intermediary's jurisdiction is the jurisdiction in which is located the office identified in an account statement as the office serving the Entitlement Holder's account.

(4) If an agreement between the Securities Intermediary and its Entitlement Holder does not specify a jurisdiction as provided in paragraph (b)(1) or (b)(2) and an account statement does not identify an office serving the Entitlement Holder's account as provided in paragraph (b)(3), the Securities Intermediary's jurisdiction is the jurisdiction in which is located the chief executive office of the Securities Intermediary.

(c) Notwithstanding the general rule in paragraph (a)(5) of this section, the law (but not the conflict-of-law rules) of the jurisdiction in which the Person creating a security interest is located governs whether such security interest may be perfected by filing a financing statement and the effect of perfection or nonperfection and priority of such security interest.

(d) If the jurisdiction specified in paragraph (b) of this section is a State or territory or possession of the United States that has not adopted Revised Article 8, then the law for the matters specified in paragraph (a) of this section shall be Revised Article 8. For purposes of the application of the matters specified in paragraph (a) of this section, the Federal Reserve Bank maintaining the Securities Account shall be deemed a clearing corporation, and the Participant's interest in a Book-entry Security is a Security Entitlement.

§ 357.12 Creation of Participant's Security Entitlement; security interests.

(a) A Participant's Security Entitlement is created when a Federal

Reserve Bank indicates by book entry that a Book-entry Security has been credited to a Participant's Securities Account.

(b) A security interest in a Security Entitlement of a Participant in favor of the United States to secure deposits of public money, including without limitation deposits to the Treasury tax and loan accounts, or other security interest in favor of the United States that is required by Federal statute, regulation, or agreement, and that is marked on the books of a Federal Reserve Bank is thereby effected and perfected, and has priority over any other interest in the securities. Where a security interest in favor of the United States in a Security Entitlement of a Participant is marked on the books of a Federal Reserve Bank, the Reserve Bank may rely, and is protected in relying, exclusively on the order of an authorized representative of the United States directing the transfer of the security. For purposes of this paragraph, an ''authorized representative of the United States'' is the official designated in the applicable regulations or agreement to which a Federal Reserve Bank is a party, governing the security interest.

(c)(1) The United States and the Federal Reserve Banks have no obligation to agree to act on behalf of any Person or to recognize the interest of any transferee of a security interest or other limited interest in favor of any Person except to the extent of any specific requirement of Federal law or regulation or to the extent set forth in any specific agreement with the Federal Reserve Bank on whose books the interest of the Participant is recorded. To the extent required by such law or regulation or set forth in an agreement with a Federal Reserve Bank, or the Federal Reserve Bank Operating Circular, a security interest in a Security Entitlement that is in favor of a Federal Reserve Bank or a Person may be created and perfected by a Federal Reserve Bank marking its books to record the security interest. Except as provided in paragraph (b) of this section, a security interest in a Security Entitlement marked on the books of a Federal Reserve Bank shall have priority over any other interest in the securities.

(2) In addition to the method provided in paragraph (c)(1) of this section, a security interest, including a security interest in favor of a Federal Reserve Bank, may be perfected by any method by which a security interest may be perfected under applicable law as described in Section 357.10(b) or Section 357.11. The perfection, effect of perfection or non-perfection and priority of a security interest are governed by such applicable law. A security interest in favor of a Federal Reserve Bank shall be treated as a security interest in favor of a clearing corporation in all respects under such law, including with respect to the effect of perfection and priority of such security interest. A Federal Reserve Bank Operating Circular shall be treated as a rule adopted by a clearing corporation for such purposes.

§ 357.13 Obligations of United States; no adverse claims.

(a) Except as provided in Section 357.12(b) and (c)(1), for the purposes of this Subpart B, the United States and the Federal Reserve Banks shall treat the Participant to whose Securities Account an interest in a Book-entry Security has been credited as the person exclusively entitled to issue a Transfer Message, to receive interest and other payments with respect thereof and otherwise to exercise all the rights and powers with respect to such Security, notwithstanding any information or notice to the contrary. Neither the Federal Reserve Banks nor Treasury is liable to a Person asserting or having an adverse claim to a Security Entitlement or to a Book-entry Security in a Participant's Securities Account, including any such claim arising as a result of the transfer or disposition of a Book-entry Security by a Federal Reserve Bank pursuant to a Transfer Message that the Federal Reserve Bank reasonably believes to be genuine.

(b) The obligation of the United States to make payments of interest and principal with respect to Book-entry Securities is discharged at the time payment in the appropriate amount is made as follows:

(1) Interest on Book-entry Securities is either credited by a Federal Reserve Bank to a Funds Account maintained at such Bank or otherwise paid as directed by the Participant.

(2) Book-entry Securities are redeemed in accordance with their terms by a Federal Reserve Bank withdrawing the securities from the Participant's Securities Account in which they are maintained and by either crediting the amount of the redemption proceeds, including both principal and interest, where applicable, to a Funds Account at such Bank or otherwise paying such principal and interest as directed by the Participant. No action by the Participant is required in connection with the redemption of a Book-entry Security.

§ 357.14 Authority of Federal Reserve Banks.

(a) Each Federal Reserve Bank is hereby authorized as fiscal agent of the United States to perform functions with respect to the issuance of Book-entry Securities offered and sold by the Department to which this Subpart applies, in accordance with the terms of the applicable offering circular and with procedures established by the Department; to service and maintain Book-entry Securities in accounts established for such purposes; to make payments of principal and interest, as directed by the Department; to effect transfer of Book-entry Securities between Participants' Securities Accounts as directed by the Participants; and to perform such other duties as fiscal agent as may be requested by the Department.

(b) Each Federal Reserve Bank may issue Operating Circulars not inconsistent with this Part, governing the details of its handling of Book-entry Securities, Security Entitlements, and the operation of the book-entry system under this Part.

6. In Subpart D, Section 357.41 is revised and the text of §§ 357.42 and 357.44 are added, to read as follows:

Subpart D—Additional Provisions

* * * * *

§ 357.41 Waiver of regulations.

The Secretary reserves the right, in the Secretary's discretion, to waive any provision(s) of these regulations in any case or class of cases for the convenience of the United States or in order to relieve any person(s) of unnecessary hardship, if such action is not inconsistent with law, does not adversely affect any substantial existing rights, and the Secretary is satisfied that such action will not subject the United States to any substantial expense or liability.

§ 357.42 Liability of Department and Federal Reserve Banks.

The Department and the Federal Reserve Banks may rely on the information provided in a tender, transaction request form, or Transfer Message, and are not required to verify the information. The Department and the Federal Reserve Banks shall not be liable for any action taken in accordance with the information set out in a tender, transaction request form, or Transfer Message, or evidence submitted in support thereof.

* * * * *

§ 357.44 Notice of attachment for securities in TRADES.

The interest of a debtor in a Security Entitlement may be reached by a creditor only by legal process upon the Securities Intermediary with whom the debtor's securities account is maintained, except where a Security Entitlement is maintained in the name of a secured party, in which case the debtor's interest may be reached by legal process upon the secured party. These regulations do not purport to establish whether a Federal Reserve Bank is required to honor an order or other notice of attachment in any particular case or class of cases.

* * * * *

7. Appendix B and Appendix C to Part 357 are added and reserved as follows:

Appendix B to Part 357—Revised Article 8 [Reserved]

Appendix C to Part 357—TRADES Commentary [Reserved]

Dated: February 22, 1996.

Gerald Murphy,

Fiscal Assistant Secretary.

[FR Doc. 96–4481 Filed 3–1–96; 8:45 am]

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federal register

Monday
March 4, 1996

Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 880 and 890

Medical Devices; Protective Restraints; Revocation of Exemptions From the 510(k) Premarket Notification Procedures and Current Good Manufacturing Practice Regulations; Final Rule and 510(k) Guidance Document; Availability; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91N–0487]

21 CFR Parts 880 and 890

Medical Devices; Protective Restraints; Revocation of Exemptions From the 510(k) Premarket Notification Procedures and Current Good Manufacturing Practice Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising the classification regulations for protective restraints and wheelchair accessories intended for use as restraints, by revoking the existing exemptions for these devices from premarket notification and current good manufacturing practices (CGMP) regulations. FDA is also modifying the classification regulations for protective restraints and for wheelchair accessories to clarify the definitions of these devices. FDA is taking these actions in response to a number of recent reports of deaths and serious injuries that may have been associated with improper supervision of restrained patients or improper application of protective restraints. FDA believes that these actions will have minimal economic effect and will not disrupt the supply of these devices. In a notice published elsewhere in this issue of the Federal Register, FDA is announcing the availability of a draft guidance document for the preparation of premarket notification (510(k)) submissions for protective restraints.

DATES: Effective September 3, 1996.

FOR FURTHER INFORMATION CONTACT: Viola S. Hibbard, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the Federal Register of October 21, 1980 (45 FR 69678 at 69729), FDA published a final rule, in accordance with the procedures contained in section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), classifying as a device a protective restraint, usually a wristlet, anklet, or other type of strap, that is intended for medical purposes and that limits a patient's movement to the extent necessary for treatment, examination, or protection of the patient. In that regulation, FDA exempted manufacturers of protective restraints, which are class I devices, from the premarket notification procedures in part 807 (21 CFR part 807), and the CGMP regulations in part 820 (21 CFR part 820), with the exception of §§ 820.180 and 820.198, relating to general requirements concerning records and complaint files, respectively. FDA granted these exemptions because, at that time, FDA did not have information that caused serious concerns about safety problems related to the use of protective restraint devices.

Since the October 1980 publication of these classifications that exempted protective restraints from premarket notification and CGMP requirements, FDA has become aware of numerous reports of serious injuries and deaths that have been attributed to incorrect supervision, handling, or application of protective restraints. In the Federal Register of June 19, 1992 (57 FR 27397), FDA, in response to these adverse event reports, published a proposed rule to revoke the exemptions from premarket notification procedures and CGMP regulations for protective restraints and wheelchair accessories intended for use as protective restraints. FDA's proposed revocations complement the Health Care Financing Administration (HCFA) regulations (42 CFR part 483) and HCFA's February 5, 1992 (57 FR 4516), proposed rulemaking that address clinical indications for use of restraints that protect individuals from inappropriate use of restraints for discipline or convenience. The revocation of the exemption from the premarket notification procedures will permit the agency to monitor the marketing of these devices, and review and identify unclear labeling that may result in incorrect application of the devices. The revocation of the exemption from CGMP requirements will help ensure that restraints are safe by conforming to appropriate specifications for design, materials, performance, and labeling. A 60-day comment period, ending on August 18, 1992, was provided to allow interested persons an opportunity to submit comments on the proposed changes.

In addition to this rule, FDA has taken other steps to ensure that protective restraints are used safely. On July 15, 1992, FDA issued a Safety Alert on potential hazards with restraint devices (Ref. 1) to hospital administrators, directors of nursing, directors of emergency room services, and long-term care facilities. FDA also issued a letter to manufacturers in February 1992 stating that FDA considered restraints to be prescription devices which must bear a prescription legend as prescribed in § 801.109 (21 CFR 801.109) to help ensure appropriate medical intervention in the application and use of restraints (Ref. 2).

FDA received 24 comments in response to the proposal of June 19, 1992, from individuals, manufacturers, professional societies, and consumer and health associations. The comments were primarily supportive of FDA's proposed actions. Several comments, however, stated that FDA should consider additional regulation of protective restraints. These comments are discussed below.

II. Summary and Analysis of Comments and FDA's Response

A. General Comments

1. One comment stated that it would be helpful for FDA to recommend that facilities use one standard brand of each type of restraint (e.g., vest) to provide consistency and increase the likelihood that the restraint would be applied correctly. Another comment suggested restraints be uniformly designed so the front and back are easily identifiable.

Although standardization of brands in a facility may increase the likelihood that restraints will be applied correctly, it is critical that the correct type and size restraint be applied to maximize the safety of these devices. Accordingly, FDA encourages standardization as long as it can be achieved without compromising the use of the appropriate restraint type and size. Ultimately, however, this decision must be made by each facility. FDA cannot endorse one uniform design. Restraints used under different circumstances must necessarily incorporate different designs.

2. Several comments indicated support for a prescription requirement by licensed health care practitioners, specifying the appropriate restraint type, duration of application, and circumstances for use. One comment stated that FDA has avoided the issue of whether anyone other than a licensed health care worker should be permitted to apply restraints. Another comment stated that FDA did not address the issue of appropriate frequency of monitoring.

The determination of appropriate individuals to apply restraints or appropriate frequency of monitoring is beyond the scope of this regulation. However, FDA believes the use of restraints should be limited to those circumstances when they are clearly clinically indicated, and that they

should be used only for a strictly defined period of time and only under the supervision of a licensed health care provider. For these reasons, FDA informed protective restraint manufacturers in February 1992 that it considered these devices to be prescription devices that may only be used under the direction of a licensed health care practitioner. In addition, FDA strongly encourages that after restraints are prescribed by a licensed health care practitioner, they be applied only by adequately trained personnel, in accordance with State licensure and Federal certification requirements for facilities.

3. While several comments were supportive of FDA's proposal to revoke 510(k) and CGMP exemptions, three comments opposed the revocation of the exemptions. One comment suggested withdrawing the proposed regulations until more complete information is available. Another comment stated that the revocations are unjustified based on the relatively small number of associated deaths and injuries compared to the large annual usage of restraints. Another comment by a manufacturer stated that the revocations were unwarranted because it was unaware of any deaths or serious injuries associated with its restraint products.

FDA disagrees that it needs to have more complete information before it revokes premarket notification and CGMP requirements. Although complete information concerning the problems associated with restraints is not available, FDA does have sufficient information about these problems to warrant revocation of the exemptions from premarket notification and CGMP requirements. As explained in the preamble to the proposed rule, the revocation of these exemptions will allow FDA to gather more information to help ensure the safety of these devices.

FDA believes that the exemption revocations are justified based on the numbers of reports of deaths and injuries associated with protective restraint use. FDA notes that since publication of the proposed rule of June 19, 1992, the total numbers of deaths and serious injuries reported under the Device Experience Network (DEN), which includes the mandatory Medical Device Reporting Program and the MedWatch Reporting Program, have increased from 41 deaths and 16 serious injuries to 130 deaths and 48 injuries. In addition, several comments support FDA's belief that injuries and deaths associated with protective restraints are seriously underreported.

FDA does not agree with the comment from one manufacturer that revocations of the exemptions were not warranted for its restraints because the manufacturer was not aware of any deaths or serious injuries associated with its products. Reports of these problems encompass many different restraint types, regardless of manufacturer or design; various types of patient populations, regardless of clinical indications for the use of the restraint; and various types of health care facilities, including hospitals, home use situations, and nursing homes. The fact that problems have been reported from a wide spectrum of protective restraint types and situations indicates that the problems associated with protective restraints are not specific to one particular type of restraint. Moreover, given the probability of underreporting of protective restraint-associated deaths and injuries, the absence of complaints for one particular manufacturer does not indicate that that manufacturer's devices are free of the problems associated with other restraints.

4. One comment from a restraint manufacturer disagreed with the economic impact analysis of the proposed rule and stated that revocations of the exemptions would result in substantial economic costs. To avoid incurring the costs associated with compliance with the regulation, the manufacturer stated that their company may disavow the ''medical device'' classification of their product line and continue to sell their restraint devices to interested members of the health care industry.

FDA advises that protective restraints, within the meaning of section 201(h) of the act (21 U.S.C. 321(h)), are medical devices because they are intended for use in the cure, mitigation, treatment, or prevention of disease. Therefore, on or after the effective date of this final rule, any manufacturer distributing a restraint device not meeting the provisions of this final rule would violate the act by distributing devices that are: (1) Misbranded, in that no premarket notification submission has been filed pursuant to section 510(k) of the act (21 U.S.C. 360(k)); and (2) adulterated, if CGMP requirements are not met under section 520(f) of the act (21 U.S.C. 360j(f)). FDA strongly discourages any noncompliance with this regulation and is prepared to take enforcement actions against persons who violate this regulation. Such actions may include seizure, injunction, civil penalties, and criminal prosecution.

Furthermore, FDA disagrees that a substantial economic impact would result from these regulations. The comment estimated that the company would incur costs of $200,000 for 100 510(k) applications and as much as $500,000 to attain compliance with CGMP's, which could force the company out of business. The comment did not present any data to support claims of substantially higher costs for complying with CGMP's.

FDA has reconsidered its economic analysis and believes that the costs of premarket notification submissions and compliance with CGMP's are considerably lower than suggested in this comment. Also, FDA expects to allow some grouping by product category in a 510(k) submission as discussed in comment 10 of this document, which should limit the number of 510(k)'s that have to be submitted by any particular manufacturer.

5. One comment questioned the benefit of simply revoking the exemptions, but believed that the revocations were necessary as an interim measure while reclassification of the devices to a more stringent regulatory category is considered. Three comments believed the proposed revocations to be a totally inadequate response to problems with restraints and inconsistent with requirements issued by HCFA. These comments stated that FDA should convene a device classification panel to determine whether restraint devices should be reclassified to class II or III.

FDA is continuing to evaluate the need for reclassification of these devices. However, FDA believes that revocation of the premarket notification exemption will facilitate more immediate improvements in the labeling of restraint devices that quickly will provide increased safety and effectiveness in the use of restraints, and that revocation of CGMP exemptions will facilitate improvements in the manufacture of restraint devices. FDA believes that these measures will greatly reduce the risk associated with use of protective restraints. FDA retains the option to reclassify the devices at a later time, if such additional action is believed necessary to protect the public health.

FDA disagrees that its actions are inconsistent with those of HCFA. As stated in the preamble to FDA's June 19, 1992, proposed rule, the intent of HCFA's requirements on use of restraints in nursing homes is to protect nursing home residents from use of restraints for purposes of convenience or discipline. FDA's actions complement these requirements by ensuring that for those instances where

restraints are clinically indicated, the labeling and instructions for use of the restraints will facilitate correct application by health care providers.

6. One comment requested immediate recall action on restraints that have a higher association with death and serious injury than others. The comment believed that criss-crossed vests were the most dangerous, although the comment acknowledged that the higher number of death reports associated with vest restraints may be due to more frequent use of those devices.

FDA does not believe that the criteria for requiring the recall of any particular protective restraint have been met. Under section 518(e) of the act (21 U.S.C. 360h(e)), FDA may order a recall of a device only after finding that the device would cause serious adverse health consequences or death. FDA does not have information that any type of restraint, including criss-crossed vests *if used properly*, would cause serious adverse health consequences or death. Furthermore, restraints can provide benefits that outweigh the risks for some patients, for example, by preventing patients with medically related cognitive deficits from involuntarily discontinuing life-support or other needed medical interventions, by temporarily reducing the mobility of agitated patients who may otherwise hurt themselves or others, or by helping patients feel safer in a bed or wheelchair. FDA does not believe that recalling these restraints where the benefits outweigh the risks would be in the best interest of the public health. Furthermore, FDA believes that the risks associated with restraints will be further reduced by the measures taken in this regulation. FDA, however, will certainly initiate 518(e) recall action in the future if the agency determines that individual circumstances warrant such action.

7. Four comments requested that FDA resume plans to conduct clinical and human factors engineering tests on restraining devices to assess their safety and effectiveness. Several comments stated that FDA should gather and study information from other sources besides DEN, including the Consumer Product Safety Commission, HCFA, State and local agencies that regulate nursing homes, the courts, review of patient records, review of the literature, and consultation with experts in the field.

FDA notes that in developing its course of action regarding protective restraints, the agency gathered considerable information from many other sources besides DEN, including literature reviews, interviews with health care professionals and professional organizations, visits to user facilities, and discussions with manufacturers of restraints. It is the manufacturers' responsibility to conduct testing to assess safety and effectiveness. FDA, however, would welcome any additional research information regarding restraint use from health and consumer groups and encourages research by such groups that would promote safer use of restraints. By revoking the premarket notification and CGMP exemptions, FDA will gain further information that will enable the agency to ensure safe use of these devices. FDA will continue to evaluate information received from other available sources.

8. One comment stated that FDA has ''exhibited confusion'' about the appropriate circumstances for use of restraints. The comment noted that the proposed rule states that restraints may be needed to keep agitated patients from hurting themselves, but an FDA Medical Alert warned that restraints may only add to this agitation and confusion and therefore may place the patient in jeopardy.

Whether restraints should be used may vary depending on the circumstances presented by the individual patient. While FDA realizes that restraints can adversely affect a patient by increasing agitation, they may sometimes be necessary under certain circumstances to restrain agitated patients from harming themselves. The determination of whether restraint use is appropriate should be made by clinicians for each patient individually, after assessing the risks and benefits of restraint use.

9. Several comments that supported the revocations suggested that manufacturers who fail to submit a 510(k) or fail to adhere to CGMP's should not only be prohibited from future sales of restraints, but should be compelled to remove from use (at the manufacturers' expense) all previously sold restraint products.

FDA disagrees that recalling devices is necessarily an appropriate remedy for failure to comply with CGMP or premarket notification requirements. As explained in comment 6 of this document, FDA will initiate recalls only if the statutory criteria under section 518(e) of the act are met, and will decide whether those criteria are met on a case-by-case basis. As stated in FDA's response to comment 4 of this document, manufacturers who fail to comply with CGMP and premarket notification requirements are subject to various enforcement actions by FDA.

10. Five comments requested that manufacturers be allowed to submit 510(k)'s by product category (e.g., vests, limb holders etc.), rather than for each individual product, because some products differ only in minor design aspects, while their function, application, and use is identical.

FDA agrees that grouping of similar devices in a 510(k) submission would be acceptable to a limited extent. For example, vests of similar design but composed of different fabrics might be grouped into one 510(k). However, submissions for devices differing substantially in design (and therefore risk) should not be grouped in a single 510(k). FDA will review this issue on a case-by-case basis.

11. One comment expressed concern regarding what criteria FDA is using to determine safety and effectiveness, and whether manufacturers could be assured that 510(k)'s will not be delayed on the basis of individual reviewers' perceptions of what constitutes safe and effective.

FDA advises that there will be uniformity in the criteria that reviewers consider to determine the safety and effectiveness of these devices. Section 513(i) of the act (21 U.S.C. 360c(i)) and its implementing regulations in part 807 (21 CFR part 807) describe the criteria used by FDA to determine substantial equivalence. FDA provided guidance that described labeling for restraints at an October 1991 meeting with a medical device trade organization. This guidance has been incorporated into a draft 510(k) submission guidance that will be used by FDA reviewers to assist in evaluating 510(k) submissions. Additional general labeling guidance is available in the Human Health Services (HHS) publication ''Labeling: Regulatory Requirements for Medical Devices'' (Ref. 3), the Office of Device Evaluation's labeling guidance document (Ref. 4), and the publication ''Write It Right,'' a guidance on labeling for home use products (Ref. 5). The draft 510(k) submission guidance recommends that manufacturers' 510(k) submissions for restraints address the following: (1) Specific intended use of the device; (2) ease of release of the device in the event of emergencies; (3) tear strength of the materials; (4) potential for injury (e.g., whether there are abrasive materials, such as metal fasteners, that would come in contact with the patient's skin, and similar considerations); (5) ease of identification of size; (6) completeness, conspicuousness, and simplicity of directions and labeling; (7) care/cleaning instructions; (8) whether the material is biocompatible; and (9) any safety testing data available for the device, including an analysis of bench simulation testing data; and for certain circumstances, (10) patient testing data.

Manufacturers may contact the reviewing division to discuss the appropriate content of their submissions on a case-by-case basis. FDA, elsewhere in this issue of the Federal Register, is publishing a notice of availability of this draft guidance and requesting comments on it.

12. Five comments stated that to ensure that protective restraints continue to be available for medical use, manufacturers need to be able to continue to market their products during the interim period between the effective date of the final rule revoking the 510(k) exemptions and the date that products are cleared by FDA. The comments also stated that manufacturers need to be given a reasonable amount of time (at least 6 months) after their final labeling is approved to exhaust the remaining existing supplies of their products and phase in products with the new labeling. Additionally, three comments stated that manufacturers need to be given a reasonable amount of time (for example, 2 years) to attain compliance with CGMP's.

FDA realizes that there will be a time period between the filing of a 510(k) submission required by this regulation, and FDA's determination, based on that submission, of whether the device has marketing clearance. During the time period between the filing of a 510(k) and the FDA's substantial equivalence decision, FDA, in exercising its enforcement discretion, does not intend to initiate enforcement action relating to the distribution of protective restraint devices that are adulterated under 21 U.S.C. 351(f)(1)(B) because they fail to have FDA marketing clearance if: (1) The devices were initially introduced into interstate commerce prior to September 3, 1996; and (2) the sponsor has filed a 510(k) submission as of September 3, 1996.

FDA, however, intends to exercise its enforcement discretion to initiate regulatory action against protective restraint devices that have not received marketing clearance after June 4, 1997 if FDA has been unable to reach a decision determining substantial equivalence because the 510(k) submission fails to contain sufficient information. FDA will notify the sponsor if such additional information is necessary.

FDA has extended the effective date of the final rule requiring submission of 510(k)s and compliance with CGMP's from 90 days to 180 days. FDA believes this time period is appropriate.

FDA first informed restraint manufacturers about FDA's planned actions regarding 510(k) and CGMP requirements at a meeting with a medical device trade organization in October 1991. FDA again notified manufacturers in FDA's June 19, 1992, proposed rule, that the agency intended to revoke these exemptions. Given the fact that industry has been on notice since 1991 of FDA's plans to revoke these exemptions, FDA does not believe manufacturers need an additional 2 years to comply with CGMP's or 6 months after their labeling is approved to exhaust supplies of labeling.

B. Restraint Identification

13. Two comments agreed with FDA's identification of a protective restraint as it was published in the proposed rule. Several comments stated that the identification of restraint used in the proposed rule is too narrow, leaving major gaps in the coverage of a growing list of potentially dangerous devices that are routinely used to restrain patients or residents and that are ''falsely marketed'' as alternatives to restraints. To alleviate these concerns, several comments suggested using the broader definition of restraint proposed by HCFA in order to include the concept of a method of restriction of movement.

FDA disagrees that the identification of protective restraints is too narrow and leaves major gaps that do not cover devices that are ''falsely marketed'' as alternatives to restraints. Although the identification gives examples of protective restraints, such as wristlets, vests, and straps, the identification of protective restraints is not limited to those examples. The identification is based on the product's intended use. Under § 801.4, evidence of a device's intended use is not limited to labeling claims or to verbal representations. It may be shown by the circumstances that the device is offered and used for a purpose for which it is neither labeled nor advertised. FDA considers any actions that otherwise represent a device's intended use, as well as labeling, to determine a device's intended use. Therefore, even devices that are ''falsely marketed'' as alternatives to restraints will fall under the identification of protective restraint if their intended use is to function as a protective restraint. If a manufacturer intends a device to be used as a restraint or is aware that the device is used as a restraint, that manufacturer must comply with requirements for protective restraints. FDA encourages consumers or health care workers to report instances where manufacturers of such products are not complying with the requirements for protective restraints.

Other comments suggested that the identification should state that a restraint is any device which a resident cannot remove easily and which restricts freedom of movement or easy access to their body. FDA does not agree that the protective restraint identification should be this broad. FDA may only regulate as devices products that fall within the definition under section 201(h) of the act. Many products that restrict freedom of movement or easy access to the body do not fall under FDA's jurisdiction (e.g., safety belts, car seats). Also, even if products that restrict freedom or access are medical devices (e.g., geriatric chairs), FDA believes it is inappropriate to identify all such devices as protective restraints where that is not the intended use of such devices.

14. One comment objected to the use of ''or others'' after ''protection of the patient'' at the end of § 880.6760 (21 CFR 880.6760) because it is an established rule that restraints may only be used to ''ensure the physical safety of the resident *or other residents*'' (Social Security Act, section 1919 (42 U.S.C. 1396q)). The comment also objected to the use of the term ''patients'' in the restraint identification, because it is not appropriate in many non-hospital settings. The term ''patients or other residents'' was suggested as a substitute.

FDA disagrees with the comments. Restraints are sometimes used in situations to protect individuals other than the person in restraints. For example, hospitals may use restraints in emergency rooms to protect staff, or other patients/residents from harm (e.g., due to patient drug abuse or comparable circumstances). With regard to the objection to the term ''patients'' in the context of non-hospital settings, FDA believes that since restraints are medical devices, any resident who is restrained constitutes a patient within the broad meaning of the term in this section while wearing the restraint. Therefore, FDA rejects these comments.

15. One comment stated that FDA should define bedrails and geriatric chairs as restraints.

FDA notes that bedrails and geriatric chairs are currently classified under §§ 880.5100, 880.5110, 880.5120, and 880.5140 (bedrails); and §§ 890.3100 and 890.3110 (21 CFR 890.3100 and 890.3110) (geriatric chairs). For the reasons stated in response to comment 13 of this document, FDA believes that the current definition of restraints is appropriate.

16. One comment requested that FDA modify the restraint identification to exclude from the regulation those restraints that are used with radiotherapy linear accelerators and simulators, because of the controlled

conditions under which such restraints are used and the benefit they provide. The comment requested that the identification of a restraint be modified as follows:

A protective restraint is a device * * * that is intended for medical purposes and that limits the patient's movements to the extent necessary for treatment, examination, or protection of the patient or others, excluding restraints which are used for a short duration under the continual supervision of qualified personnel.

FDA does not believe that it would be appropriate to modify the restraint identification to exclude restraints which are used for a short duration under continual supervision from 510(k) and CGMP requirements. These requirements are necessary for restraints that are intended to be used for short periods of time under supervision because such restraints may pose risks to patients if they are not used in the manner the manufacturer intended. FDA advises that ''restraints'' for use with radiation therapy systems are included under the classification regulations for radiation therapy systems in §§ 892.5050 and 892.5300 (21 CFR 892.5050 and 892.5300). Under those classification regulations, such restraints are already subject to 510(k) and CGMP requirements. Manufacturers of restraints that are accessories to other devices should submit their 510(k) submissions to the appropriate reviewing division for the primary device.

C. Wheelchair Accessories

17. Two comments supported the proposal to revise the classification regulation for wheelchair accessories labeled or otherwise represented as restraints. One comment, however, stated that restraints should not be classified as wheelchair accessories because this minimizes the importance of decisions regarding whether a restraint should be used at all and the selection of the appropriate type of restraint.

FDA disagrees that the chosen classification of wheelchair accessories intended for use as restraints diminishes the importance of decisions regarding use of those devices. FDA specifically emphasized in the proposed rule and in the July 1992 FDA Safety Alert that the same safety considerations, including proper selection and labeling, are equally important for wheelchair accessories that are used as protective restraints.

18. Two comments recommended that FDA adopt an identification of wheelchair accessories intended for use as restraints that includes all accessories and all wheelchair components that are manufactured and marketed with the intent of restricting the patients' movement, regardless of whether the devices are labeled or represented as restraints.

FDA agrees with these comments. As discussed in paragraph 13 of this document, the definition of protective restraint includes any device that ''is intended for medical purposes and that limits the patient's movements to the extent necessary for treatment, examination, or protection of the patient or others.'' In stating in FDA's June 19, 1992, proposed regulation that FDA was exempting wheelchair accessories from CGMP and premarket notification requirements that were not ''labeled or otherwise represented'' as a protective restraint, FDA did not mean to imply that it was exempting those wheelchair accessories that are not labeled or represented as restraints if they are intended for use as restraints. To clarify that all wheelchair accessories which are intended to be used as protective restraints must comply with premarket notification and CGMP requirements, FDA is replacing the words ''labeled or otherwise represented'' with ''intended for use'' in the final regulation.

D. Labeling/Human Factors

19. Six comments requested that the agency consider the wide variety of protective restraints available and evaluate each device according to its intended use/size/design, without imposing a ''blanket'' labeling requirement for all restraints. For example, devices such as vests should be labeled to clearly distinguish the front and back of the restraint, whereas other restraints which have no front and back should not be required to have such labeling.

FDA agrees that a ''blanket'' labeling requirement in this sense should not be imposed and that the risks and benefits of each restraint device should be reviewed individually in determining appropriate specific labeling for restraint devices. FDA believes, however, that similar protective restraints should have similar labeling. FDA also believes that protective restraints should include step-by-step instructions on how to apply the device and where to secure the ties, have securely attached warning labels that clearly identify the front and back of the restraints, and warn users of the dangers of reversal, preferably using pictorials. Additional labeling instructions are listed in the draft guidance document discussed in comment 12 of this document.

20. Several comments expressed concern that the FDA regulation implies that the only danger of restraints is in their potential misapplication and that they are safe when used in accordance with the manufacturer's instructions, and that HCFA's regulations will be undermined.

FDA disagrees with these comments. FDA's regulation does not imply that it alone will ensure safe and effective use of restraints. As explained more fully in both the preamble to FDA's June 1992 proposed rule and comment 5 of this final rule, FDA's regulations and HCFA's regulations complement each other, they do not undermine each other. HCFA laws and regulations ensure that restraints are only used on persons who need restraints, and FDA's regulations will help ensure that if clinically appropriate, such restraints will be applied safely.

21. Several comments requested that FDA require that restraint labeling contain specific information including information about all potentially harmful effects from the use of restraints, including hazards, side effects, warnings/precautions, and contraindications for their use. The comments also requested requiring clear delineation in the device labeling as follows: (1) The front and back of the restraint; (2) top and bottom of the restraint; (3) length of time the restraint can be applied safely; (4) frequency with which the restraint should be released; (5) frequency with which the patient should be monitored; and (6) minimum standards or qualifications of personnel to administer restraints. Several comments stated that labeling should be required to be on the inside or underside of the device in as discrete a manner as possible to convey necessary information and/or instructions to users, in order to preserve the dignity and self-esteem of the individual being restrained.

FDA advises that this regulation will allow FDA to review the labeling for protective restraints, and that all labeling must provide material information related to its safe use in accordance with section 502(a) of the act (21 U.S.C. 352(a)). In the preamble to the proposed rule, FDA stated certain labeling practices that FDA believes are necessary to help ensure the safe use of devices. Also, specific suggested labeling is stated in the draft guidance document discussed in comment 11 of this document. After receipt of individual premarket notifications, FDA will review the labeling on a case-by-case basis.

With regard to placement of labeling, FDA encourages placement of labeling in a manner that respects the patient's dignity, as long as the placement does

not compromise the visibility of the labeling to the person applying the restraint.

22. Several comments noted support for the utilization in all product labeling of pictorials, languages other than English, and textual information written for low language comprehension levels, in sufficiently large type to clearly express the message. Several comments suggested that the use of languages other than English is not feasible and that the manufacturer's obligation should be limited to adequate step-by-step instructions in English, with translations made available by individual employers.

FDA agrees that pictorials and text materials written for low language comprehension levels are important for effective conveyance of application and hazard information. FDA also encourages manufacturers that distribute devices for use by populations who do not use English as a first language to provide instructions in foreign languages to the extent possible and in accordance with the foreign language requirements of § 801.15(c). FDA has discussed human factors considerations related to labeling with manufacturers, including the selection of legible font types and sizes. Under 21 U.S.C. 352(c) labeling statements required by or under the authority of the act must be placed with conspicuousness and in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use. See 21 CFR 801.15.

23. Several comments suggested that in addition to improved labeling, posters should be made available for use and kept in accessible view, such as in the restrained patient's room, nurses stations, and physical therapy facilities.

FDA agrees that posters could be very helpful in promoting proper use of restraints and has encouraged manufacturers to develop such posters. Several manufacturers have already implemented instructions on posters. Placement of such posters should be done in such a way that they will be readily accessible to personnel but still comply with nursing facility requirements for a homelike environment, in accordance with provisions of 42 CFR 483.15(h)(1).

24. One comment noted that warnings and instructions for restraints should be conveyed in a form suitable for home use as well as institutional use.

FDA agrees with the comment and encourages use of FDA's guidance on developing user instruction manuals for medical devices used in home health care (Ref. 5). The document, entitled ''Write It Right,'' has been distributed to all domestic and foreign medical device manufacturers. Copies may be obtained from the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health, 800–638–2041.

25. One comment stated that experience demonstrates that product labels and directions cannot in and of themselves protect patients from injury or death. The comment stated that while the labeling guidelines proposed by FDA represent a positive step in recognizing the potential dangers of inappropriately applied or inappropriately supervised use of restraints, such guidelines may do more to help shield manufacturers involved in product liability suits than to protect patients from avoidable accidents.

FDA agrees that product labeling alone cannot protect patients from injury or death. However, well-presented labeling that is written in a salient, informative, and concise manner can motivate the user to read instructions, which can reinforce demonstration instruction and prevent misuse of devices. Studies, as early as 1960, illustrate that behavior can be affected by warnings and safety posters in the workplace (Ref. 6). More recent studies demonstrate that user behavior is clearly influenced by the presence and location of warnings and adequate instructions for use (Ref. 7).

FDA agrees that clearer labeling may in some instances help shield manufacturers from product liability. However, regardless of any effect on product liability, improved labeling, which may help reduce the incidence of injury and death is important. To supplement the beneficial effects of improved labeling, FDA advises that adequate training and education of health care providers is necessary for safe and effective use of restraints.

26. One comment stated that knots tied in some restraints are often difficult to untie in the event of an emergency, and if it were at all possible, restraints that tie should be replaced by those that release with a clasp of some kind.

FDA supports the development of safe innovations that would improve the ease of use of restraint devices.

E. Sizing/Color Coding

27. Several comments stated that a universal color coded sizing system should be adopted throughout the industry to help facilitate selection of the appropriate restraint size and reduce incidences of misapplication of an incorrect size that could lead to deaths or injuries.

FDA agrees with the comments. FDA also notes the availability of a voluntary new sizing standard for women over the age of 55, which might be of use in designing restraints for geriatric patients, who typically have upper torso dimensions that are substantially different from younger patients. The standard, entitled ''The Development of Body Measurement Tables for Women 55 and Older and the Relationship to Ready to Wear Garment Sizes,'' is available from the American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103.

28. One comment from a manufacturer noted that for 54 years their company has manufactured restraints in accordance with a particular color code for size, and that this color code has become the most commonly used and understood color code by users of restraints. The comment stated that if FDA decides to adopt a different color standard than what the comment perceives as the ''prevailing standard,'' it will create serious confusion among users because of the extensive user familiarity with that color coding standard. Another comment stated that color coding sizes for restraints would have a substantial financial impact on industry.

This regulation is not requiring the adoption of a color-coded sizing standard. However, FDA encourages manufacturers to develop an industry-wide voluntary standard.

29. Two comments noted that manufacturers produce a selection of sizes of certain types of restraints (e.g., vests), but that this does not ensure that facilities have purchased adequate sizes or the entire line of vest restraints for utilization in their facility.

FDA advises that selection of the appropriate size and type of restraint is critical for safe and effective use of the device and that clinicians and purchasing agents should consult medical practice guidelines and instructions for use in determining the appropriate size.

F. Flame Retardancy

30. FDA explicitly solicited comments regarding whether some or all restraints should be made of flame resistant materials. Several comments supported a universal requirement for flame resistant restraints, citing the following reasons:

(1) There have been reports to FDA of at least six patients dying or being injured as a result of deliberately or accidentally igniting their restraints;

(2) Clinicians report having seen many restraints with ash and cigarette burns in them, further indicating a

safety problem with respect to flammable materials;

(3) Many of the persons who are restrained may retain their right to smoke in designated areas. These patients may have poor posture control or hand dexterity, or may be confused, increasing the chances of an accident. Also, visitors and other residents unaware of a potential fire hazard may give smoking materials to the resident without staff knowledge;

(4) Many nursing home residents may use oxygen, or be in close proximity to other residents who use oxygen, increasing the danger of fire.

Alternatively, multiple comments opposed requiring all protective restraints to be constructed of flame resistant material, citing the following reasons:

(1) Adequate and appropriate supervision is the best means of prevention of burn and smoke inhalation injuries to individuals who are being restrained;

(2) Many other items found on or near the bed are not flame resistant, such as bed linens, pajamas, clothing, and even the patient's hair, so having restraints made of flame resistant materials would not serve a useful purpose. Residents might be better served through establishment of a smoke-free environment;

(3) Labeling of restraints as flame resistant might actually encourage smoking in bed by providing a false sense of security to both residents and health care providers, who might relax smoking policies;

(4) The availability and effectiveness of flame resistant restraints is limited by current technology. Some device components are not readily available in flame resistant material, so requiring restraints with this property might be prohibitively expensive. Also, textile materials treated with flame resisting chemicals will burn if a source of ignition is present, and the flame retardancy of some devices is destroyed after the first laundering of the device. Warnings against the exposure of protective restraints to ignition sources should adequately address concerns related to burn injuries;

(5) Flame resistant vests are now marketed with very little success due to the higher price (approximately 30 percent). This cost outweighs the negligible benefit that might be derived with a universal requirement for flame resistant restraints.

Several comments also stated that FDA should study the actual contribution to patient safety that would be afforded by flame resistant restraints versus the economic impact of replacing devices currently in use. One comment suggested that the comfort and care of the patient should be the primary concern and that secondary issues should include whether fire resistant materials make the restraint less flexible or more likely to cause rubbing or irritation; the effect on safety features of the device; and the extent of protection flame resistant materials would actually offer in the event of fire.

FDA has carefully considered the comments submitted and concluded that although there are potential fire hazard concerns for some patients, adequate and appropriate supervision is the most effective and useful means of preventing fire-related injuries associated with restrained patients. Some additional benefit, however, may occur by using flame-resistant restraint material on patients who smoke. Although FDA does not believe it is appropriate to require the use of flame-resistant materials for all restraints, FDA recommends that health care institutions develop and implement policies for the use of flame-resistant restraints for patients who smoke while in restraints.

G. Training, Education, and Guidelines for Use

31. Several comments advocated increased training, education, and FDA development of guidelines for restraint use to promote the safe application of restraint devices. Several comments suggested that FDA should publish a consumer (family) guide or brochure on the appropriate use of restraints, the risks and benefits of restraint prescription and application, and the potential side effects and hazards of restraint use.

FDA agrees that adequate training and education for users of restraints in all care scenarios is critical to the safe and effective use of restraints and FDA strongly encouraged increased education about restraint use in its July 1992 Safety Alert issued to health care professionals. FDA has actively participated with health care associations in the development of guidelines for use of medical devices in the past and is willing to participate in such efforts for protective restraints. FDA advises that in using restraints, institutions are required to meet all State and local laws and HCFA requirements, and are encouraged to meet guidelines developed by professional health care organizations. With regard to publication of a consumer guide, the FDA 1992 Safety Alert on restraints contains information about restraint use specifically directed towards patients and family members. Copies of FDA's Safety Alert are available upon request from the Office of Surveillance and Biometrics (HFZ–500), Center for Devices and Radiological Health, 5600 Fishers Lane, Rockville, MD 20857.

32. One comment stated that because the liability burden for patient morbidity and mortality caused by restraints is increasingly shifted to nursing home staff, FDA should consider requiring manufacturers to offer training and accessible advice to nursing homes with device questions or problems, as a component of the new premarket notification and CGMP rules.

Such requirements are beyond the scope of this rulemaking. However, FDA encourages health care facilities to request training when purchasing restraints and if such training is not made available, to reconsider their purchasing policies. Manufacturers have already been strongly urged by FDA to develop training videos and other materials to assist health care facilities in training their staff in the proper application and use of their products.

H. Chemical Restraints

33. Two comments noted that they do not support the use of pharmaceutical options as chemical restraints in substitute for physical restraints and stated that FDA is well positioned to address the issue of the misuse of chemical restraints. The comments recommended that FDA consider labeling recommendations for manufacturers of drug products frequently used for chemical restraint.

FDA is advised that guidelines for the use of chemical restraints in nursing homes are being finalized by HCFA, but such controls are beyond the scope of this medical device rule. If the comments wish to express concerns regarding labeling of specific drug products believed to be misused as chemical restraints, those comments should be referred to FDA's Center For Drug Evaluation and Research, Division of Neuropharmacological Drug Products (HFD–120), 5600 Fishers Lane, Rockville, MD 20857.

III. The Final Rule

Persons required to file premarket notification submissions under section 510(k) of the act (21 U.S.C. 360(k)) and the procedures in subpart E of 21 CFR part 807 must file a premarket notification submission for any protective restraint device already marketed or intended to be introduced or delivered for introduction into interstate commerce for commercial distribution on or after September 3, 1996.

All protective restraints that are introduced or delivered for introduction into interstate commerce on or after September 3, 1996, are required to be manufactured in compliance with the CGMP regulations in 21 CFR part 820.

In a notice published elsewhere in this issue of the Federal Register, FDA is announcing the availability of a draft guidance document for the preparation of a premarket notification (510(k)) submission.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule only removes an exemption and subjects manufacturers of patient restraints to the same requirements as manufacturers of other devices, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. ''FDA Safety Alert: Potential Hazards with Restraint Devices,'' Food and Drug Administration, Rockville, MD, July 15, 1992.

2. Johnson, R., FDA, letter to restraint manufacturers, February, 1992.

3. ''Labeling: Regulatory Requirements for Medical Devices,'' HHS Publication No. FDA 89–4203, Food and Drug Administration, Rockville, MD, August, 1989.

4. Office of Device Evaluation, ''Device Labeling Guidance,'' No. G91–1, Food and Drug Administration, Rockville, MD, March 8, 1991.

5. ''Write It Right: Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care,'' Food and Drug Administration, Rockville, MD, August, 1993.

6. Laner, S., and R. G. Sell, ''An Experiment on the Effect of Specially Designed Safety Posters,'' *Occupational Psychology*, 34:153–169, 1960.

7. Wolgalter, M. S. et al., ''Effectiveness of Warnings,'' *Human Factors*, 29(5):599–612, 1987.

List of Subjects

21 CFR Parts 880 and 890

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 880 and 890 are amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 880.6760 is revised to read as follows:

§ 880.6760 Protective restraint.

(a) *Identification*. A protective restraint is a device, including but not limited to a wristlet, anklet, vest, mitt, straight jacket, body/limb holder, or other type of strap, that is intended for medical purposes and that limits the patient's movements to the extent necessary for treatment, examination, or protection of the patient or others.

(b) *Classification*. Class I (general controls).

PART 890—PHYSICAL MEDICINE DEVICES

3. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

4. Section 890.3910 is revised to read as follows:

§ 890.3910 Wheelchair accessory.

(a) *Identification*. A wheelchair accessory is a device intended for medical purposes that is sold separately from a wheelchair and is intended to meet the specific needs of a patient who uses a wheelchair. Examples of wheelchair accessories include but are not limited to the following: armboard, lapboard, pusher cuff, crutch and cane holder, overhead suspension sling, head and trunk support, and blanket and leg rest strap.

(b) *Classification*. Class I (general controls). If the device is not intended for use as a protective restraint as defined in § 880.6760 of this chapter, it is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, and is also exempt from current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Dated: February 15, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–4719 Filed 3–1–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91N–0487]

Medical Devices; Protective Restraints; Draft 510(k) Guidance Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document for the preparation of premarket notification (510(k)) submissions for protective restraints and wheelchair accessories intended for use as restraints. The draft guidance document is intended to assist manufacturers in complying with premarket notification requirements. Elsewhere in this issue of the Federal Register, FDA is publishing a final rule revoking exemptions for these devices from premarket notification and current good manufacturing practices regulations.

DATES: Written comments by June 3, 1996.

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, or 1–800–638–2041. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the 510(k) guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: James E. Dillard, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287.

SUPPLEMENTARY INFORMATION: FDA is revising the classification regulations for protective restraints (21 CFR 880.6760) and wheelchair accessories intended for use as restraints (21 CFR 890.3910). In a final rule published elsewhere in this issue of the Federal Register, FDA is revoking the existing exemptions for these devices from premarket notification and current good manufacturing practices regulations. This action is being taken in response to a number of recent reports of deaths and serious injuries that may have been associated with improper supervision of restrained patients or improper application of protective restraints.

Manufacturers and initial distributors of protective restraints and wheelchair accessories intended for use as restraints will be required to submit premarket notification submissions by September 3, 1996. Therefore, FDA is announcing the availability of a draft guidance document for the preparation and submission of 510(k) submissions for these devices. This draft guidance will be used by FDA reviewers to assist in evaluating 510(k) submissions. Characteristics that manufacturers should address in their 510(k) submissions for restraints include the following: (1) Specific intended use of the device; (2) ease of release of the device in the event of emergencies; (3) tear strength of the materials; (4) potential for injury (e.g., whether there are abrasive materials, such as metal fasteners, that would come in contact with the patient's skin, and similar considerations); (5) ease of identification of size; (6) completeness, conspicuousness, and simplicity of directions and labeling; (7) care/cleaning instructions; (8) whether the material is biocompatible; (9) any safety testing data available for the device, including an analysis of bench simulation testing data; and for certain circumstances, (10) patient testing data. The draft guidance document contains more detailed information on restraint premarket submission requirements and should be useful to manufacturers during 510(k) preparation. The draft guidance document may be obtained from the Division of Small Manufacturers Assistance (address above). Manufacturers may contact the reviewing division to discuss the appropriate contents of their submissions on a case-by-case basis.

Guidance documents do not create or confer any rights for or on any person and do not operate to bind FDA or others; however, they do represent the agency's current thinking on the subjects of the guidance documents. Interested persons may, on or before June 3, 1996, submit to the Dockets Management Branch (address above) written comments on the 510(k) guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 15, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–4718 Filed 3–1–96; 8:45 am]

BILLING CODE 4160–01–F

federal register

Monday
March 4, 1996

Part VI

Department of Housing and Urban Development

Office of Assistant Secretary for Community Planning and Development

Notice of Funding Availability; Youthbuild Program—Fiscal Year 1996; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Assistant Secretary for Community Planning and Development

[Docket No. FR–4005–N–01]

Notice of Funding Availability Youthbuild Program—Fiscal Year 1996

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of Funding Availability for the FY 1996 Youthbuild Competition.

SUMMARY: This Notice of Funds Availability (NOFA) announces the expected availability of up to $37.5 million of Fiscal Year 1996 program funds for grant assistance under the Youthbuild Program established by the Housing and Community Development Act of 1992. These funds will be awarded competitively. Only implementation grants will be funded. The body of this NOFA contains information on the following: the purpose of the NOFA, information regarding eligibility, available funding, the application process and selection criteria.

The Congress has not yet enacted a FY 1996 appropriations for HUD. However, HUD is publishing this notice in order to give potential applicants adequate time to prepare applications. The amount of funds announced in this NOFA is an estimate of the amount that may be enacted in 1996. HUD is not bound by the estimate set forth in this notice. The estimated amount may be adjusted downward based on the enacted 1996 appropriation.

APPLICATION SUBMISSION: An original and one copy of the completed application for grant funds must be received in HUD Headquarters prior to 12 midnight EST on May 6, 1996. Applicants may include another copy of their application on 3.5'' computer diskettte. Applications will be accepted at the following address: Processing and Control Unit, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7255, Washington, DC 20410. ATTN: Youthbuild. At close of business on the deadline date, applications will be received at either room 7255 or the South Lobby of the Department of Housing and Urban Development at the above address.

Applications which are mailed prior to May 6, 1996, but not received until after the deadline will be deemed to have been received by the date if postmarked by the United States Postal Service by no later than May 3, 1996. Express delivery items received after May 6, 1996 will be deemed to have been received by the deadline upon submission of documentary evidence that they were placed in transit with the express delivery service by no later than May 5, 1996. Applications may not be submitted by facsimile (FAX).

FOR A COPY OF THE APPLICATION PACKAGE, CONTACT: Requests for application packages, including an instructional video, for the current competition can be made by calling Community Connections at 1–800–998–9999 or through the internet at gopher://amcom.aspensys.com:75/11/funding. You may also contact the HUD Processing and Control Unit, Office of Community Planning and Development, U. S. Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7255, Washington, DC 20410. Requests for application packages may be faxed to HUD at (202) 708–3363. (This is not a toll-free number.) Requests for application packages must refer to ''Youthbuild'' document FR–4005–N–01. The Youthbuild application package contains appropriate instructions, forms and required certifications for completing a grant request. Requests for Youthbuild application packages for the current competition should be made immediately.

FOR FURTHER INFORMATION CONTACT: All procedural and substantive questions should be directed to the Office of Economic Development, Department of Housing and Urban Development, Room 7136, 451 Seventh Street SW., Washington DC 20410; telephone (202) 708–2035 or TDD (202) 708–1455 for the hearing impaired. These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: The information collection requirements contained in this Notice have been approved under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501–3520) by the Office of Management and Budget (OMB), and have been assigned OMB control number 2506–0142, expiration date August 31, 1996.

I. Program Purpose

The purposes of the Youthbuild program are (1) to provide economically disadvantaged young adults with opportunities to obtain education, employment skills and meaningful on-site work experience as a service to their communities and a means to achieve self-sufficiency; (2) to foster the development of leadership skills and commitment to community; and (3) to expand the supply of permanent affordable housing for homeless and low- and very low-income persons by providing planning grants for program design and implementation grants for carrying out a Youthbuild Program.

A. Authority

The Youthbuild program is authorized under subtitle D of title IV of the National Affordable Housing Act (42 U.S.C. 8011) (the Act), as added by section 164 of the Housing and Community Development Act of 1992 (Pub. L. 102–550). Implementing regulations are found in the Final Rule published in the Federal Register dated February 21, 1995 and in CFR 24 part 585.

B. Funding Availability

This Notice announces the availability of approximately $37.5 million in program funds. Five percent of the funds may be set aside for emergency purposes. In addition, $1.87 million (five percent of the appropriation) is planned for technical assistance consistent with section 458(d) of the Act.

The Congress has not yet enacted a FY 1996 appropriations for HUD. However, HUD is publishing this notice in order to give potential applicants adequate time to prepare applications. The amount of funds announced in this NOFA is an estimate of the amount that may be enacted in 1996. HUD is not bound by the estimate set forth in this notice. The estimated amount may be adjusted downward based on the enacted 1996 appropriation.

C. Objectives

The Youthbuild program is designed to help disadvantaged young adults who have dropped out of high school to 1) obtain the education and employment skills necessary to achieve economic self-sufficiency and 2) develop leadership skills and a commitment to community development in low-income communities. Grant funds can be used to fund eligible educational and support services and activities, as defined by the Act, composed of basic skills instruction and remedial education, employment skills and leadership development, and counseling and other support services.

Another important objective of the Youthbuild program is to expand the supply of permanent affordable housing for homeless persons and members of low- and very low-income families. Providing disadvantaged young adults with meaningful on-site training experiences in housing construction and rehabilitation enables them to provide a service to their communities by helping

to meet the housing needs of homeless and low-income families.

An additional purpose of the program is to give, to the greatest extent feasible, and consistent with existing Federal, State, and local laws and regulations, job training, employment, contracting and other economic opportunities to low-income persons and business concerns. To that purpose, section 3 of the Housing and Urban Development Act of 1968 (12 U.S.C. 1701u) is applicable to Youthbuild implementation grant recipients.

II. Overview of Youthbuild Implementation Grants

HUD will award Youthbuild implementation grants to eligible applicants for the purpose of carrying out Youthbuild programs in accordance with subtitle D of title IV of the National Affordable Housing Act (NAHA). Applications will be selected in a competition in accordance with the grant selection process described in section V. below.

B. Maximum Awards

Under the competitions established by this NOFA, the maximum award for a Youthbuild implementation grant is $700,000. HUD reserves the right to determine the maximum or minimum of any Youthbuild award per application, project, program or budget line item. No amendments will be made to awards under this competition that will increase previously approved grant amounts.

C. Locational Considerations

Each application for an implementation grant may only include activities to carry out one Youthbuild program, i.e., to start a new Youthbuild program or to fund new classes of Youthbuild participants for an existing program. The same applicant organization may submit more than one application in the current competition if the proposed program's participant recruitment and housing areas are in different jurisdictions. HUD will not approve multiple applications for implementation grants in the same jurisdiction unless HUD determines that the jurisdiction is sufficiently large to justify approval of more than one application.

D. Eligible Applicants

Eligible applicants are public or private nonprofit agencies, state or local housing agencies or authorities, state or local units of general local government, Indian tribes or any other entity eligible to provide education and employment training under other Federal employment training programs, as further defined in 24 CFR 585.4.

E. Youthbuild Program Components

Youthbuild programs receiving assistance under this NOFA must contain the three components described in items (1), (2) and (4) below. Other activities described in item (3) are optional.

(1) Educational and job training services.

(2) Leadership training, counseling and other support activities.

(3) Special activities such as entrepreneurial training, drivers' education, internships, programs for those with learning disabilities, and in-house staff training. (Optional)

(4) On-site training through actual housing rehabilitation and/or construction work. Each program must be structured so that 50 percent of each participant's time is spent in on-site training.

Refer to 24 CFR 585.3 for a detailed description of program components.

F. Eligible Participants

Participants in a Youthbuild program must be very low-income high school dropouts between the ages of 16 and 24, inclusive, at the time of enrollment. Up to 25 percent of participants may be above very low-income or high school graduates (or equivalent), but must have educational needs that justify their participation in the program.

G. Eligible Activities

Activities used to conduct a Youthbuild implementation program may include:

(a) Work and activities associated with the acquisition, rehabilitation, or construction of the housing and related facilities to be used in the program;

(b) Relocation payments and other assistance required to comply with 24 CFR 585.308;

(c) Costs for the ongoing training and technical assistance needs of the applicant that are related to carrying out a Youthbuild program;

(d) Education, job training, counseling, employment and leadership development services and activities;

(e) Wages, benefits and need-based stipends for participants; and

(f) Administrative costs. Youthbuild funds for these costs may not exceed 15 percent of the total amount of Youthbuild assistance.

Refer to 24 CFR 585.305 for further details on eligible implementation activities.

H. Resources From Other Federal, State, Local or Private Entities

Applicants are encouraged to use existing housing and homeless assistance programs administered by HUD or other Federal, State, local or private housing programs as part of their Youthbuild programs. Use of other Federal, State, local or private funds available for vocational, adult and bilingual education programs or for job training under the JTPA Act and the Family Support Act of 1988 is also encouraged. The selection process described in this NOFA provides for applicants to receive points where grant applications contain commitments from Federal, State, local, or private sources to provide resources to carry out Youthbuild activities.

I. Environmental Procedures and Standards

Applicants are encouraged to select hazard-free and problem-free properties for their Youthbuild projects. Environmental procedures apply to HUD approval of implementation grants when the applicant proposes to use Youthbuild funds to cover any costs for the lease, acquisition, rehabilitation, or new construction of real property proposed for housing project development. Environmental procedures do not apply to HUD approval of implementation applications when applicants propose to use their Youthbuild funds solely to cover any costs for classroom and/or on-the-job construction training and support services.

For those applicants that propose to use their Youthbuild funds to cover any costs of the lease, acquisition, rehabilitation, or new construction of real property, the applicant shall submit all relevant environmental information in its application to support HUD decision-making in accordance with the environmental procedures and standards set forth in 24 CFR 585.307.

J. Grant Period

Funds awarded for an implementation grant should be used within 30 months of the effective date of the implementation grant agreement.

III. Selection Criteria for Youthbuild Applications

HUD will review each application and assign points in accordance with the selection criteria described in this section. Each application will be assigned up to 100 points. In addition, applications may receive up to 5 bonus points for AmeriCorps participation (see section F below), and 10 housing priority points (see section G below).

A. Capability

The qualifications and experience of the applicant and participating parties. (Maximum Points: 25) The capability of the applicant and participating parties to implement a successful young adult education and training program within a reasonable time period and in an a cost-effective manner as demonstrated through past performance. In assigning points for this criterion, HUD will consider evidence in the application that demonstrates:

(a) Experience in implementing a comprehensive, integrated, multi-disciplinary program with the following components:

(1) Young adult education and training programs, including programs for low-income persons from economically distressed neighborhoods.

(2) Young adult leadership development training and activities for young adults.

(3) Young adult on-site training in housing construction or rehabilitation for the production of sound and affordable housing for the homeless and low-income families.

(b) The extent to which the applicant has been successful in past education, training and employment programs and activities.

(c) The extent to which the applicant has demonstrated past ability to leverage other resources to cover administrative, educational and training costs and has demonstrated ability to implemented creative and innovative cost-saving measures.

(d) The extent of prior program quality and cost-effectiveness.

B. Need

The need for the proposed program, as determined by the degree of distress of the community. (Maximum Points: 20) In assigning points for this criterion, HUD will consider the relative degree of distress of the jurisdiction(s) from which participants will be recruited and in which the housing will be constructed or rehabilitated. HUD will calculate the degree of need of the jurisdiction(s) in which the program will be located from generally available data. In addition, HUD will consider information provided by the applicant on the distress of target areas within the jurisdiction(s).

C. Program Quality and Feasibility

Comprehensiveness and effectiveness of the proposed Youthbuild program. (Maximum Points: 35) HUD will consider the overall quality and feasibility of the proposed program as measured by the principles and goals of the proposed program, whether proposed program activities meet the overall objectives of the Youthbuild program, whether the proposed program activities will be accomplished within a reasonable time and in a cost effective manner, whether the proposed program activities are comprehensive and integrated, and the potential success of the proposed program. Areas to be considered in the evaluation of the overall quality of the proposed program are:

(1) Outreach, recruitment and selection activities: A description of the proposed (a) outreach, recruitment (including specific steps to be taken to attract potential eligible participants who are unlikely to be aware of this program because of race, ethnicity, sex, or disability) and selection strategies; (b) special outreach efforts to recruit eligible young women and young women with dependent children; and (c) recruitment arrangements made with public agencies, courts, homeless shelters, local school systems, community-based organizations, etc.;

(2) Educational and job training services and activities: A description of the educational component of the program, including: (a) the types of instructional services to be provided; (b) the number and qualifications of program instructors and ratio of instructors to participants; (c) realistic scheduling plan for classroom and on-the-job training; and (d) reasonable payments of participant wages, stipends, and incentives.

(3) Leadership development and support services: A description of the leadership development, counseling, and referral services to be offered to participants, including: (a) leadership development strategies and activities and plans to build group cohesion and peer support; and (b) the type of counseling and support services and/or need-based stipends to be provided.

(4) Coordination and Cost-efficiency: A description of how the Youthbuild program will benefit the maximum number of young adults by making use of other public and private resources, programs, services and facilities to sufficiently reduce the cost burden to the Youthbuild program in the following areas: (a) educational, job training, child care, social services, counseling and referral services; (b) on-site housing construction/rehabilitation training; (c) homeless and housing programs; (d) apprenticeship programs of local building trade unions; and (e) administrative, overhead and salary costs.

(5) On-site training: A description of (a) the housing construction or rehabilitation activities to be undertaken by participants at the site(s) to be used for the on-site training component of the program, (b) the qualifications and number of on-site supervisors; and (c) the amounts, reasonable wages and/or stipends to be paid to participants during on-site work.

(6) Job placement assistance: A description of the applicant's strategies and procedures for (a) participant placement in meaningful employment, enrollment in post-secondary education programs, job development, starting business enterprises, or other opportunities leading to economic independence; and (b) follow-up assistance and support activities to program graduates.

(7) Program evaluation: A description of a comprehensive evaluation plan that is designed to measure the success of the program.

(8) Innovativeness and creativity.

D. Program Resources

Commitment of resources obtained from other Federal, State, local and private sources. (Maximum Points: 10) In assigning points for this criterion, HUD will consider the level of non-housing resources obtained for cash or in-kind contributions to cover the following kinds of areas:

(1) Social services (i.e, counseling and training);

(2) Use of existing vocational, adult, bilingual educational courses;

(3) Donation of labor, resource personnel, supplies, materials, classroom and/or meeting space;

(4) other commitments.

E. Empowerment Zone/Enterprise Community

Up to 10 points will be assigned if the proposed Youthbuild program's participant recruitment and/or housing areas are, in whole or in part, in a Federally designated urban or rural Empowerment Zone, Enterprise Community, or Supplemental Empowerment Zone, as selected by HUD. Application must receive a combined score of at least 50 points for selection criteria (A), (B) and (C) under Section III in order be eligible for Empowerment Zone/Enterprise Community points.

F. AmeriCorps Participation Bonus

Up to 5 points may be assigned to Youthbuild applicants who provide evidence of application and/or selection as an AmeriCorps program sponsor. Application must receive a combined score of at least 50 points for selection criteria (A), (B) and (C) under Section III

in order be eligible for Empowerment Zone/Enterprise Community points.

G. Housing Program Priority Points

Ten (10) priority points will be assigned to all applications that contain evidence of housing resources from other Federal, State, local or private sources are available to cover the costs, in full, for the following housing activities for the proposed Youthbuild program: acquisition, architectural and engineering fees, construction, and rehabilitation. Implementation applications proposing to use Youthbuild grant funds, in whole or in part, for any one of the housing activities listed above will not be entitled to the ten priority points. Housing resources will not be used in evaluation of program resources criterion.

IV. Application Requirements

Applicants must complete and submit applications for Youthbuild grants in accordance with instructions contained in the FY 1996 Youthbuild application package. The application package will request information in sufficient detail for HUD to determine whether the proposed activities are feasible and meet all the requirements of applicable statutes and regulations. The application package requires a description of the applicant's and participating parties' experiences in young adult and housing programs, a description of the proposed Youthbuild program, a description of other public and private resources to be used for the program, including other housing resources, a schedule for the program, budgets, identification of housing sites(s), and demonstration of site access. The application package also contains certifications that the applicant will comply with fair housing and civil rights requirements, program regulations, regulations in 24 CFR part 135 with regard to economic opportunities for low-income persons and business concerns, and other Federal requirements. Applicants must also certify that the proposed activities are consistent with the HUD-approved Consolidated Plan in accordance with 24 CFR part 91. Applicants should refer to the Youthbuild application package for further instructions.

V. Selection process

In order to afford applicants every opportunity to submit a ratable application, while at the same time ensuring the fairness and integrity of the selection process, HUD is adopting the following application submission and selection procedures:

A. Initial Screening

During the period immediately following the application deadline, HUD will screen each application to determine eligibility. Applications will be rejected if they (1) Are submitted by ineligible applicants, (2) do not use the current FY 96 application package, (3) propose a program for which significant activities are ineligible, (4) there are any outstanding findings of noncompliance with civil rights statutes, Executive Orders, or regulations, as a result of formal administrative proceedings, or the Secretary has issued a charge against the applicant under the Fair Housing Act, unless the applicant is operating under a conciliation or compliance agreement designed to correct the areas of noncompliance, and (5) are submitted by applicants that have major unresolved audit or monitoring findings.

B. Rating and Ranking

Each eligible application will be rated based upon the criteria described in section III of this NOFA, with a maximum of 115 points assigned. Using the scores assigned, the applications will be placed in rank order. Applications will be preliminarily selected for funding in accordance with their rank order. To promote geographic diversity, HUD reserves the right to select lower-rated applications if necessary or to limit the amount or number of awards per application, project, program, jurisdiction or State.

If two or more applications have the same score and there are insufficient funds to fund all of them, the application(s) with the highest score for the Program Quality and Feasibility criterion shall be selected for funding. If a tie still remains, the application(s) with the highest score for the Capability criterion shall be selected. In the event of a procedural error that, when corrected, would result in selection of an otherwise eligible applicant during the funding round under this NOFA, HUD may select that application when sufficient funds become available.

C. Clarification of Application Information

In accordance with the provisions of 24 CFR part 4, subpart B, HUD may contact an applicant to seek clarification of an item in the application, or to request additional or missing information, but the clarification or the request for additional or missing information shall not relate to items that would improve the substantive quality of the application pertinent to the funding decision. For the Youthbuild program, these clarification items include, but are not limited to: (a) missing or unsigned program certifications; (b) budget errors or inconsistencies; (c) failure to identify the address or equivalent property site identification for the housing project(s) to be used for the on-site training; (d) incomplete documentation to show that the applicant has obtained access to the housing site(s) if the applicant does not own it; (e) failure to structure the proposed program so that fifty percent of the time spent by program participants is devoted to educational and support services and activities and fifty percent to on-site training; (f) failure to target the outreach and recruitment efforts to disadvantaged young adults between the ages of 16 and 24 years old; and (g) failure to designate the housing to be produced in conjunction with the program for the use of the homeless and low- and very low-income families. If an applicant fails to provide the clarification as requested, the application may be rejected.

D. Potential Environmental Disqualification

HUD reserves the right to disqualify an implementation application where one or more environmental thresholds are exceeded if it is determined that the environmental review cannot be conducted and satisfactorily completed by HUD within the HUD review period. (See 24 CFR 585.307.)

E. Reduction in Requested Grant Amount

As provided in Section B above, HUD may approve an application for an amount lower than the amount requested by the applicant. In addition, HUD will adjust line items in the proposed grant budget within the amount requested if it determines that:

(1) The amount requested for one or more eligible activities is not supported in the application or is unreasonably related to the service or activity to be carried out;

(2) An activity proposed for funding does not qualify as an eligible activity and can be separated in the budget;

(3) The amount requested exceeds the total cost limitation established for an implementation grant; or

(4) Insufficient funds remain for the entire request.

F. Notification of Approval or Disapproval

HUD will notify the selected applicants and the applicants that have not been selected. HUD's notification to a selected applicant of the amount of the

grant award, based on the approved application, will constitute a preliminary approval by HUD, subject to HUD and recipient execution of the grant agreement to initiate program activities.

VI. Other Matters

A. Environmental Impact.

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 (42 U.S.C. 4332). 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.

B. Family Executive Order

The General Counsel, as the Designated Official under Executive Order 12606, *The Family,* has determined that some of the policies contained in this NOFA will have a potential significant impact on the formation, maintenance, and general well-being of the family. The expected expansion of the housing supply for homeless and low- and very low-income persons and the provision of opportunities to economically disadvantaged young adults to enhance their education and employment skills will provide a positive impact on the family maintenance and general well-being. However, since the impact on the family is beneficial and the program involves very little HUD discretion, no further review is necessary.

C. Federalism Executive Order

The General Counsel, as the Designated Official under section 6(a) of the Executive Order 12612, *Federalism,* has determined that the policies contained in this NOFA do not have ''Federalism'' implications because they do not have substantial direct effects on the States (including their political subdivisions), or on the distribution of power and responsibilities among the various levels of government.

D. Section 102 of the HUD Reform Act—Accountability in the Provision of HUD Assistance

1. Documentation and Public Access

HUD will ensure that documentation and other information regarding each application submitted pursuant to this NOFA are sufficient to indicate the basis upon which assistance was provided or denied. This material, including any letters of support, will be made available for public inspection for a five year period beginning not less than thirty days after the award for assistance. Material will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations at 24 CFR part 15. In addition, HUD will include the recipients of assistance pursuant to this NOFA in its Federal Register notice of all recipients of HUD assistance awarded on a competitive basis. (See 24 CFR part 12, subpart B, and the notice published in the Federal Register on January 16, 1992 (57 FR 1942) for further information on these requirements.)

2. Disclosures

HUD will make available to the public for five years all applicant disclosure reports (form HUD–2880) submitted in connection with this NOFA. Update reports (also form HUD–2880) will be made available along with the applicants disclosure reports, but in no case for a period of less than three years. All reports—both applicant disclosures and updates—will be made available in accordance with the Freedom of Information Act (95 U.S.C. 552) and HUD's implementing regulations at 24 CFR part 15. (See 24 CFR part 12, subpart C, and the notice published in the Federal Register on January 16, 1992 (57 FR 1942) for further information on disclosure requirements.)

E. Section 103 of the HUD Reform Act—Prohibition of Advance Disclosures of Funding Decisions

HUD's regulation implementing section 103 of the Department of Housing and Urban Development Reform Act of 1989, codified as 24 CFR part 4, applies to the funding competition announced today. The requirements of the rule continue to apply until the announcement of the selection of successful applicants. HUD employees involved in the review of applications and in the making of funding decisions are limited by part 4 from providing advance information to any person (other than an authorized employee of HUD) concerning funding decisions, or from otherwise giving any applicant an unfair competitive advantage. Persons who apply for assistance in this competition should confine their inquiries to the subject areas permitted under 24 CFR part 4.

Applicants or employees who have ethics related questions should contact the HUD Office of Ethics (202) 708–3815. (This is not a toll-free number.) For HUD employees who have specific program questions, such as whether particular subject matter can be discussed with persons outside HUD, the employee should contact the appropriate Regional or Field Office Counsel, or Headquarters counsel for the program to which the question pertains.

F. Prohibition Against Lobbying Activities

The use of funds awarded under this NOFA is subject to the disclosure requirements and prohibitions of section 319 of the Department of Interior and Related Agencies Appropriations Act for Fiscal Year 1990 (31 U.S.C. 1352) and the implementing regulations at 24 CFR part 87. These authorities prohibit recipients of Federal contracts, grants, or loans from using appropriated funds for lobbying the Executive or Legislative Branches of the Federal Government in connection with a specific contract, grant, or loan. The prohibition also covers the awarding of contracts, grants, cooperative agreements, or loans unless the recipient has made an acceptable certification regarding lobbying. Under 24 CFR part 87 and 7 CFR part 1944, Subpart G, applicants, recipients, and subrecipients of assistance exceeding $100,000 must certify that no Federal funds have been or will be spent on lobbying activities in connection with the assistance.

Indian Housing Authorities (IHAs) established by an Indian tribe as a result of the exercise of the tribe's sovereign power are excluded from coverage of the Byrd Amendment, but IHAs established under State law are not excluded from the statute's coverage.

Required Reporting. A certification is required at the time application for funds is made that Federally appropriated funds are not being or have not been used in violation of section 319 and the *disclosure* will be made of payments for lobbying with other than federally appropriated funds. Also, there is a standard disclosure form, SF-LLL, ''Disclosure Form to Report Lobbying'', which must be use to disclose lobbying with other than Federally appropriated funds at the time of application.

G. Drug-Free Workplace

The Drug-Free Workplace Act of 1988 (41 U.S.C. 701) requires grantees of Federal agencies to certify that they will provide drug-free workplaces. Each potential recipient under this NOFA must certify that it will comply with the drug-free workplace requirements of the

Drug-Free Workplace Act of 1988 and HUD's implementing regulations at 24 CFR part 24, subpart F.

H. Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance program title and number is 14.243.

Authority: 42 U.S.C. 8011; Pub.L. 102–550.

Dated: January 6, 1996.

Andrew Cuomo,

Assistant Secretary for Community Planning and Development.

[FR Doc. 96–4680 Filed 3–1–96; 8:45 am]

BILLING CODE 4210–29–P

federal register

Monday
March 4, 1996

Part VII

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 330

Labeling of Drug Products for Over-the-Counter Human Use; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 330

[Docket No. 92N–454A]

RIN 0910–AA01

Labeling of Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its general labeling policy for over-the-counter (OTC) drug products to allow for the interchangeable use of certain labeling terms required by an OTC drug monograph. Examples of words already allowed include: ''doctor'' or ''physician,'' ''consult'' or ''ask,'' and ''indications'' or ''uses.'' This proposal provides an additional phrase (''unless a doctor tells you'') that can be used in place of several other phrases found in various OTC drug monographs.

DATES: Written comments by May 20, 1996; written comments on the agency's economic impact determination by May 20, 1996. The agency is proposing that any final rule that may issue based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–105), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2304.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of April 5, 1993 (58 FR 17553), the agency proposed to amend its general labeling policy for OTC drug products to allow for the interchangeable use of certain words in the labeling required by an OTC drug monograph. The agency had previously proposed in a number of tentative final monographs and included in a number of final monographs a provision that the words ''doctor'' and ''physician'' may be used interchangeably in the labeling of OTC drug products. Instead of including this provision in each OTC drug monograph, the agency proposed to include such a provision in § 330.1 (21 CFR 330.1) as part of the general conditions under which an OTC drug is generally recognized as safe, effective, and not misbranded. The agency also proposed that, at manufacturers' discretion, the word ''ask'' could be substituted for the word ''consult,'' which appears in the directions for many OTC drug monograph ingredients. Thus, the agency proposed that the phrases ''consult a physician,'' ''consult a doctor,'' ''ask a physician,'' and ''ask a doctor'' could be used interchangeably. The agency invited comments and suggestions as to such other terms that could be used interchangeably, i.e., terms general in nature that appear in more than one OTC drug monograph. The comments received in response to the proposed rulemaking were favorable and suggested a number of additional terms that could be used interchangeably.

In a final rule published in the Federal Register of January 28, 1994 (59 FR 3998), the agency allowed the following terms to be used interchangeably in the labeling of OTC drug products: (1) ''Ask'' or ''consult,'' (2) ''assistance'' or ''help,'' (3) ''clean'' or ''cleanse,'' (4) ''continue'' or ''persist,'' (5) ''continues'' or ''persists,'' (6) ''doctor'' or ''physician,'' (7) ''indication'' or ''use,'' (8) ''indications'' or ''uses,'' and (9) ''lung'' or ''pulmonary.'' These terms are included in § 330.1(i).

In the Federal Register of August 3, 1994 (59 FR 39499), the agency proposed to amend § 330.1(i) so that the phrases ''Drug interaction precaution,'' ''Avoid mixing drugs,'' or ''Do not mix drugs'' could be used interchangeably. The agency also requested public comment on changing the wording of warnings from negative phraseology to a more positive approach (e.g., ''Do not use more than 7 days'' to ''Use only 7 days,'' ''Do not use in * * *'' to ''Avoid use in * * *,'' ''Do not use longer than 1 week * * *'' to ''Use only 1 week * * *,'' and ''Do not use this product except under the advice and supervision of a physician if * * *,'' to ''Use only with a physician's help if * * *'' or ''Use only with the help of a doctor if * * *'').

The agency has received a number of comments on the proposal, and they are being evaluated at this time. The agency intends to publish a final rule in a future issue of the Federal Register.

The agency intends to continue to examine labeling required by OTC drug monographs to provide consumers more simplified and understandable information. This includes interchangeable terms, alternative phraseology, and possibly a new or different labeling format. At this time, the agency is proposing an additional phrase that could be used interchangeably.

Labeling information about not using an OTC drug product under certain circumstances (e.g., ''unless directed by a doctor,'' or ''except under the advice and supervision of a physician'') appears in different OTC drug monographs in different language. This has occurred because various OTC advisory review panels recommended different wording, and OTC drug rulemakings have been completed over a period of years.

The phrase ''* * * unless directed by a doctor'' appears in the warning statements of many recent OTC drug monographs. (See, for example, § 341.76(c)(2) (21 CFR 341.76(c)(2)) which states: ''Do not use this product if you have * * * unless directed by a doctor.'') In a number of other monographs, terms with the same (or similar) meaning have been used. For example, the OTC antacid drug products monograph in § 331.30(c)(1) and (c)(4) through (c)(7) (21 CFR 331.30(c)(1) and (c)(4) through (c)(7)) uses the phrase ''except under the advice and supervision of a physician,'' and the OTC ophthalmic drug products monograph in § 349.75(c)(2) (21 CFR 349.75(c)(2)) uses the phrase ''except under the advice and supervision of a doctor.'' That terminology has not been used in more recent OTC drug monographs.

For OTC antihistamine drug products in § 341.72(c)(3) and (c)(4) (21 CFR 341.72(c)(3) and (c)(4)), and for OTC anorectal drug products in § 346.50(c)(7)(ii) (21 CFR 346.50(c)(7)(ii)), the phrase ''* * * without first consulting your doctor'' is used. In § 341.72(c)(6)(i) through (c)(6)(iii), the phrase ''* * * without first consulting the child's doctor'' is used. The warning statements for OTC dandruff, seborrheic dermatitis, and psoriasis drug products in § 358.750(c)(2)(ii), (c)(3), and (c)(4) (21 CFR 358.750(c)(2)(ii), (c)(3), and (c)(4)) include the phrases ''* * * without consulting a doctor,'' ''* * * except on the advice of a doctor,'' and ''* * * unless directed to do so by a doctor.'' Thus, a number of different phrases have been used to convey the same message. The phrase ''unless directed by a doctor'' has been used more recently and most frequently.

The agency believes that all of these phrases can be interpreted in the same way (e.g., ''* * * unless a doctor tells you''). The agency believes this simpler phrase may be better understood by consumers than some of the other phrases. Accordingly, the agency is proposing to amend § 330.1(i) to include the phrase ''unless a doctor tells you'' as an alternative for these other phrases

where they appear in the labeling of OTC drug products. In a few instances, the words ''or your child's doctor'' would be used as part of this phrase. The agency is asking whether it would be preferable to say ''your'' child's doctor or ''the'' child's doctor, or whether it does not make any difference which wording is used. The agency is requesting comment from manufacturers, health professionals, and consumers on whether it would be desirable to use this alternative phrase interchangeably with the other phrases and/or whether a single uniform phrase should appear in all of the cited regulations. The agency also seeks comment whether there are additional, simpler, informative ways in which this information may be stated.

II. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and, thus, is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. If this proposed rule becomes a final rule, the labeling options could be implemented at very little cost by manufacturers at the next printing of labels, for those products for which the manufacturer chooses to make a change. Accordingly, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on the labeling of OTC drug products. Types of impact may include, but are not limited to, costs associated with relabeling. Comments regarding the impact of this rulemaking on OTC drug products should be accompanied by appropriate documentation. 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.

III. Paperwork Reduction Act of 1995

FDA tentatively concludes that the labeling requirements proposed in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the proposed labeling statements are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before May 20, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Written comments on the agency's economic impact determination may be submitted on or before May 20, 1996. Three copies of all comments are to be submitted, except that individuals may submit one copy. Comments 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 330

Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 330 be amended as follows:

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

1. The authority citation for 21 CFR part 330 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).

2. Section 330.1 is amended by adding new paragraph (i)(11), to read as follows:

§ 330.1 General conditions for general recognition as safe, effective and not misbranded.

* * * * *

(i) * * *

(11) ''Unless a doctor'' (or ''your child's doctor,'' where applicable) ''tells you'' may be used in place of any of the following phrases:

(i) ''Except on the advice of a doctor''.

(ii) ''Except under the advice and supervision of a'' [''physician'' or ''doctor''].

(iii) ''Unless directed by a doctor''.

(iv) ''Unless directed to do so by a doctor''.

(v) ''Without consulting a doctor''.

(vi) ''Without first consulting your'' (or ''your child's'' or ''the child's'') ''doctor''.

* * * * *

Dated: February 23, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–4912 Filed 3–1–96; 8:45 am]

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federal register

Monday
March 4, 1996

Part VIII

Department of Education

34 CFR Part 75

Education Department General Administrative Regulations—Direct Grant Programs; Final Rule

DEPARTMENT OF EDUCATION

34 CFR Part 75

RIN 1880–AA68

Education Department General Administrative Regulations—Direct Grant Programs

AGENCY: Department of Education.

ACTION: Final Regulations.

SUMMARY: The Secretary amends the Education Department General Administrative Regulations (EDGAR) that govern discretionary grant programs. These regulations clarify that the Secretary may reject applications that propose project funding levels that exceed the maximum award amount established in an application notice published in the Federal Register. The Secretary issues these regulations to clarify the meaning of existing regulations that govern the application review process.

EFFECTIVE DATE: These regulations take effect on April 3, 1996.

FOR FURTHER INFORMATION CONTACT: Mary A. Smith, Office of the General Counsel, U.S. Department of Education, 600 Independence Avenue SW., Room 5113, FB10, Washington, D.C. 20202–2241. Individuals who use a telecommunications device for the deaf may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Secretary takes this action to implement a recommendation made by a quality improvement team for improving the discretionary grant award process.

Under current practice, the Department reviews applications that exceed the upper dollar limit of the estimated range of grant awards expected to be made under a competition but, when the awards are made, in most cases, the Department funds the projects at amounts within the funding range.

In conducting competitions, the Department generally publishes application notices that specify the estimated amounts or estimated ranges of awards. However, because these amounts or ranges are estimated, applicants often request funding at levels above the estimated levels. Under most competitions, the practice of the Department has been to establish grant award amounts for successful applicants that are at or below the amounts specified in the estimates. However, in some cases, the Department has made awards that exceeded the estimates specified in the application notice.

The Department has been guided by the underlying principle that applicants for discretionary grants must be afforded basic fairness in the competitive grant award process. Most of the time applicants who propose projects that exceed the upper limit of the specified range of awards can propose to do significantly more than applicants who propose funding consistent with the estimates. In these circumstances, applicants who request funds that exceed these amounts are likely to receive better scores from reviewers. If those applicants are then selected for funding, the Department, in most cases, negotiates with the applicants to reduce the cost of the projects to bring them within the estimated funding range. As a result, many of the activities in these applications have to be significantly modified, reduced, or eliminated. The result is that the projects negotiated for final award often differ substantially from the applications that were highly rated by the reviewers. This practice has the potential of rewarding applicants who originally request funding above the funding range and penalizing applicants who follow the estimates.

However, this is not always the case. Sometimes the Department is unsure what a highly qualified project should cost. This is especially true when an educational technology is being explored or the Department is supporting research in a new field. In these situations, the Department may not have confidence that it has correctly estimated what the funded projects will cost. Thus, the Secretary would not put a maximum limitation on the competition to account for the possibility that applicants might need more funds than specified in the expected range in order to successfully implement the program's goals.

These regulations would clarify that the Secretary has discretion to establish funding limits for awards, and provide for the inclusion of information on maximum funding levels in application notices.

Under § 75.101(a)(2), the Secretary may include in an application notice the amount of funds available for grants and the estimated number and amounts of those grants. Some application notices have included the estimated amount of funds available for each grant, and some application notices have given an estimated award amount. As the provision in § 75.101(a)(2) is currently worded, it is unclear whether the application notice may include a maximum award amount. These amendments to § 75.101 clarify that the Secretary may include an estimated amount of funds available for each grant and, if appropriate, a maximum amount of funds available for each grant.

The Secretary also amends 34 CFR 75.104 to require that if a maximum award amount is established, the Secretary may reject applications that propose a budget that would exceed the maximum award amount.

These amendments will ensure better service to the Department's customers by permitting the Department to reject applications that exceed a maximum amount. This process will enable the Department to make awards more quickly and at less cost.

Executive Order 12866

These regulations have been reviewed in accordance with Executive Order 12866. Under the terms of the order the Secretary has assessed the potential costs and benefits of the regulatory action.

In assessing the potential costs and benefits—both quantitative and qualitative—the Secretary has determined that the benefits of the regulations in clarifying and improving the Department's grant application review process justify the costs.

The Secretary has also determined that this regulatory action does not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

Summary of potential costs and benefits: There are no identified costs associated with these regulations. The potential benefits of these regulations are discussed elsewhere in this preamble under the following heading: Supplementary Information.

Regulatory Flexibility Act Certification

The Secretary certifies that these regulations would not have a significant economic impact on a substantial number of small entities. The small entities affected would be small local educational agencies, community-based organizations, nonprofit organizations, and institutions of higher education. However, these regulations would have no economic impact on any of the entities affected and would merely ensure a fairer application review process.

Paperwork Reduction Act of 1995

These regulations have been examined under the Paperwork Reduction Act of 1995 and have been found to contain no information collection requirements.

Waiver of Rulemaking

It is the practice of the Secretary to offer interested parties the opportunity to comment on proposed regulations in accordance with the Administrative Procedure Act (5 U.S.C. 553). However, because the Secretary is interpreting existing regulations to allow an application notice to include an estimated amount of funds available for each grant or a maximum amount of funds available for each grant and because the Secretary is establishing a procedural rule necessary for the Department to conduct grant application review processes, the Secretary has determined, pursuant to 5 U.S.C. 553(b)(A), that proposed rulemaking requirements do not apply.

List of Subjects in 34 CFR Part 75

Education Department, Grant programs—education, Grant administration, Incorporation by reference.

Dated: February 28, 1996.

Richard W. Riley,

Secretary of Education.

(Catalog of Federal Domestic Assistance Number does not apply)

The Secretary amends Part 75 of Title 34 of the Code of Federal Regulations as follows:

PART 75—DIRECT GRANT PROGRAMS

1. The authority citation for Part 75 continues to read as follows:

Authority: 20 U.S.C. 1221e-3 and 3474, unless otherwise noted.

2. Section 75.101 is amended by revising paragraph (a)(2) to read as follows:

§ 75.101 Information in the application notice that helps an applicant apply.

(a) * * *

(2) The amount of funds available for grants, the estimated number of those grants, the estimated amounts of those grants and, if appropriate, the maximum award amounts of those grants.

* * * * *

3. Section 75.104 is revised to read as follows:

§ 75.104 Applicants must meet procedural rules.

(a) The Secretary may make a grant only to an eligible party that submits an application.

(b) If a maximum award amount is established in a notice published in the Federal Register, the Secretary may reject without consideration or evaluation any application that proposes a project funding level that exceeds the stated maximum award amount.

(Authority: 20 U.S.C. 1221e–3 and 3474)

[FR Doc. 96–4911 Filed 3–1–96; 8:45 am]

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federal register

Monday
March 4, 1996

Part IX

Department of Housing and Urban Development

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Part 202

Approval of Lending Institutions and Mortgagees Streamlining; Final Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing-Federal Housing Commissioner

24 CFR Part 202

[Docket No. FR–4036–F–01]

RIN 2502–AG68

Approval of Lending Institutions and Mortgagees Streamlining

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Final rule.

SUMMARY: This final rule amends HUD's regulations at 24 CFR part 202 relating to Approval of Lending Institutions and Mortgagees. In an effort to comply with the President's regulatory reform initiatives, this rule will streamline subparts A & B, which relate to approval of Title I Lending Institutions and Approval of Mortgagees, respectively, because certain provisions are not necessary.

EFFECTIVE DATE: April 3, 1996.

FOR FURTHER INFORMATION CONTACT: Karen Garner-Wing, Director, Lender Approval and Recertification Division, Office of Lender Activities and Land Sales Registration, Room 9146, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410. Telephone: (202) 708–3976. (This is not a toll-free number.) For hearing- and speech-impaired persons, this number may be accessed via TDD by calling the Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: On March 4, 1995, President Clinton issued a memorandum to all Federal departments and agencies regarding regulatory reinvention. In response to this memorandum, the Department of Housing and Urban Development conducted a page-by-page review of its regulations to determine which can be eliminated, consolidated, or otherwise improved. HUD has determined that the regulations for Approval of Lending Institutions and Mortgagees can be streamlined to remove provisions which are no longer necessary to be codified in the Code of Federal Regulations. This rule will not change the substantive requirements of the part but will eliminate redundant provisions.

Justification for Final Rulemaking

HUD generally publishes a rule for public comment before issuing a rule for effect, in accordance with its own regulations on rulemaking in 24 CFR part 10. However, part 10 provides for exceptions to the general rule if the agency finds good cause to omit advance notice and public participation. The good cause requirement is satisfied when prior public procedure is ''impracticable, unnecessary, or contrary to the public interest'' (24 CFR 10.1). HUD finds that good cause exists to publish this rule for effect without first soliciting public comment. This rule merely removes unnecessary regulatory provisions and does not establish or affect substantive policy. Therefore, prior public comment is unnecessary.

Other Matters

Regulatory Flexibility Act

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed and approved this final rule, and in so doing certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule merely streamlines regulations by removing unnecessary provisions. The rule will have no adverse or disproportionate economic impact on small businesses.

Environmental Impact

This rulemaking does not have an environmental impact. This rulemaking simply amends an existing regulation by eliminating administrative provisions and does not alter the environmental effect of the regulations being amended. A Finding of No Significant Impact with respect to the environment was made in accordance with HUD regulations in 24 CFR part 50 that implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332) at the time of development of regulations regarding the Approval of Lending Institutions and Mortgagees. That finding remains applicable to this rule and 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 General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC.

Executive Order 12612, Federalism

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, *Federalism,* has determined that this rule will not have substantial direct effects on States or their political subdivisions, or the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. No programmatic or policy changes will result from this rule that would affect the relationship between the Federal Government and State and local governments.

Executive Order 12606, The Family

The General Counsel, as the Designated Official under Executive Order 12606, *The Family,* has determined that this rule will not have the potential for significant impact on family formation, maintenance, or general well-being, and thus is not subject to review under the Order. No significant change in existing HUD policies or programs will result from promulgation of this rule.

List of Subjects in 24 CFR Part 202

Administrative practice and procedure, Home improvement, Manufactured homes, Mortgage insurance, Reporting and recordkeeping requirements.

Accordingly, 24 CFR part 202 is amended as follows:

PART 202—APPROVAL OF LENDING INSTITUTIONS AND MORTGAGES

1. The authority citation for part 202 continues to read as follows:

Authority: 12 U.S.C. 1703, 1709, and 1715b; 42 U.S.C. 3535(d).

Subpart A—Approval of Title I Lending Institutions

2. Section 202.3 is amended by:

a. Removing and reserving paragraph (d); and

b. Revising paragraph (j) to read as follows:

§ 202.3 General approval requirements.

* * * * *

(d) [Reserved]

* * * * *

(j) Except for Government Institutions as defined in § 202.2, it shall pay an application fee and annual fee, including an additional fee for each branch office authorized by the Secretary to originate Title I loans. These fees shall be in such amounts as the Secretary may require.

* * * * *

§ 202.4 [Amended]

3. Section 202.4 is amended by removing and reserving paragraph (b).

§ 202.5 [Amended]

4. Section 202.5 is amended by removing and reserving paragraph (b).

5. Section 202.9 is revised to read as follows:

§ 202.9 Administrative actions.

(a) *General.* The provisions of 24 CFR part 25 shall be applicable to a lender participating in the Title I program. Administrative actions which may be applied are set forth in 24 CFR 25.5. Civil money penalties may also be imposed against Title I lenders pursuant to 24 CFR 25.13 and part 30 of this title. For purposes of this section the term ''lender'' shall also include loan correspondents as defined in § 202.2(b) of this subpart A.

(b) *Grounds for administrative actions.* Administrative actions shall be based upon both the grounds set forth in 24 CFR 25.9 and as follows:

(1) Failure to properly supervise and monitor dealers under the provisions of 24 CFR part 201;

(2) Exhaustion of the general insurance reserve established under 24 CFR part 201;

(3) Maintenance of a claims/loan ratio representing an unacceptable risk to the Department; or

(4) Transfer of a Title I loan to a party that does not have a valid Contract of Insurance.

Subpart B—Approval of Mortgagees

6. Section 202.11 is amended by:

a. Revising paragraphs (a)(1) introductory text, (a)(1)(i), and (b); and

b. Removing and reserving paragraphs (a)(3) and (c), to read as follows:

§ 202.11 Approval, recertification, withdrawal of approval and termination of approval agreement.

(a) *Approval.* (1) A mortgagee may be approved for participation in the mortgage insurance programs authorized by the National Housing Act upon filing a request for approval on a form prescribed by the Secretary and signed by the applicant. The approval form shall be accompanied by such documentation as may be prescribed by the Secretary to support the request for approval. Approval of the application shall constitute:

(i) The Secretary's agreement that the mortgagee shall be considered an approved mortgagee unless suspended or withdrawn pursuant to 24 CFR part 25, or unless the mortgagee voluntarily relinquishes its approval;

* * * * *

(3) [Reserved]

* * * * *

(b) *Recertification of approval.* On each anniversary of the approval of a mortgagee, the Secretary shall undertake a recertification procedure to determine whether continued approval is appropriate. The Secretary shall review the yearly verification report required by § 202.12(h)(2) and other pertinent documents, determine whether all application and annual fees which are due have been paid, and request any additional information needed to make a determination regarding continuation of approval.

(c) [Reserved]

* * * * *

7. Section 202.12 is amended by:

a. Removing and reserving paragraph (e), and

b. Redesignating paragraph (o) as paragraph (n)(5) and revising newly redesignated paragraph (n)(5); and

c. Reserving paragraph (o), to read as follows:

§ 202.12 General approval requirements.

* * * * *

(e) [Reserved]

* * * * *

(n) * * *

(5) Mortgagees shall have the required net worth upon approval, except that supervised and nonsupervised mortgagees may have a net worth of $250,000 for the first year of approval.

(o) [Reserved]

* * * * *

8. Section 202.18 is revised to read as follows:

§ 202.18 Approval for servicing.

All mortgagees who wish to service FHA-insured mortgages must be approved by the Secretary under § 202.13, (supervised mortgagees), § 202.14, (nonsupervised mortgagees), or § 202.17 (governmental institutions).

9. Section 202.19 is revised to read as follows:

§ 202.19 Report requirements.

(a) *Definitions.* For the purpose of this section:

(1) Normal rate for early serious defaults and early claims means the rate set forth in § 202.11(d)(i).

(2) Early serious defaults or claims higher than the normal rate means the rate set forth in §§ 202.11(d)(ii) and 202.11(d)(iii).

(3) Endorsement means initial endorsement or initial/final endorsement, as applicable, with respect to multifamily mortgages.

(b) *Requirements.* If a mortgagee approved for participation in the insurance programs under §§ 202.10 through 202.18 is notified by the Secretary that it had a rate of early serious defaults or early claims on HUD-insured mortgages during the preceding year, or during recent years, which was higher than the normal rate for the geographic area or areas in which it does business, it shall submit a report, within 60 days, containing an explanation for the above-normal rate of early serious defaults or early claims and, if required by the Secretary, a plan for corrective action with regard to mortgages in default and its mortgage processing system in general. In determining whether a plan is required, the Secretary may consider relevant information and statements from the mortgagee.

10. Section 202.20 is amended by revising paragraph (i) to read as follows:

§ 202.20 Tiered Pricing.

* * * * *

(i) Request for determination of compliance. Pursuant to section 539(a) of the National Affordable Housing Act, any person may file a request that the Secretary determine whether a mortgagee or Title I lender is in compliance with this section or with sections implementing sections 223(a)(7) and 535 of the National Housing Act (12 U.S.C. 1701 *et seq.*) , such as §§ 201.10(g), 203.18d, and 203.43(c)(5) of this chapter (only Section 535 applies to Title I lenders). The request for determination shall be made to the following address: Department of Housing and Urban Development, Office of Lender Activities and Land Sales Registration, 45l Seventh Street, SW, Washington, DC 204l0. The Secretary shall inform the requestor of the disposition of the request. The Secretary shall publish in the Federal Register the disposition of any case referred by the Secretary to the Mortgagee Review Board.

Dated: February 22, 1996.

Nicolas P. Retsinas,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 96–4909 Filed 3–1–96; 8:45 am]

BILLING CODE 4210–27–P

federal register

Monday
March 4, 1996

Part X

The President

Presidential Determination No. 96–10 of February 23, 1996

Presidential Determination No. 96–11 of February 23, 1996

Federal Register
Vol. 61, No. 43
Monday, March 4, 1996

Presidential Documents

Title 3—

The President

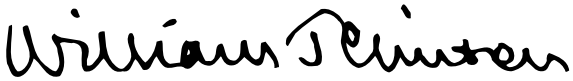
Presidential Determination No. 96–10 of February 23, 1996

Eligibility of Bosnia and Herzegovina to be Furnished Defense Articles and Services Under the Foreign Assistance Act and the Arms Export Control Act

Memorandum for the Secretary of State

Pursuant to the authority vested in me by section 503(a) of the Foreign Assistance Act of 1961, as amended, and section 3(a)(1) of the Arms Export Control Act, I hereby find that the furnishing of defense articles and services to the Government of Bosnia and Herzegovina will strengthen the security of the United States and promote world peace.

You are authorized and directed to report this finding to the Congress and to publish it in the Federal Register.



THE WHITE HOUSE,
Washington, February 23, 1996.

[FR Doc. 96–5161
Filed 3–1–96; 8:45 am]
Billing code 4710–10–M

Presidential Documents

Presidential Determination No. 96–11 of February 23, 1996

Presidential Determination on Military Drawdown for Jordan

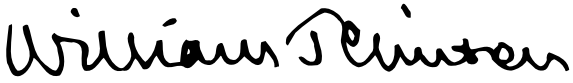
Memorandum for the Secretary of State and the Secretary of Defense

Pursuant to the authority vested in me by the laws and Constitution of the United States, including section 572 of the Foreign Operations, Export Financing and Related Programs Appropriations Act, 1996 (Public Law 104–107) (the ''Act''), and section 301 of title 3 of the United States Code, I hereby:

(1) direct the drawdown for Jordan for the purpose of part II of the Foreign Assistance Act of 1961, of up to $100 million in defense articles from the stocks of the Department of Defense, defense services of the Department of Defense, and military education and training;

(2) delegate the functions vested in me pursuant to section 572(a) of the Act to the Secretary of Defense, who is authorized to redelegate those functions consistent with applicable law.

The Secretary of State is authorized and directed to publish this memorandum in the Federal Register.



THE WHITE HOUSE,
Washington, February 23, 1996.

[FR Doc. 96–5162
Filed 3–1–96; 8:45 am]
Billing code 4710–10–M

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An asterisk (*) precedes each entry that has been issued since last week and which is now available for sale at the Government Printing Office.

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140–199	(869–026–00044–1)	13.00	Jan. 1, 1995
200–1199	(869–026–00045–0)	23.00	Jan. 1, 1995
1200–End	(869–026–00046–8)	16.00	Jan. 1, 1995
15 Parts:			
0–299	(869–026–00047–6)	15.00	Jan. 1, 1995
300–799	(869–026–00048–4)	26.00	Jan. 1, 1995
800–End	(869–026–00049–2)	21.00	Jan. 1, 1995
16 Parts:			
0–149	(869–026–00050–6)	7.00	Jan. 1, 1995
150–999	(869–026–00051–4)	19.00	Jan. 1, 1995
1000–End	(869–026–00052–2)	25.00	Jan. 1, 1995
17 Parts:			
1–199	(869–026–00054–9)	20.00	Apr. 1, 1995
200–239	(869–026–00055–7)	24.00	Apr. 1, 1995
240–End	(869–026–00056–5)	30.00	Apr. 1, 1995
18 Parts:			
1–149	(869–026–00057–3)	16.00	Apr. 1, 1995
150–279	(869–026–00058–1)	13.00	Apr. 1, 1995
280–399	(869–026–00059–0)	13.00	Apr. 1, 1995
400–End	(869–026–00060–3)	11.00	Apr. 1, 1995
19 Parts:			
1–140	(869–026–00061–1)	25.00	Apr. 1, 1995
141–199	(869–026–00062–0)	21.00	Apr. 1, 1995
200–End	(869–026–00063–8)	12.00	Apr. 1, 1995
20 Parts:			
1–399	(869–026–00064–6)	20.00	Apr. 1, 1995
400–499	(869–026–00065–4)	34.00	Apr. 1, 1995
500–End	(869–026–00066–2)	34.00	Apr. 1, 1995
21 Parts:			
1–99	(869–026–00067–1)	16.00	Apr. 1, 1995
100–169	(869–026–00068–9)	21.00	Apr. 1, 1995
170–199	(869–026–00069–7)	22.00	Apr. 1, 1995
200–299	(869–026–00070–1)	7.00	Apr. 1, 1995
300–499	(869–026–00071–9)	39.00	Apr. 1, 1995
500–599	(869–026–00072–7)	22.00	Apr. 1, 1995
600–799	(869–026–00073–5)	9.50	Apr. 1, 1995
800–1299	(869–026–00074–3)	23.00	Apr. 1, 1995
1300–End	(869–026–00075–1)	13.00	Apr. 1, 1995
22 Parts:			
1–299	(869–026–00076–0)	33.00	Apr. 1, 1995
300–End	(869–026–00077–8)	24.00	Apr. 1, 1995
23	(869–026–00078–6)	22.00	Apr. 1, 1995
24 Parts:			
0–199	(869–026–00079–4)	40.00	Apr. 1, 1995
200–219	(869–026–00080–8)	19.00	Apr. 1, 1995
220–499	(869–026–00081–6)	23.00	Apr. 1, 1995
500–699	(869–026–00082–4)	20.00	Apr. 1, 1995
700–899	(869–026–00083–2)	24.00	Apr. 1, 1995
900–1699	(869–026–00084–1)	24.00	Apr. 1, 1995
1700–End	(869–026–00085–9)	17.00	Apr. 1, 1995
25	(869–026–00086–7)	32.00	Apr. 1, 1995
26 Parts:			
§§ 1.0-1–1.60	(869–026–00087–5)	21.00	Apr. 1, 1995
§§ 1.61–1.169	(869–026–00088–3)	34.00	Apr. 1, 1995
§§ 1.170–1.300	(869–026–00089–1)	24.00	Apr. 1, 1995
§§ 1.301–1.400	(869–026–00090–5)	17.00	Apr. 1, 1995
§§ 1.401–1.440	(869–026–00091–3)	30.00	Apr. 1, 1995
§§ 1.441-1.500	(869-026-00092-1)	22.00	Apr. 1, 1995
§§ 1.501–1.640	(869–026–00093–0)	21.00	Apr. 1, 1995
§§ 1.641–1.850	(869–026–00094–8)	25.00	Apr. 1, 1995
§§ 1.851–1.907	(869–026–00095–6)	26.00	Apr. 1, 1995
§§ 1.908–1.1000	(869–026–00096–4)	27.00	Apr. 1, 1995
§§ 1.1001–1.1400	(869–026–00097–2)	25.00	Apr. 1, 1995
§§ 1.1401–End	(869–026–00098–1)	33.00	Apr. 1, 1995
2–29	(869–026–00099–9)	25.00	Apr. 1, 1995
30–39	(869–026–00100–6)	18.00	Apr. 1, 1995
40–49	(869–026–00101–4)	14.00	Apr. 1, 1995

Title	Stock Number	Price	Revision Date
50–299	(869–026–00102–2)	14.00	Apr. 1, 1995
300–499	(869–026–00103–1)	24.00	Apr. 1, 1995
500–599	(869–026–00104–9)	6.00	[4] Apr. 1, 1990
600–End	(869–026–00105–7)	8.00	Apr. 1, 1995
27 Parts:			
1–199	(869–026–00106–5)	37.00	Apr. 1, 1995
200–End	(869–026–00107–3)	13.00	[7] Apr. 1, 1994
28 Parts:			
1-42	(869–026–00108–1)	27.00	July 1, 1995
43-end	(869-026-00109-0)	22.00	July 1, 1995
29 Parts:			
0–99	(869–026–00110–3)	21.00	July 1, 1995
100–499	(869–026–00111–1)	9.50	July 1, 1995
500–899	(869–026–00112–0)	36.00	July 1, 1995
900–1899	(869–026–00113–8)	17.00	July 1, 1995
1900–1910 (§§ 1901.1 to 1910.999)	(869–026–00114–6)	33.00	July 1, 1995
1910 (§§ 1910.1000 to end)	(869–026–00115–4)	22.00	July 1, 1995
1911–1925	(869–026–00116–2)	27.00	July 1, 1995
1926	(869–026–00117–1)	35.00	July 1, 1995
1927–End	(869–026–00118–9)	36.00	July 1, 1995
30 Parts:			
1–199	(869–026–00119–7)	25.00	July 1, 1995
200–699	(869–026–00120–1)	20.00	July 1, 1995
700–End	(869–026–00121–9)	30.00	July 1, 1995
31 Parts:			
0–199	(869–026–00122–7)	15.00	July 1, 1995
200–End	(869–026–00123–5)	25.00	July 1, 1995
32 Parts:			
1–39, Vol. I		15.00	[2] July 1, 1984
1–39, Vol. II		19.00	[2] July 1, 1984
1–39, Vol. III		18.00	[2] July 1, 1984
1–190	(869–026–00124–3)	32.00	July 1, 1995
191–399	(869–026–00125–1)	38.00	July 1, 1995
400–629	(869–026–00126–0)	26.00	July 1, 1995
630–699	(869–026–00127–8)	14.00	[5] July 1, 1991
700–799	(869–026–00128–6)	21.00	July 1, 1995
800–End	(869–026–00129–4)	22.00	July 1, 1995
33 Parts:			
1–124	(869–026–00130–8)	20.00	July 1, 1995
125–199	(869–026–00131–6)	27.00	July 1, 1995
200–End	(869–026–00132–4)	24.00	July 1, 1995
34 Parts:			
1–299	(869–026–00133–2)	25.00	July 1, 1995
300–399	(869–026–00134–1)	21.00	July 1, 1995
400–End	(869–026–00135–9)	37.00	July 5, 1995
35	(869–026–00136–7)	12.00	July 1, 1995
36 Parts			
1–199	(869–026–00137–5)	15.00	July 1, 1995
200–End	(869–026–00138–3)	37.00	July 1, 1995
37	(869–026–00139–1)	20.00	July 1, 1995
38 Parts:			
0–17	(869–026–00140–5)	30.00	July 1, 1995
18–End	(869–026–00141–3)	30.00	July 1, 1995
39	(869–026–00142–1)	17.00	July 1, 1995
40 Parts:			
1–51	(869–026–00143–0)	40.00	July 1, 1995
52	(869–026–00144–8)	39.00	July 1, 1995
53–59	(869–026–00145–6)	11.00	July 1, 1995
60	(869-026-00146-4)	36.00	July 1, 1995
61–71	(869–026–00147–2)	36.00	July 1, 1995
72–85	(869–026–00148–1)	41.00	July 1, 1995
86	(869–026–00149–9)	40.00	July 1, 1995
87–149	(869–026–00150–2)	41.00	July 1, 1995
150–189	(869–026–00151–1)	25.00	July 1, 1995
190–259	(869–026–00152–9)	17.00	July 1, 1995
260–299	(869–026–00153–7)	40.00	July 1, 1995
300–399	(869–026–00154–5)	21.00	July 1, 1995
400–424	(869–026–00155–3)	26.00	July 1, 1995
425–699	(869–026–00156–1)	30.00	July 1, 1995
700–789	(869–026–00157–0)	25.00	July 1, 1995
790–End	(869–026–00158–8)	15.00	July 1, 1995
41 Chapters:			
1, 1–1 to 1–10		13.00	[3] July 1, 1984
1, 1–11 to Appendix, 2 (2 Reserved)		13.00	[3] July 1, 1984
3–6		14.00	[3] July 1, 1984
7		6.00	[3] July 1, 1984
8		4.50	[3] July 1, 1984
9		13.00	[3] July 1, 1984
10–17		9.50	[3] July 1, 1984
18, Vol. I, Parts 1–5		13.00	[3] July 1, 1984
18, Vol. II, Parts 6–19		13.00	[3] July 1, 1984
18, Vol. III, Parts 20–52		13.00	[3] July 1, 1984
19–100		13.00	[3] July 1, 1984
1–100	(869–026–00159–6)	9.50	July 1, 1995
101	(869–026–00160–0)	29.00	July 1, 1995
102–200	(869–026–00161–8)	15.00	July 1, 1995
201–End	(869–026–00162–6)	13.00	July 1, 1995
42 Parts:			
1–399	(869–026–00163–4)	26.00	Oct. 1, 1995
400–429	(869–026–00164–2)	26.00	Oct. 1, 1995
430–End	(869–026–00165–1)	39.00	Oct. 1, 1995
43 Parts:			
1–999	(869–026–00166–9)	23.00	Oct. 1, 1995
1000–3999	(869–026–00167–7)	31.00	Oct. 1, 1995
4000–End	(869–026–00168–5)	15.00	Oct. 1, 1995
44	(869–026–00169–3)	24.00	Oct. 1, 1995
45 Parts:			
1–199	(869–022–00170–7)	22.00	Oct. 1, 1995
200–499	(869–026–00171–5)	14.00	Oct. 1, 1995
500–1199	(869–026–00172–3)	23.00	Oct. 1, 1995
1200–End	(869–026–00173–1)	26.00	Oct. 1, 1995
46 Parts:			
1–40	(869–022–00171–0)	20.00	Oct. 1, 1994
41–69	(869–026–00175–8)	17.00	Oct. 1, 1995
70–89	(869–026–00176–6)	8.50	Oct. 1, 1995
90–139	(869–026–00177–4)	15.00	Oct. 1, 1995
140–155	(869–026–00178–2)	12.00	Oct. 1, 1995
156–165	(869–026–00179–1)	17.00	Oct. 1, 1995
166–199	(869–026–00180–4)	17.00	Oct. 1, 1995
200–499	(869–026–00181–2)	19.00	Oct. 1, 1995
500–End	(869–026–00182–1)	13.00	Oct. 1, 1995
47 Parts:			
0–19	(869–026–00183–9)	25.00	Oct. 1, 1995
20–39	(869–026–00184–7)	21.00	Oct. 1, 1995
40–69	(869–026–00185–5)	14.00	Oct. 1, 1995
70–79	(869–026–00186–3)	24.00	Oct. 1, 1995
80–End	(869–026–00187–1)	30.00	Oct. 1, 1995
48 Chapters:			
1 (Parts 1–51)	(869–022–00185–0)	36.00	Oct. 1, 1994
1 (Parts 52–99)	(869–022–00186–8)	23.00	Oct. 1, 1994
*2 (Parts 201–251)	(869–026–00190–1)	17.00	Oct. 1, 1995
2 (Parts 252–299)	(869–026–00191–0)	13.00	Oct. 1, 1995
3–6	(869–022–00189–2)	23.00	Oct. 1, 1994
*7–14	(869–026–00193–6)	28.00	Oct. 1, 1995
15–28	(869–026–00194–4)	31.00	Oct. 1, 1995
29–End	(869–026–00195–2)	19.00	Oct. 1, 1995
49 Parts:			
1–99	(869–026–00196–1)	25.00	Oct. 1, 1995
100–177	(869–022–00194–9)	30.00	Oct. 1, 1994
178–199	(869–022–00195–7)	21.00	Oct. 1, 1994
200–399	(869–026–00199–5)	30.00	Oct. 1, 1995
400–999	(869–022–00197–3)	35.00	Oct. 1, 1994
1000–1199	(869–026–00201–1)	18.00	Oct. 1, 1995
1200–End	(869–026–00202–9)	15.00	Oct. 1, 1995
50 Parts:			
1–199	(869–022–00200–7)	25.00	Oct. 1, 1994
200–599	(869–026–00204–5)	22.00	Oct. 1, 1995
600–End	(869–026–00205–3)	27.00	Oct. 1, 1995

Title	Stock Number	Price	Revision Date
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Complete set (one-time mailing)		244.00	1994
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[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period Apr. 1, 1990 to Mar. 31, 1995. The CFR volume issued April 1, 1990, should be retained.

[5] No amendments to this volume were promulgated during the period July 1, 1991 to June 30, 1995. The CFR volume issued July 1, 1991, should be retained.

[6] No amendments to this volume were promulgated during the period January 1, 1993 to December 31, 1994. The CFR volume issued January 1, 1993, should be retained.

[7] No amendments to this volume were promulgated during the period April 1, 1994 to March 31, 1995. The CFR volume issued April 1, 1994, should be retained.