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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.
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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 250

Donation of Food for Use in the United States, Its Territories and Possessions and Areas Under Its Jurisdiction

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule would amend the Food Distribution Program Regulations (7 CFR Part 250) by permitting processors to pay refunds later than 10 days after receipt of the refund application for processed end products containing donated cheese. Since the surpluses of cheese have been reduced so drastically, the Department can no longer fill requests for cheese in unlimited amounts. Set amounts of cheese have been made available to each distributing agency. Current regulations require processors to make refund payments to recipient agencies within 10 days of receipt of a refund application. The Department anticipates delays in the delivery of cheese during the second and third quarter of school year 1988–1989. The Department plans to catch up with any delayed shipments during the fourth quarter. The intended effect of this action is to amend procedures to take into consideration delayed shipments of cheese.

EFFECTIVE DATE: This final rule is effective November 16, 1988.

FOR FURTHER INFORMATION CONTACT: Susan Proden, Chief, Program Administration Branch, Food Distribution Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Alexandria, Virginia 22302 or telephone (703) 756–3660.

SUPPLEMENTARY INFORMATION:

Classification

This action has been reviewed under Executive Order 12291 and has been classified not major. We anticipate that this rule will not have an annual impact on the economy of more than $100 million. No major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies or geographic regions is anticipated. This action is not expected to have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Permitting processors to pay refunds later than 10 days after receipt of the refund application for processed end products containing cheese is necessary for the 1988–1989 school year. Shipments of donated cheese are expected to be behind schedule for the second and third quarters of the school year. The Department anticipates catching up with deliveries by the fourth quarter. The Administrator has determined pursuant to 5 U.S.C. 533(b), that prior notice and public procedure are impracticable, unnecessary and contrary to the public interest. A significant portion of the cheese available to States for this fiscal year will be delivered too late in the year for effective use. Without the change instituted by this rule, recipient agencies would be forced to buy products containing cheese at full price, because few processors will be willing to advance refunds if they have not received adequate donated cheese to account for the refunds. By allowing processors to delay payment of the refunds, recipient agencies can receive the processed products with the assurance that refunds for donated cheese will eventually be forthcoming. This rule must be put in place immediately to benefit recipient agencies and processors this school year. This rule relieves processors from having to pay refunds within 10 days if anticipated shipments of cheese are delayed. For this reason, the Administrator has also determined in accordance with 5 U.S.C. 553(d), that good cause exists for making this rule effective less than 30 days after publication.

This action has been reviewed with regard to requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612). Anna Kondratas, Administrator of the Food and Nutrition Service, has certified that this action will not have a significant economic impact on a substantial number of small entities.

This program is listed in the Catalog of Federal Domestic Assistance under 10.550 and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials (7 CFR Part 3015, Subpart V and the final rule related notice published June 24, 1983 (48 FR 29112)).

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501–3520), the additional recordkeeping and reporting requirements contained in this rule are subject to review and approval by the Office of Management and Budget (OMB). Current reporting and recordkeeping requirements for Part 250 were approved by OMB under control number 0584–0007.

Background

Section 250.30 of the current regulations sets forth the terms and conditions under which State distributing agencies, subdistributing agencies and recipient agencies may enter into contracts with food processors to incorporate government-donated commodities into processed end products.

Donated cheese has been available to schools and other outlets such as charitable institutions in any amounts that could be utilized without waste since 1981. As a result of the abundant supply of this commodity, many distributing agencies entered into numerous processing agreements for the conversion of donated cheese into end products such as pizza. Also, the Department established the National Commodity Processing Program to further increase the number of recipient agencies receiving the benefits of commodity assistance through processing agreements.

Since 1981, over 5 billion pounds of surplus dairy commodities have been distributed to low-income households. These distributions as well as ones made to schools and other outlets have substantially reduced the surplus of cheese available for various Food Distribution Programs. Moreover, modifications in agricultural price-support programs have brought supply

and demand into better balance, thereby reducing the volume of commodities the Government has been required to purchase under price-support programs.

Since the surpluses of cheese have been reduced so drastically, the Department can no longer fill requests for cheese in unlimited amounts. Therefore, for the 1988–1989 School Year, State distributing agencies were notified in June of the total amount of cheese to be made available to them for the entire year. The cheese made available to States could be distributed directly to recipient agencies or furnished to processors to be used in the manufacture of end products. State agencies were also informed as to the total amount of cheese that could be ordered each quarter against the total available amount.

It was recommended that State agencies inform processors of the total amount of cheese to be furnished to them for the 1988–1989 contract year as well as the amounts of cheese to be delivered each quarter of the contract year. Processors were further to be informed that sales for the year could not exceed the total amount of cheese to be delivered for the year plus any carryover inventory from the previous year. If processors went into a negative inventory status (used more cheese than was available from the State), they did so at their own financial risk.

Section 250.30(k)(3) of the current regulations requires that processors make refund payments for the value of government commodities contained in processed end products to recipient agencies not later than 10 days after receipt of the refund application. The Department anticipates delays in the delivery of cheese during the second and third quarters of School Year 1988–1989. Because of these delays, processors may not receive the total amounts of cheese that are anticipated for these quarters. The Department, however, plans to catch up with any delayed shipments during the fourth quarter, ensuring that the total amount of cheese made available for 1988–1989 is delivered.

Processors who experience delays in shipments may not have physical inventory of cheese on hand to cover refund applications received during the second and third quarters. Section 250.30(k)(3) of this rule is being amended to permit processors to make refund payments to recipient agencies for end products containing cheese later than 10 days after receipt of the refund application in those quarters where cheese deliveries to the processor fell short of their allocation; *Provided however*, that the processor has first honored all requests for refunds received for end products sold during the period for which it had USDA cheese. Processors will be required to notify recipient agencies in writing that they are unable to process their refund payments at this time. This notification to the recipient agencies should take place within 10 days of receipt of the refund application. Once cheese is delivered, processors will be required to pay refunds which have been held based on the date the refund application was received. Those applications are to be processed on a first come first serve basis and payments must be processed within 10 days of receipt of the commodity.

Under no circumstances should processors make sales with a promise of a refund payment in excess of their cheese allocation for the entire 1988–1989 school year.

List of Subjects in 7 CFR Part 250

Aged, Agricultural commodities, Business and industry, Food assistance programs, Food donations, Food processing, Grant programs-social programs, Infants and children, Price support programs, Reporting and recordkeeping requirements, School breakfast and lunch programs, Surplus agricultural commodities.

Accordingly, 7 CFR Part 250 is amended as follows:

PART 250—DONATIONS OF FOOD FOR USE IN THE UNITED STATES, ITS TERRITORIES AND POSSESSIONS AND AREAS UNDER ITS JURISDICTION

1. The authority citation for Part 250 is revised to read as follows:

Authority: Sec 32, Pub. L. 74–320, 49 Stat. 744 (7 U.S.C. 612c); Pub. L. 75–165, 50 Stat. 323 (15 U.S.C. 713c); secs. 6, 9, Pub. L. 79–396, 60 Stat. 231, 233, (42 U.S.C. 1755, 1758); sec. 416, Pub. L. 81–439, 63 Stat. 1058 (7 U.S.C. 1431); sec. 402, Pub. L. 91–665, 68 Stat. 843 (22 U.S.C. 1922); sec. 210, Pub. L. 84–540, 70 Stat. 202 (7 U.S.C. 1859); sec. 9, Pub. L. 985–931, 72 Stat. 1792 (7 U.S.C. 1431b); Pub. L. 86–756, 74 Stat. 899 (7 U.S.C. 1431 note); sec. 709, Pub. L. 89–321, 79 Stat. 1212 (7 U.S.C. 1446a–1); sec. 3, Pub. L. 90–302, 82 Stat. 117 (42 U.S.C. 1761); secs. 409, 410, Pub. L. 93–288, 88 Stat. 157 (42 U.S.C. 5179, 5180); sec. 2, Pub. L. 93–326, 88 Stat. 286 (42 U.S.C. 1762a); sec. 16, Pub. L. 94–105, 89 Stat. 522 (42 U.S.C. 1766); sec. 1304a, Pub. L. 95–113, 91 Stat. 980 (7 U.S.C. 612c note); sec. 311, Pub. L. 95–478, 92 Stat. 1533 (42 U.S.C. 3030a); sec. 10, Pub. L. 95–627, 92 Stat. 3623 (42 U.S.C. 1760); Pub. L. 96–6, 97 Stat. 35 (7 U.S.C. 612c note); (5 U.S.C. 301); Pub. L. 100–237, 101 Stat. 1733 (7 U.S.C. 612 note).

2. In § 250.30, a new paragraph (k)(4) is added to read as follows:

§ 250.30 State processing of donated foods.

* * * * *

(k) *Refund payments* * * *

(4) State distributing agencies shall notify processors of the total amount of donated cheese they can receive during the 1988–1989 school year and shall inform processors of the amount of cheese to be delivered each quarter. During the 1988–1989 school year, processors shall be permitted to pay refunds later than 10 days after receipt of the refund application for processed end products containing donated cheese. However, the processor shall honor all requests for refunds received for end products sold during the period for which it had USDA cheese. Payment may only be delayed if delays in shipments of cheese to processors occur Processors shall notify recipient agencies within 10 days of receipt of the refund application that the refund payment is being delayed. Once cheese has been delivered to the processor, the processor shall make refund payments to recipient agencies within 10 days of receipt of the commodity. Processors shall process refund applications in chronological order based on the date the applications were received. In no event shall the processors solicit or make sales to eligible recipient agencies which will cause them to exceed the total amount of cheese for which they have been allocated for the school year 1988–1989.

* * * * *

Date: November 9, 1988.

Anna Kondratas,

Administrator.

[FR Doc. 88–26436 Filed 11–15–88; 8:45 am]

BILLING CODE 3410–30–M

Animal and Plant Health Inspection Service

9 CFR Part 77

[Docket 87–181]

Tuberculosis in Cattle; State Designations; West Virginia

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Clarification.

SUMMARY: This document clarifies the status of amendments contained in an interim rule published June 26, 1987, and in a final rule published October 23, 1987. It confirms the designation of West Virginia as an accredited-free state in the tuberculosis regulations governing the interstate movement of cattle.

FOR FURTHER INFORMATION CONTACT: Dr. Ralph L. Hosker, Senior Staff Veterinarian, Domestic Programs Support Staff, VS, APHIS, USDA, Room 815, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-8715.

SUPPLEMENTARY INFORMATION:

Background

In an interim rule published in the **Federal Register** and effective June 26, 1987 (52 FR 23936-23937, Docket Number 87-057), we amended the regulations in 9 CFR Part 77 governing the interstate movement of cattle because of tuberculosis. Specifically, we amended 9 CFR 77.4 by changing the classification of West Virginia from a modified accredited area to an accredited-free state. The comment period closed on August 25, 1987. We did not receive any comments.

As a result of a final rule published in the **Federal Register** on October 23, 1987 (52 FR 39613-39616), and effective November 23, 1987, the list of accredited-free states, including West Virginia, now appears in the definition of "accredited-free state" in 9 CFR 77.1. The facts presented in the interim rule still provide a basis for West Virginia's inclusion in this list of accredited-free states.

Authority: 21 U.S.C. 111, 114, 114a, 115-117, 120, 121, 134b, 134f; 7 CFR 2.17, 2.51, and 371.2(d).

Done in Washington, DC this 9th day of November 1988.

Larry B. Slagle,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 88-26415 Filed 11-15-88; 8:45 am]

BILLING CODE 3410-34-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 4

[T.D. 88-71]

Reporting Requirements for Small Vessels

AGENCY: Customs Service, Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations to implement recent legislative changes to enhance Customs enforcement of the currency reporting and controlled substances laws and assist in preventing the importation of merchandise contrary to law. The statutory changes concern reporting requirements for individuals and various modes of transportation, penalties, searches and seizures. To clarify vessel reporting requirements and to implement new vessel reporting requirements for small vessels arriving in the Miami, Florida, Customs District, operators of small vessels arriving in that area will be required to stop at a designated reporting location and, through a clearly marked Customs telephone, report their arrival before proceeding in their destination. In addition to the reporting requirements, the amendments also implement legislative provisions of the Act which provide for civil and criminal monetary penalties and for the seizure and forfeiture of conveyances used to transport unmanifested merchandise or controlled substances as well as the merchandise thereon.

This action is being taken as part of Customs continuing efforts to interdict the smuggling of controlled substances and other merchandise being introduced contrary to law into the southern Florida area and to enforce the currency reporting laws. These regulations will close a loophole in interdiction efforts concerning the significant number of small vessels arriving in that area carrying controlled substances, unreported monetary instruments or undeclared merchandise.

EFFECTIVE DATE: December 16, 1988.

FOR FURTHER INFORMATION CONTACT: (Operational matters) Glenn Ross, Office of Passenger Enforcement and Facilitation (202) 566-5607 or (Legal matters) Larry L. Burton, Carrier Rulings Branch, Office of Regulations and Rulings (202) 566-5706.

SUPPLEMENTARY INFORMATION:

Background

The Anti-Drug Abuse Act of 1986 (Pub. L. 99-570) (the Act), made various changes to the Tariff Act of 1930 relating to the arrival and reporting to Customs of persons and transportation conveyances; penalties; search and seizure of persons and conveyances; forfeiture and disposition of articles and conveyances; the Customs Forfeiture Fund; aviation smuggling; preclearance; and investigation matters such as records production, undercover Customs operations, informer compensation and the exchange of information with domestic and foreign Customs and law enforcement agencies.

The reporting requirements are consolidated in section 433, Tariff Act of 1930, as amended (19 U.S.C. 1433), which provides, in pertinent part, that vessels must generally report to Customs immediately upon their arrival and in such manner as the Secretary of the Treasury may prescribe by regulation. The Act amended section 401(k), Tariff Act of 1930, as amended (19 U.S.C. 1401(k)), to clarify that vessels arriving in the United States after visiting a hovering vessel or a point or place where it has received merchandise is deemed to be arriving from a foreign port or place and that controlled substances are generally to be considered as prohibited merchandise. The Act amended section 594, Tariff Act of 1930, as amended (19 U.S.C. 1594), relating to the seizure and forfeiture of conveyances used for the importation of prohibited merchandise, by narrowing and clarifying the previously existing exceptions to the seizure and forfeiture provisions of that section. This document implements the arrival, reporting, and conveyance seizure and forfeiture provisions of the Act as to "small vessels", as defined. Initially, the special procedures for reporting arrival of small vessels are being limited to arrivals within the Miami, Florida, Customs District, as defined in § 101.3(b), Customs Regulations (19 CFR 101.3(b)). Operators of small vessels arriving in the United States in that area will be required to stop at a small vessel reporting location before proceeding to their intended destination and, through a clearly marked Customs telephone, immediately report their arrival to Customs. The Customs officer answering the call will ask for information such as: Registration number, name of vessel, owner name, operator/passenger name(s), date(s) of birth, foreign ports or places visited, duration of stay, foreign acquisitions, and user fee decal number, if any. The Customs officer will then instruct the vessel operator that the vessel may proceed or that further action, which may include inspection/examination at another location, is required. The District Director of Customs at Miami will retain the authority to change the reporting locations, their number, or location. The 14 small vessel reporting stations established within the Miami, Florida, Customs District by T.D. 87-150 for small vessel arrival reporting have been expanded to 24 in number. They are:

Vessels entering the Miami District southern intracoastal waterway.

1. A & B Marina, 700 Marina St., Key West, Florida 33040.

2. Tavernier Creek Marina, P.O. Box 1000, Tavernier, Florida 33070.

3. Faro Blanco Marine Resort, 1996 Overseas Highway, Marathon, Florida 33050.

4. Ocean Reef Club, 31 Ocean Reef Dr., Key Largo, Florida 33037.

5. Oceanside Marina, 5950 Maloney Avenue, Key West, Florida 33040.

Vessels entering the Miami District northern intracoastal waterway.

1. Government Cut, Phillips 66 Marina, Waston Island, 1050 MacArthur Causeway, Miami, Florida 33132.

2. Haulover Cut, Bakers Haulover Marina, 10800 Collins Ave., Miami Beach, Florida 33154.

3. Port Everglades Cut, Lauderdale Marina, 1900 S.E. 15th St., Ft. Lauderdale, Florida 33316.

4. Hillsboro Inlet, Sands Harbor Marina/Hotel, 125 North Riverside Dr., Pompano Beach, Florida 33662.

5. The Cove Marina, 1755 S.E. 3rd Court, Deerfield Beach, Florida 33441.

6. Boynton Beach Inlet, Lake Worth Boating Center, 7848 South Federal Highway, Hypoloxo, Florida 33462.

7. Lake Worth Inlet (AKA Palm Beach), Sailfish Marina, 98 Lake Drive, Palm Beach Shores, Florida 33404.

8. Jupiter Inlet, Jupiter Marina, Route 1, Jupiter, Florida 33494.

9. St. Lucie Inlet, Sailfish Marina, 3565 Southeast St., Stuart, Florida 33477.

10. Ft. Pierce Inlet, Pelican Yacht Club, 1120 Seaway Dr., Ft. Pierce, Florida 33454.

11. Sebastian Inlet, Sebastian Inlet Marina and Trading, 1580 U.S. 1, P.O. Box 1507, Sebastian, Florida 32958.

12. Crandon Park Marina, 4000 Crandon Blvd.—Virginia Beach, Miami, Florida 33149.

13. Matheson Hammock Marina, 9610 Old Cutler Rd.—Matheson Hammock Park, Miami, Florida 33156.

14. Sunset Harbour Marina, 1928 Purdy Avenue, Miami Beach, Florida 33139.

15. Pier 66, 2301 S.E. 17 Street, Ft. Lauderdale, Florida 33316.

16. Bahia Mar, 801 Sea Breeze Blvd., Ft. Lauderdale, Florida 33316.

17. Light House Point Marina, 2830 N.E. 29 Avenue, Pompano Beach, Florida 33064.

18. Riviera Beach Municipal Marina, 200 E. 13 Street, Riviera Beach, Florida 33404.

19. Delray Harbour Club Marina, 1035 South Federal Highway, Delray Beach, Florida 33483.

The interim regulations established procedures for reporting the arrival of small vessels in the Miami District, see § 4.2a, Customs Regulations (19 CFR 4.2a). They also implemented the provisions of the Act which provide for civil monetary penalties for the failure to report arrival and additional civil monetary penalties if unmanifested merchandise was on board a non-reporting vessel. The vessel manifest penalties of section 584, Tariff Act of 1930, as amended (19 U.S.C. 1584), were made applicable if the merchandise on board a non-reporting vessel consists of controlled substances. Criminal monetary penalties and imprisonment were provided for if the failure to report arrival was intentional and if controlled substances were found on board the non-reporting vessel. The civil penalty included seizure and forfeiture provisions related to the vessel and the merchandise in addition to the monetary penalties.

These regulations, it was noted, were part of Customs continuing effort to combat the problem of drug smuggling by vessel and to more specifically deal with techniques developed by drug smugglers utilizing small vessels for that purpose. It was also noted that Customs would now have greater control over small vessels in the southern Florida area because those vessels will now be required to go to designated reporting locations and immediately report their arrival. Thus, smugglers will not be able to proceed to private docks and unload contraband before continuing to their intended destination and then reporting their arrival to Customs. This was possible under the previously existing law and regulations which permitted the report of arrival to be delayed for as long as 24 hours after arrival in the U.S.

The December 21, 1987, **Federal Register** notice solicited public comments on the new requirements. The comments received have been taken into consideration in formulating the final rule and are discussed in this document.

Analysis of Comments

On hundred sixteen comments were received in response to the solicitation of comments contained in the **Federal Register** notice. The comments noted operational difficulties caused by the implementation of the small boat reporting procedures in the Miami, Florida, District.

Several commenters indicated that the facilities at the Watson Island reporting station, the only Dade County, Florida, location, were inadequate and that the conditions there were unsafe and crowded. Repairs have been made to the docking area, and the city of Miami has been requested to enforce the "No Wake" provision around the Watson Island area. In addition, reporting facilities have been established at three new locations—Matheson Hammock, Sunset Harbour and Crandon Park Marinas.

Many commenters expressed concern about crowded conditions at reporting locations in the Miami and Ft. Lauderdale areas. A new reporting location near the entrance to Hillsboro Inlet was requested. The Customs Service has established ten additional reporting stations in the Miami District, with three in the Miami Area as indicated above, and two in the Ft. Lauderdale vicinity. A new reporting location has been established near the entrance to Hillsboro Inlet at the Light House Point Marina in Pompano Beach. In addition, Customs has established a Private Marina Visa Plan in the Miami District. The plan allows the clientele of a private marina, after the marina obtains prior approval from Customs, to discharge arrival reporting responsibilities, pursuant to § 4.2a, Customs Regulations (19 CFR 4.2a), at that location. This plan, along with the additional reporting locations, should relieve the crowded conditions which were the subject of these comments.

Several commenters complained of the inconvenience of having to go to a specific location to report their arrival. They believed that they were being discriminated against and that drug smugglers still were not going to report under the new system. We do not agree with the claim of discrimination. We note that prior to the new reporting requirements, private vessels had up to 24 hours to report their arrival. This created a large loophole in our interdiction efforts in that vessels involved in smuggling could off-load their contraband at a remote location and then report to Customs. With immediate reporting, private vessels are channeled into specific locations where they will report and possibly be subject to inspection. Customs, the Coast Guard, and State and local marine untis will be in a better position to more quickly distinguish suspect and non-suspect vessels. This more efficient targeting of suspect vessels will result in more efficient use of limited marine law enforcement resources which otherwise may be wasted on launches and boardings of no-suspect vessels.

One commenter stated that boaters should be permitted to utilize VHF radio aboard boats to report arrival. Customs disagrees with this proposal. We believe that such reporting scheme would recreate the situation that existed before the Anti-Drug Abuse Act of 1986 was enacted. Since section 433, Tariff Act of 1930, as amended by the Anti-Drug Abuse Act of 1986, requires an immediate report of arrival, and report by radio transmission can be made from an unfixed location at any time, Customs would be unable to confirm that the statutory requirement had been met.

After consideration of all the comments received, and following further review of the matter, it has been determined to adopt the interim regulations as published.

Executive Order 12291

Because this document does not meet the criteria for a "major rule" as defined in E.O. 12291, a regulatory impact analysis was not prepared.

Regulatory Flexibility Act

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

Drafting Information

The principal author of this document was Arnold L. Sarasky, Regulations and Disclosure Law Branch, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 4

Cargo vessels, Coastal zone, Customs duties and inspection, Fishing vessels, Freight, Harbors, Imports, Maritime carriers, Reporting and recordkeeping requirements, Seamen, Vessels and yachts.

Amendments to the Regulations

Part 4, Customs Regulations (19 CFR Part 4), is amended as set forth below:

PART 4—VESSELS IN FOREIGN AND DOMESTIC TRADE

1. The general authority for Part 4 continues to read as follows:

Authority: 5 U.S.C. 301, 19 U.S.C. 66, 1624, and 46 U.S.C. 3, 2103.

2. Section 4.2(a) is revised to read as follows:

§ 4.2 Report of arrival of vessels.

(a) The report of arrival required by section 433, Tariff Act of 1930, as amended (19 U.S.C. 1433), or as supplemented in local instruction by the district director and made available to interested parties by posting in Customs offices, publication in a newspaper of general circulation, and other appropriate means, shall be made by any means of communication to the district director or to a Customs officer assigned to board a vessel. The Customs officer may require the production of any documents or papers deemed necessary for the proper inspection/examination of a vessel, cargo, passengers, or crew.

* * * * *

3. Part 4 is amended by revising § 4.2a to read as follows:

§ 4.2a Small vessel reporting of arrival, Miami District.

(a) *Scope.* This section imposes special requirements for the report of arrival from any foreign port or place by small vessels whose intended destination is at a point within the jurisdiction of the Miami, Florida, Customs District, as defined in § 101.3(b) of this chapter. The operators of vessels will be required to immediately report their arrival in the U.S., as prescribed by § 4.2(a) of this chapter, or as supplemented in local instruction issued by the district director and made available to interested parties by posting in Customs offices, publication in a newspaper of general circulation within the Miami District, and other appropriate means, by proceeding to locations designated by the District Director of Customs, Miami, Florida, prior to proceeding to their destination. The report will be made through a clearly marked Customs telephone. After securing some information from the person reporting, the Customs officer responding to the report of arrival will instruct the vessel operator that the vessel may proceed or that further action, which may include inspection at another location, is required.

(b) *Definitions.* For the purposes of this section:

(1) "*Foreign port or place*" includes a hovering vessels as defined in section 401(k)), Tariff Act of 1930, as amended (19 U.S.C. 1401(k)), and any point in the Customs waters beyond the territorial sea or on the high seas at which a vessel arriving in a port or place in the U.S. has received merchandise.

(2) "*Small vessel*" includes any vessel of less than 5 net tons, and any private pleasure vessel, regardless of displacement.

(3) "*Arrival of a vessel*" occurs when a small vessel comes to rest within the waters of the Miami District, whether at anchor or at a dock, in any harbor or other location.

(c) *Vessels entering the southern and western portion of the Miami District.* The operators of vessels arriving from a foreign port or place with an intended destination at a point south of the entrance to Biscayne Bay known as Broad Creek, which is north of Key Largo between Swan Key and Broad Key or that portion of the west coast of the State of Florida within the Miami Customs District, as described in § 101.3(b), of this chapter, shall immediately report their arrival by the use of special clearly marked Customs telephones provided for that purpose, at the Customs designated location in the Florida Keys nearest to their intended destination point, before proceeding to the destination point.

(d) *Vessels entering the northern portion of the Miami District.* The operators of vessels arriving from a foreign port or place with an intended destination at or north of the entrance to Biscayne Bay known as Broad Creek, which is north of Key Largo and between Swan Key and Broad Key, shall immediately report their arrival by the use of special clearly marked Customs telephones provided for that purpose, at the Customs designated location nearest to point at which the Biscayne Bay may be first entered or the intracoastal waterway is first entered through a "cut", "channel" or "inlet", before proceeding to their destination point. This provision shall apply to vessels whose intended destination is on the Florida mainland or the barrier islands east of the intracoastal waterway.

(e) *Penalties*—(1) *Civil Penalty.* The master or person in charge of any vessel who fails to report arrival as required under this section is liable for a civil penalty of $5,000 for the first violation, and $10,000 for each subsequent violation. Any vessel used in connection with any such violation is subject to seizure and forfeiture.

(2) *Criminal penalty.* In addition to the civil penalty prescribed for violation of this section, the master or person in charge who intentionally fails to report arrival as required by this section is liable, upon conviction, for a fine of not more than $2,000 or imprisonment for 1 year, or both. If the vessel is found to have or to have had on board any merchandise the importation of which is prohibited, such individual is liable for an additional fine of not more than $10,000 or imprisonment for not more than 5 years, or both.

(3) *Additional civil penalty.* If any merchandise, other than sea stores, is imported or brought into the U.S. aboard a vessel which has failed to report arrival as prescribed by this section, the master or person in charge shall be liable for a civil penalty equal to the value of the merchandise, and the merchandise may be seized and forfeited, unless properly entered by the importer or consignee. If any of the merchandise consists of a controlled substance listed in section 584, Tariff Act of 1930, as amended (19 U.S.C.

1584), the penalties prescribed in that section shall apply.

William von Raab,

Commissioner of Customs.

Approved: October 7, 1988.

Salvatore R. Martoche,

Assistant Secretary of the Treasury.

[FR Doc. 88-26365 Filed 11-15-88; 8:45 am]

BILLING CODE 4820-02-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Part 235

[Docket No. R-88-1429; FR-2590]

Mortgage Insurance; Changes in Interest Rates

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Final rule.

SUMMARY: This change in the regulations decreases the maximum allowable interest rate on section 235 (Homeownership for Lower Income Families) insured loans. This final rule is intended to bring the maximum permissible financing charges for this program into line with competitive market rates.

EFFECTIVE DATE: November 1, 1988.

FOR FURTHER INFORMATION CONTACT: John N. Dickie, Chief Mortgage and Capital Market Analysis Branch, Office of Financial Management, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410. Telephone (202) 755-7270. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The following amendments to 24 CFR Chapter II have been made to decrease the maximum interest rate which may be charged on loans insured by this Department under section 235 of the National Housing Act. The maximum interest rate on the HUD/FHA Section 235 insurance programs has been lowered from 10.50 percent to 10.00 percent.

Until recently, HUD regulated interest rates not only for the Section 235 Program, but also for fire safety equipment loans insured under section 232 of the National Housing Act. However, section 429(e)(2) of the Housing and Community Development Act of 1987 (Pub. L. 100-242, approved February 5, 1988) amended the National Housing Act to provide that interest on fire safety equipment loans under section 232(i) of the Act will be "at such rate as may be agreed upon by the mortgagor and the mortgagee." Accordingly, these loans, like most other National Housing Act-authorized loans, now have their interest rates determined by negotiation. Accordingly, this annnouncement of a change in interest rate ceilings for FHA-insured mortgages is limited to the Section 235 Program.

The Secretary has determined that this change is immediately necessary to meet the needs of the market and to prevent speculation in anticipation of a change.

As a matter of policy, the Department submits most of its rulemaking to public comment, either before or after effectiveness of the action. In this instance, however, the Secretary has determined that advance notice and public comment procedures are unnecessary and that good cause exists for making this final rule effective immediately. HUD regulations published at 47 FR 56266 (1982), amending 24 CFR Part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969, contain categorical exclusions from their requirements for the actions, activities and programs specified in § 50.20. Since the amendments made by this rule fall within the categorical exclusions set forth in paragraph (*1*) of § 50.20, the preparation of an Environmental Impact Statement or Finding of No Significant Impact is not required for this rule. This rule does not constitute a "major rule" as that term is defined in section 1(b) of Executive Order 12291 on Federal Regulation issued on February 17, 1981. Analysis of the rule indicates that it does not (1) have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, State or local governmental agencies, or geographic regions; or (3) have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the provisions of 5 U.S.C. 605(b) (the Regulatory Flexibility Act), the undersigned hereby certifies that this rule does not have a significant economic impact on a substantial number of small entities. The rule provides for a small increase in the mortgage interest rate in programs of limited applicability, and thus of minimal effect on small entities. This rule was not listed in the Department's Semiannual Agenda of Regulations published on October 24, 1988 (53 FR 41974) pursuant to Executive Order 12291 and the Regulatory Flexibility Act. The Catalog of Federal Domestic Assistance program numbers are 14.108, 14.117, and 14.120.

List of Subjects in 24 CFR Part 235

Condominiums, Cooperatives, Low and moderate income housing, Mortgage insurance, Homeownership, Grant programs: housing and community development.

Accordingly, the Department amends 24 CFR Part 235 as follows:

PART 235—MORTGAGE INSURANCE AND ASSISTANCE PAYMENTS FOR HOME OWNERSHIP AND PROJECT REHABILITATION

1. The authority citation for 24 CFR Part 235 continues to read as follows:

Authority: Sections 211, 235, National Housing Act (12 U.S.C. 1715b, 1715z); Section 7(d), Department of Housing and Urban Development Act, (42 U.S.C. 3535(d)).

2. In § 235.9, paragraph (a) is revised to read as follows:

§ 235.9 Maximum interest rate.

(a) The mortgage shall bear interest at the rate agreed upon by the mortgagee and the mortgagor, which rate shall not exceed 10.00 percent per annum, except that where an application for commitment was received by the Secretary before November 1, 1988, the loan may bear interest at the maximum rate in effect at the time of application.

* * * * *

3. In § 235.540, paragraph (a) is revised to read as follows:

§ 235.540 Maximum interest rate.

(a) On or after November 1, 1988, the loan shall bear interest at the rate agreed upon by the lender and the borrower, which rate shall not exceed 10.00 percent per annum, with the exception of applications submitted pursuant to feasibility letters, or outstanding conditional or firm commitments, issued prior to the effective date of the new rate. In these instances, applications will be processed at a rate not exceeding the applicable previous maximum rates, if the higher rate was previously agreed upon by the parties. Notwithstanding these exceptions, the application will be processed at the new lower rate if requested by the mortgagee.

* * * * *

Date: October 31, 1988.

James E. Schoenberger,

General Deputy Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 88-26433 Filed 11-15-88; 8:45 am]

BILLING CODE 4210-27-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[PP 8E3597/R991; FRL-3477-4]

Pesticide Tolerance for 2-[1-(Ethoxyimino)Butyl]-5-[2-(Ethylthio)Propyl]-3-Hydroxy-2-Cyclohexene-1-One

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a tolerance for the combined residues of the herbicide 2-[1-(ethoxyimino)-butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexene-1-one and its metabolites in or on the raw agricultural commodity lentils. The Interregional Research Project No. 4 (IR-4) petitioned for this tolerance.

EFFECTIVE DATE: November 16, 1988.

ADDRESS: Written objections, identified by the document control number, [PP 8E3597/R991], may be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt Jamerson, Emergency Response and Minor Use Section (TS-767C), Registration Division (TS-767C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 716, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703)-557-2310.

SUPPLEMENTARY INFORMATION: EPA issued a proposed rule, published in the Federal Register of September 28, 1988 (53 FR 37801), in which it was announced that the Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, had submitted pesticide petition 8E3597 to EPA on behalf of Dr. Robert H. Kupelian, National Director, IR-4 Project, and the Agricultural Experiment Stations of Idaho and Washington.

The petition requested that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act, propose the establishment of a tolerance for the combined residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexene-1-one and its metabolites containing the 2-cyclohexene-1-one moiety (calculated as the herbicide) in or on the raw agricultural commodity lentils at 30.0 parts per million (ppm).

There were no comments or requests for referral to an advisory committee received in response to the proposed rule.

The data submitted in the petition and all other relevant material have been evaluated and discussed in the proposed rule. Based on the data and information considered, the Agency concludes that the tolerance will protect the public health. Therefore, the tolerance is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections with the Hearing Clerk, at the address given above. Such objections should specify the provisions of the regulation deemed objectionable and the grounds for the objections. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 4, 1988.

Douglas D. Campt,

Director, Office of Pesticide Programs.

Therefore, 40 CFR Part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for Part 180 continues to read as follows:

Authority: 21 U.S.C. 346a.

2. Section 180.412(a) is amended by adding and alphabetically inserting the listing for the raw agricultural commodity lentils, to read as follows:

§ 180.412 2-[1-(Ethoxyimino)butyl)]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexene-1-one; tolerances for residues.

(a) * * *

Commodities	Parts per million
* * * * *	
Lentils	30.0
* * * * *	

[FR Doc. 88-26423 Filed 11-15-88; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 87-407; RM-5608 and RM-5925]

Radio Broadcasting Services; Mandeville and Lacombe, LA and Long Beach, MS

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document denies a proposal to allot Channel 234A to Mandeville, Louisiana due to noncompliance with the principal city coverage requirement of § 73.315 of the Commission's Rules. The conflicting proposal to allot Channel 234A to Lacombe, Louisiana is granted. The document also denies a counterproposal by William Seiler for Channel 235A for Mandeville as well as a petition for reconsideration filed by William Seiler directed against an earlier action returning his petition for rule making for Channel 235A at Mandeville. These latter two actions are premised on the fact that a Channel 235A allotment at Mandeville would require a substitution of Channel 235A at Reserve, Louisiana, which was alloted in MM Docket No. 84-231. Finally, this document dismisses counterproposals filed by John Watkins and Beach Broadcasting Limited Partnership for the upgrade of the Channel 233A allotment at Long Beach, Mississippi, because there are merely pending applications for the Long Beach allotment and the upgrade procedure is only available to permittees or licensees. With this action, this proceeding is terminated.

DATES: Effective December 22, 1988. The window period for filing applications on Channel 234A at Lacombe, Louisiana will open on December 23, 1988, and close on January 23, 1989.

FOR FURTHER INFORMATION CONTACT: Robert Hayne, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order*, MM Docket No. 87-407, adopted October 18, 1988, and released November 11, 1988. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, (202) 857-3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments, is amended under Louisiana by adding Lacombe, Channel 234A.

Federal Communications Commission.

Bradley P. Holmes,

Chief, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 88-26464 Filed 11-15-88; 8:45 am]

BILLING CODE 6712-01-M

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47 CFR Part 73

[MM Docket No. 87-475; RM-5905; RM-6209]

Radio Broadcasting Services; Broken Arrow and Bixby, OK and Coffeyville, KS

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of KCMA, Inc., substitutes Channel 221C2 for Channel 221A at Broken Arrow, OK, and modifies its license for Station KCMA(FM) to specify operation on the higher powered channel, and substitutes Channel 255A for Channel 221A at Coffeyville, Kansas, and modifies the license of Midwest Broadcasting Co. for Station KQQF(FM) to specify the new Coffeyville channel. The Commission found that the allotment of Channel 221C2 to Broken Arrow could provide increased FM service to the area while not significantly impacting noncommercial educational services in the area. It also found that Midwest Broadasting Co. had not presented a substantial and material question of fact which would warrant a hearing on the modification of Station KQQF(FM)'s license. In addition, the Commission denied the counterproposal of Midwest Broadcasting Co. to substitute Channel 287C2 for Channel 221A at Broken Arrow and substitute Channel 221A for Channel 287A at Bixby, Oklahoma. Channel 221C2 can be allotted to Broken Arrow in compliance with the Commission's minimum distance separation requirements with a site restriction of 19.7 kilometers (12.4 miles) west to avoid a short-spacing to Station KKEG, Channel 221A, Fayetteville, Arkansas. The coordinates for this allotment are North Latitude 36-03-37 and West Longitude 96-00-57. Channel 255A can be allotted to Coffeyville in compliance with the Commission's minimum distance separation requirements and can be used at Station KQQF(FM)'s present transmitter site. The coordinates for this allotment are North Latitude 37-06-28 and West Longitude 96-43-22. With this action, this proceeding is terminated.

EFFECTIVE DATE: December 22, 1988.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 87-475, adopted October 11, 1988, and released November 9, 1988. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service (202) 857-3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the FM Table of Allotments is amended by revising the entry for Coffeyville, Kansas, by deleting Channel 221A and adding Channel 255A, and by revising the entry for Broken Arrow, Oklahoma, by deleting Channel 221A and adding Channel 221C2.

Federal Communications Commission.

Steve Kaminer,

Deputy Chief, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 88-26463 Filed 11-15-88; 8:45 am]

BILLING CODE 6712-01-M

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47 CFR Part 73

[MM Docket No. 87-545; RM-6046, RM-6256, RM-6257]

Radio Broadcasting Services; Hereford and Littlefield, TX and Texico, NM

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document allots Channel 278C2 to Hereford, Texas, Channel 238A to Littlefield, Texas, and Channel 243A to Texico, New Mexico, at the request Don Werlinger, d/b/a The Broadcast Development Group, Inc., James E. Tucker and Paul Abalos, respectively. The communities of Littlefield and Texico could receive a first local FM service and Hereford could be provided with its second local FM service. The allotments can be made consistent with the Commission's minimum distance separation requirements at the city reference coordinates which are 34-49-18; 102-23-54 (Hereford, TX), 33-55-12; 102-19-54 (Littlefield, TX); and 34-23-30; 103-02-48 (Texico, NM). With this action, this proceeding is terminated.

DATES: Effective December 22, 1988; The window period for filing applications will open on December 23, 1988, and close on January 23, 1989.

FOR FURTHER INFORMATION CONTACT: Patricia Rawlings, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 87-545, adopted October 14, 1988, and released November 8, 1988. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, (202) 857-3800, 2100 M Street NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments is amended, by adding Channel 278C2 at Hereford, Texas; by adding Littlefield, Texas, Channel 238A;

and by adding Texico, New Mexico, Channel 243A.

Steve Kaminer,

Deputy Chief, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 88-26462 Filed 11-15-88; 8:45 am]

BILLING CODE 6712-01-M

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47 CFR Part 73

[MM Docket No. 87-443; RM-5968, RM-6208]

Radio Broadcasting Services; Dishman and Spokane, WA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document allots Channel 293A to Dishman, Washington, as that community's first FM service, at the request of Dishman Broadcasting. Also based on expressions of interest by P-N-P Broadcasting, Inc., and AliMar Communications, Inc., licensee of AM Station KRSS at Spokane, Washington, this document allots Channels 245A and 284A to Spokane, providing that community with its ninth and tenth local FM service. Channel 293A at Dishman requires a site restriction of 0.9 kilometer (0.6 mile) south of the city at coordinates 47-38-55 and 117-16-59. Channel 284A at Spokane requires a site restriction of 4.7 kilometers (2.9 miles) southwest of the city at coordinates 47-39-15 and 117-27-44. The reference coordinates at 47-40-18 and 117-24-18 can be used for Channel 245A at Spokane. In addition, the Canadian government has concurred. With this action, this proceeding is terminated.

DATES: Effective December 22, 1988; The window period for filing applications will open on December 23, 1988, and close on January 23, 1989.

FOR FURTHER INFORMATION CONTACT: Patricia Rawlings, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 87-443, adopted October 13, 1988, and released November 8, 1988. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, (202) 857-3800, 2100 M Street NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments is amended, under Washington, by adding Dishman, Channel 293A and by adding Channels 245A and 284A at Spokane.

Steve Kaminer,

Deputy Chief, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 88-26461 Filed 11-15-88; 8:45 am]

BILLING CODE 6712-01-M

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47 CFR Part 73

[MM Docket No. 88-167; RM-6125]

Radio Broadcasting Services; Staunton, VA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document substitutes Channel 232B1 for Channel 232A at Staunton, Virginia, and modifies the permit of Station WTON-FM to specify operation on the higher class co-channel, as requested by Ogden Broadcasting of Virginia, Inc. Staunton could receive its second wide coverage area FM service. A site restriction of 13.4 kilometers (8.3 miles) is required at coordinates 38-04-00 and 79-11-00. The upgrade must comply with § 73.1030(a) of the Commission's Rules. With this action, this proceeding is terminated.

EFFECTIVE DATE: December 22, 1988.

FOR FURTHER INFORMATION CONTACT: Patricia Rawlings, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 88-167, adopted October 12, 1988, and released November 8, 1988. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International transcription Service, (202) 857-3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio Broadcasting.

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments is amended, under Virginia, by removing Channel 232A and adding Channel 232B1 at Staunton.

Steve Kaminer,

Deputy Chief, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 88-26460 Filed 11-15-88; 8:45 am]

BILLING CODE 6712-01-M

INTERSTATE COMMERCE COMMISSION

49 CFR Part 1140

[Ex Parte No. 402]

Reasonably Expected Costs

AGENCY: Interstate Commerce Commission.

ACTION: Final rule.

SUMMARY: The Commission adopts a technical revision to its final rules governing the computation of reasonably expected costs in connection with light density line surcharges. Specifically, the revised rules would recognize income tax liabilities, if any, in the determination of the investment base used to compute the return on investment component of reasonably expected costs. This rule change is being implemented without notice and comment, since it has already been approved (but never implemented) in *Reasonably Expected Costs*, 1 I.C.C.2d 252 (1984) (Ex Parte No. 402).

EFFECTIVE DATE: The rules are effective December 16, 1988.

FOR FURTHER INFORMATION CONTACT: Ward L. Ginn, Jr., (202) 275-7489, [TDD for hearing impaired: (202) 275-1721].

SUPPLEMENTARY INFORMATION: The revised rules are set forth below.

Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to, call, or pickup in person from: Dynamic Concepts, Inc., Room 2229, Interstate Commerce Commission Building, Washington, DC 20423. Telephone: (202) 289-4357/4359. (Assistance for the hearing impaired is available through TDD services (202) 275-1721.)

The rule modifications will not have a significant economic impact on a substantial number of small entities. Nor will this action significantly affect either the quality of the human environment or energy conservation.

List of Subjects in 49 CFR Part 1140

Administrative practice and procedure, Railroads, Reporting and recordkeeping requirements, Uniform system of accounts, Abandonment and discontinuances, Investigations, Public use conditions, Environmental protection, National trail system, National resources, Recreation and recreation areas.

Decided: November 8, 1988.

By the Commission, Chairman Gradison, Vice Chairman Andre, Commissioners Simmons, Lamboley, and Phillips.

Noreta R. McGee,

Secretary.

Title 49, Subtitle B. Chapter X, Part 1140 of the Code of Federal Regulations is amended as follows:

PART 1140—REASONABLY EXPECTED COSTS UNDER 49 U.S.C. 10705a

1. The authority citation for 49 CFR Part 1140 is revised to read as follows:

Authority: 49 U.S.C. 10321, 11161, 11162, 11163, and 10705a; and 5 U.S.C. 559.

2. Section 1140.2 is amended by revising paragraph (b)(12)(i)(D) to read as follows:

§ 1140.2 Reasonably expected costs.

* * * * *

(b) * * *

(12) * * *

(i) * * *

(D) The amount of current income tax benefits the carrier could realize were it to abandon the line which would have been applicable to the period of the surcharge. (Conversely, if the railroad would incur an income tax liability from abandonment, the liability should be deducted from the investment base.) An average investment base value for the period of the surcharge shall be computed by the carrier by the method of its choice, provided that the method employed is reasonable and rational.

* * * * *

[FR Doc. 88-26319 Filed 11-15-88; 8:45 am]

BILLING CODE 7035-01-M

Proposed Rules

Federal Register
Vol. 53, No. 221
Wednesday, November 16, 1988

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.

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 1

Rule Amendments Concerning the Exchange of Futures for Cash Commodities or of Futures in Connection With Cash Commodity Transactions

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed rule amendments.

SUMMARY: The Commodity Futures Trading Commission proposes to amend its Regulation 1.35, 17 CFR 1.35, to require futures commission merchants ("FCMs"), introducing brokers ("IBs"), and other contract market members to obtain from their customers, and their customers to create, and to make available upon request of the Commission, the United States Department of Justice, or a contract market, documentation of cash transactions underlying exchanges of futures for cash commodities or exchanges of futures in connection with cash commodity transactions and to provide that documentation to the requesting body.[1] The Commission also proposes to amend Regulation 1.35 to require that all contract markets adopt, as necessary, corresponding rules requiring members to provide such documentation to the contract markets, the Commission, or the United States Department of Justice upon request.

DATE: Comments on the proposed amendments to Regulation 1.35 must be received on or before January 17, 1988.

ADDRESS: Comments should be sent to Jean A. Webb, Secretary of the Commission, Commodity Futures Trading Commission, 2033 K Street NW., Washington, DC 20581.

FOR FURTHER INFORMATION CONTACT: Patricia C. Apfelbaum, Special Counsel, or Elizabeth A. Patterson, Attorney-Advisor, Division of Trading and Markets, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581. Telephone: (202) 254-8955.

SUPPLEMENTARY INFORMATION:

I. Introduction

The legislative history of section 4c(a) reveals that the overall purpose of that section was to prohibit certain types of noncompetitive transactions that might facilitate fraud and manipulation.[2] The EFP exception to the section was added to preserve "a common and necessary practice" utilized by commercial market participants to facilitate basis trading, hedging, and the pricing of cash commodity transactions.[3] Section 4c(a) of the Commodity Exchange Act states in pertinent part that: [4]

> It shall be unlawful to offer to enter into, enter into or confirm the execution of, any transaction involving any commodity, * * * if [the] transaction is * * * a "wash sale", "cross trade", or "accommodation trade", or is a fictitious sale * * * or if [the] transaction is used to cause any price to be reported, registered, or recorded which is not a true and bona fide price.
>
> Nothing in this section shall be construed to prevent the exchange of futures in connection with cash commodity transactions or of futures for cash commodities, or of transfer trades or office trades if made in accordance with board of trade rules * * * approved by the Commission.

The Division of Trading and Markets ("Division") presented a report on EFPs to the Commission in October of 1987. In that report, the Division stated that the statutory exception for EFPs should be limited to bona fide transactions which strictly comply with the terms of section 4c(a) and exchange rules and which are not designed to accomplish some otherwise illegal purpose. At the same time, however, the Division stated that, subject to these requirements, the exception for EFPs contained in section 4c(a) should not be confined solely to those practices in existence at the time the statute was adopted. Rather, in the Division's view, permitting EFPs to accommodate the changing needs of market participants is consistent with the intent of Congress to preserve commercial transactions, so long as those transactions are in strict compliance with the requirements of section 4c(a) and exchange rules.[5] Under the Division's analysis, an evaluation of the bona fides of any EFP involves a determination of whether the cash transaction is consistent with commercial practices for other such transactions, independent of EFPs.[6] Accordingly, the Division concluded that the failure to conform to standard commercial practices may be an indication that the cash transaction, and thus the EFP, is not bona fide.

As a result of the importance of the cash transaction component of the EFP to the Division's analysis, the Division recommended the adoption of regulations specifically requiring disclosure of documentation of the cash

[1] These transactions are referred to in section 4c(a) of the Commodity Exchange Act ("Act"), 7 U.S.C. 6c(a) and Regulation 1.38(b), 17 CFR 1.38(b), as exchanges of futures for cash commodities or exchanges of futures in connection with cash commodity transactions, but are more commonly known as exchange of futures for physicals ("EFPs").

[2] *See* Amend the Grain Futures Act to Prevent and Remove Obstructions and Burdens Upon Interstate Commerce in Grain and Other Commodities by Regulating Transactions Therein on Commodity Futures Exchanges, To Limit or Abolish Short Selling, To Curb Manipulation, and for Other Purposes, S. Rep. No. 1431, 74th Cong., 1st Sess. 3 (1935).

[3] Commodity Short Selling, H.R. Rep. No. 1151, 72d Cong., 1st Sess. 3 (1932).

[4] Regulation 1.38(a) further provides: (a) *Competitive execution required; exceptions.* All purchases and sales of any commodity for future delivery, and of any commodity option, on or subject to the rules of a contract market shall be executed openly and competitively by open outcry or posting of bids and offers or by other equally open and competitive methods, in the trading pit or ring or similar place provided by the contract market, during the regular hours prescribed by the contract market for trading in such commodity or commodity option: *Provided, however,* That this requirement shall not apply to transactions which are executed noncompetitively in accordance with written rules of the contract market which have been submitted to and approved by the Commission, specifically providing for the noncompetitive executive or such transactions.

[5] In this connection, the Division set forth three requirements of all EFPs derived from section 4c(a). In general, the Division concluded that all EFPs (1) must consist of integrally related cash and futures transactions, (2) must provide for a transfer of ownership of the cash commodity to the cash buyer upon performance of the terms of the contract, with delivery to take place within a reasonable period of time thereafter, and (3) must be between separate parties to the EFP.

[6] It is the existence of a cash commodity transaction which distinguishes EFPs from other types of futures transactions. Accordingly, other indicia of EFP bona fides discussed in the report relate to the nature of the cash component, the pricing of the cash and futures legs of the EFP, the seller's ability to fulfill the obligation to deliver the commodity, and the buyer's acquisition of the commodity following the EFP.

portion of an EFP in order to ensure that the exchanges and the Commission have the means of assess fully the bona fides of such transactions and to monitor this limited exception to the prohibitions against noncompetitive trading. The Commission finds merit in this recommendation and therefore is proposing to amend Regulation 1.35 in order to ensure that records of the underlying cash transactions are fully accessible to the exchanges, the Commission, and the United States Department of Justice.

II. Recordkeeping Requirements Relating to EFPs

A. Current Rules

The present regulatory scheme broadly addresses the issue of EFP recordkeeping. Regulation 1.38(b) requires that:

> [e]very person handling, executing, clearing, or carrying trades, transactions or positions which are not competitively executed, including * * * trades involving the exchange of futures for cash commodities or the exchange of futures in connection with cash commodity transactions, shall identify and mark by appropriate symbol or designation all such transactions or contracts and all orders, records, and memoranda pertaining thereto.

Regulation 1.35(a) requires FCMs, IBs, and members of contract markets to "keep full, complete and systematic records, together with all pertinent data and memoranda, of all transactions relating to its business of dealing in commodity futures, commodity options, and cash commodities," and to retain such records and produce them upon request of the Commission or the United States Department of Justice. In addition, Regulation 1.35(e)(4) directs that each contract market maintain a record showing "by appropriate and uniform symbols, any transaction which is made noncompetitively in accordance with written rules of the contract market which have been submitted to and approved by the Commission in accordance with the provisions of [Regulation] 1.38." Further, Regulation 18.05, 17 CFR 18.05, provides that:

> [e]very trader who holds or controls a reportable futures position * * * shall keep books and records showing all details concerning all positions and transactions for future delivery in the commodity on all contract markets, * * * and all positions and transactions in the cash commodity, its products, and by-products and, in addition, commercial activities that the trader hedges in the commodity underlying the futures contract in which the trader is reportable,

and that the trader furnish information concerning the futures and cash commodity transactions to the Commission upon request.

Thus, under the Commission's current regulations, every person "handling, executing, clearing, or carrying" EFPs must identify those transactions and all related documents. Further, every FCM must keep systematic records of all transactions relating to its business of dealing in futures, options, or cash commodities, and each trader holding or controlling reportable futures positions ("large trader") must keep records of all futures and cash commodity positions and transactions. Finally, every contract market must maintain a record specifically noting all EFPs. Moreover, pursuant to sections 8 and 6(b) of the Act, 7 U.S.C. 12, 9, and Part 11 of the Commission's Regulations, 17 CFR Part 11, the Commission has access to a wide range documentation that may be relevant to matters under its jurisdiction.

The Commission believes that the availability of such documentation is essential to the success of exchange surveillance programs for monitoring EFPs and determining whether they are bona fide. It is equally necessary to the Commission's ability to monitor the effectiveness of the exchanges' surveillance programs with respect to EFPs and to the Commission's ability to review such trades in the course of routine trade practice surveillance or specific investigations. The present regulations, however, do not state specifically that customers who are not large traders must document cash transactions underlying EFPs. Further, they do not place responsibility for the collection of such documents on FCMs, IBs, and contract market members, nor do they provide the contract markets with express authority to request such documents. Accordingly, the Commission proposes to adopt rules intended to assure that specific documents evidencing cash transactions underlying EFPs are created and retained in accordance with cash market practices and that the contract markets and the Commission have an effective and efficient means of obtaining such documents upon request.

B. Proposed Rules

In light of the foregoing, the Commission proposes to amend Regulation 1.35 by adding a new paragraph (a–2), comprising subparagraphs (1), (2), (3), and (4), which relates to the production of documentation of cash transactions underlying EFPs.

1. *Proposed Subparagraph (a–2)(1)—Collection of customer Documentation by FCMs, IBs, and Members of Contract Markets*

The Commission proposes to add to Regulation 1.35 a new paragraph (A–2)(1) which would require that FCMs, IBs, and members of contract markets, upon request of the exchange, the Commission, or the United States Department of Justice, obtain from their customers and provide to the requesting body documentation of each transactions underlying exchanges of futures for physicals as such documentation is defined in proposed subparagraph (a–2)(4). The Commission believes that ready access to such documentation is necessary to the thorough evaluation of EFPs. The ability to obtain that documentation from customers will allow the contract markets to examine fully EFPs and to meet their self-regulatory duties under Commission Regulation 1.51, 17 CFR 1.51, to ensure the propriety of those transactions. The production of documents similarly will facilitate the Commission's task of monitoring the bona fides of EFPs.

2. *Proposed Subparagraph (a–2)(2)—Customer Production of Documentation Upon Reqeust*

Proposed subparagaph (a–2)(2) is designed to serve the same regulatory surveillance purposes as proposed subparagraph (a–2)(1). Proposed subparagaph (a–2)(2) would require all customers of FCMs, IBs, and contract market members to create, retain, and produce upon request of the FCM, the IB, the contract market member, the exchange, the Commission, or the United States Department of Justice documentation of the cash transactions underlying EFP transactions. Of course, a customer's inability to produce such documentation would create a strong inference that an EFP is not bona fide.[7]

The Commission believes that it would not be unreasonable or inappropriate to require customers, who are parties to the cash transactions and therefore have the best access to the requested documents, to produce those documents for examination. Without this corresponding duty upon all customers, FCMs, IBs, and contract market members may lack an enforceable means of fulfilling the regulatory requirement of proposed subparagraph (a–2)(1) and instead would be forced to rely on voluntary customer cooperation for access to documents. The Commission believes that the proposal as a whole would afford an appropriate division of responsibility for document retention, collection, and production between

FCMs, IBs, contract market members, and their customers.

3. *Proposed Subparagraph (a-2)(3)—Requirement that Contract Markets Adopt Rules Pertaining to Document Production*

The Commission further proposes to add a new subparagraph (a-2)(3), which requires each contract market to adopt rules mandating that its members produce documentation of cash transactions underlying EFPs. Proposed subparagraph (a-2)(3) would provide contract markets with an enforceable right to demand the production of the documentation maintained in response to proposed subparagraphs (a-2)(1) and (a-2)(2) in furtherance of their self-regulatory responsibilities.

4. *Proposed Subparagraph (a-2)(4)—Definition of "documentation"*

The Commission finally proposes to add a new subparagraph (a-2)(4) which sets forth a definition of the term "documentation" as it is used in proposed paragraph (a-2). The proposed definition states that such documentation consists of those documents "customarily generated in accordance with cash market practices which demonstrate the existence and nature of the cash transactions, including, but not limited to, contracts, confirmation statements, telex printouts, invoices, and warehouse receipts or other documents of title."

C. Limited Additional Recordkeeping Burden Imposed by Proposed Recordkeeping Rules

The proposed amendment to Regulation 1.35 are intended to assure that the documentation necessary to effective investigation of EFPs is available to the exchanges and to the Commission, without imposing burdensome additional recordkeeping requirements on markets or market participants. It is important to note that FCMs and members of contract markets must keep records "of all transactions relating to its business of dealing in commodity options, and cash commodities." Moreover, FCMs and members are frequently parties to one or both sides of an EFP transaction. Thus, where an EFP relates to an FCM's or contract market member's business of dealing in futures or cash commodities, the proposed amendments would not impose additional recordkeeping obligations on those entities not already required by Regulation 1.35(a). Further, IBs, who normally would not be parties to cash transactions, would not be required to maintain records of transactions for customers, but only to obtain and produce them upon request. The Commission believes therefore that the proposed amendments would impose upon FCMs, IBs, and contract market members only the minimum requirements necessary to assure effective monitoring of EFPs by the exchanges and the Commission.

Further, the amendments would require customers to produce documents which should be readily accessible. In this regard, customers who maintain documents in accordance with accepted cash market practices should be able to comply with proposed subparagraph (a-2)(2). Moreover, customers who are large traders already must maintain and produce upon request the required documentation in accordance with Regulation 18.05. Thus, the proposed amendments will not impose a significant burden on these entities.

Finally, several of the exchanges presently require that their members maintain full and complete records of EFP transactions, including cash transactions, and that members provide those records to the exchange upon request.[8] The proposed Commission rule, however, will encourage consistent treatment of similar transactions by all exchanges. Of course, regardless whether exchanges now or in the future have such rules, exchanges may continue to request voluntary cooperation from market participants under existing programs relating to the exchange responsibility to monitor trading.

In addressing these proposals, commenters are encouraged to direct their comments particularly to the likely effectiveness of the amendments in achieving the Commissions stated goals.

IV. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA"), 5 U.S.C. 601 *et seq.*, requires that agencies, in proposing rules, consider the impact of the rules on small businesses. The Regulation 1.35 amendments proposed here would affect contract markets, FCMs, IBs, contract market members, and the customers of FCMs, IBs, and contract market members. The Commission previously has determined that contract markets are not "small entities" for the purposes of the RFA, and that the Commission need not, therefore, consider the effect of proposed amendments on contract markets in relation to the RFA. 47 FR 18618, 18619, April 30, 1982. The Commission has also determined that FCMs should be excluded from the definition of "small entity" based upon the fiduciary nature of the FCM/customer relationships as well as the fact that FCMs must meet minimum financial requirements. 47 FR 18618, 18619, April 30, 1982.

With respect to IBs, the Commission has stated that it is appropriate to evaluate within the context of a particular rule proposal whether some or all IBs should be considered small entities and, if so, to analyze the economic impact on such entities at that time. 48 FR 35248, 35275-78, August 3, 1983. Proposed Regulation 1.35(a-2) will have little effect on IBs, regardless of size. Pursuant to existing Commission Regulation 1.57, 17 CFR 1.57, IBs will never handle customer EFPs independently. Regulation 1.57 requires that IBs open and carry customer accounts with FCMs and that they transmit customer orders to FCMs. Given this fact, the FCMs, not the IBs, would have primary responsibility for customer document collection. As a practical matter, an IB would be approached for customer documents only if an FCM failed in its document production duty. Thus, IBs of any size should not be significantly burdened by the proposed rules.

Like IBs, non-FCM members seldom will be called upon to produce documentation of customer EFPs. Non-FCM members generally transact EFPs for their own accounts. In those instances where non-FCM members may act as brokers to arrange EFPs between customers, those members will handle both the cash and the futures portions of the trade and will be acting as IBs. In some circumstances, however, the member may act as broker between customers only as to a cash transaction, which becomes part of an EFP cleared through an FCM. In such cases, which are likely to occur infrequently, the member only will be approached for the cash documentation if the FCM clearing the EFP fails to fulfill its document production duty. Therefore, the proposed rules should not place a significant burden on non-FCM members of any size.

Finally, the Commission does not believe that proposed Regulation 1.35(a-2) significantly will affect customers of FCMs, IBs, or exchange members that

[7] The Commission understands that commercial practices in the markets in which EFPs are transacted contemplate that some documentation of the cash transaction will be created.

[8] New York Mercantile Exchange ("NYMEX") Rule 6.12 requires that each seller and buyer satisfy the Exchange that the EFP is bona fide, and provides that clearing members shall obtain all documentation related to the EFP and make that documentation available at the Exchange's request. NYMEX also affirmatively requires that each clearing member routinely submit documentation of the cash transfer for every EFP. Chicago Mercantile Exchange Rule 538 requires that clearing members and brokers handling EFPs maintain full and clear records of the transactions along with all pertinent memoranda. The Chicago Board of Trade's Rule 444.01 is similar, as is Commodity Exchange, Inc. Rule 4.36.

are also small businesses. For most EFPs, an FCM or contract market member will take the opposite side of a customer transaction and thus will be required to create and retain documentation and to report those transactions under existing Regulation 1.35(a). For most EFPs, then, the participation FCM or contract market member will be the primary source for documentation of cash transactions. Generally, only in those instances when two customers trade opposite one another would the customers be the originators of documentation of a cash transaction, although they must create and retain such documents for every transaction.

In most markets, customers using EFPs generally will be large entities such as commercial market participants (producers, users, etc.), trade houses, institutions, banks, pension funds, and dealers. Although EFP users in the currency and metals markets are also primarily large entitites (i.e., banks, bullion dealers, etc.), some participants, although not a substantial number—particularly professional traders, small trade houses, small corporations and other businesses—may be "small entitites." To the extent that any small entities do fall within the purview of the proposed Regulation 1.35(a–2), the recordkeeping required of those entities will be relatively minor. First, the proposed rules require only that customers create, retain, and produce those documents customarily generated in accordance with cash market practices.[9] Customers presumably create and retain these documents in the normal course of business for general business, financial, and tax reasons. Second, the proposed rules do not require that customers make routine submissions. The records of only a small number of transactions will be requested annually so the temporal and monetary impacts of document production on any single small entity should be minimal.

Accordingly, pursuant to section 3(a) of the Regulatory Flexibility Act, Pub. L. 96–354, 94 Stat. 1168 (5 U.S.C. 605(b)), the Chairman, on behalf of the Commission, certifies that this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. However, the Commission particularly invites comment from any small firms which believe that promulgation of these rules will have a significant economic impact on them.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1980 ("PRA"), 44 U.S.C. 3501, *et seq.*, imposes certain requirements on federal agencies, including the Commission, in connection with their conducting or sponsoring any collection of information as defined by the PRA. In compliance with the PRA, the Commission has submitted the proposed Regulation 1.35(a–2), along with the associated information collection requirements, to the Director of the Office of Management and Budget. Further, pursuant to the Office of Management and Budget's Regulation 1320.15(a), 5 CFR 1320.15(a), the Commission has set forth in the following paragraph a summary of the public reporting burden related to the proposed amendments.

The public reporting burden for this collection of information is estimated to average one-half hour per response for each of the 96 FCMs, IBs, or contract market members expected to be required to collect documents from customers during a year. This estimate includes time to request, obtain, organize, and provide documents to the Commission or the exchange. Each of the estimated 96 customers asked to provide documentation annually will spend an estimated one hour per response in locating, photocopying, and providing requested documents to an FCM, IB, contract market member, contract market, the Commission, or the United States Department of Justice. Finally, each customer will be required to maintain documentation of cash transactions underlying EFPs in order to comply with this reporting requirement. Each of the 1700 customers transacting EFPs at reportable levels is expected to spend an average of two hours refining a large trader report document filing system and two hours actually filing documents in it during the course of a year. The estimated 570 other customers who would be required to maintain documents under proposed Regulation 1.35(a–2) are expected to devote an average of six hours to developing a filing system and two hours to filing documents annually. The total annual public burden related to proposed Regulation 1.35(a–2) is estimated to be 11,504 hours. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Joseph G. Salazar, CFTC Clearance Officer, 2033 K Street, NW., Washington, DC 20581; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

List of Subjects in 17 CFR Part 1

Commodity futures, Commodity options, Contract markets, Customers, Exchanges of futures for physicals, Futures commission merchants, Introducing brokers, Members of contract markets, Noncompetitive trading, Reporting and recordkeeping requirements.

In consideration of the foregoing, and pursuant to the authority contained in the Commodity Exchange Act and, in particular, Sections 4, 4c, 4g, 5, 5a, 8, and 8a therefore, 7 U.S.C. 6, 6c, 6g, 7, 7a, 12, and 12a, the Commission hereby proposes to amend Chapter I of Title 17 of the Code of Federal Regulations as follows:

PART 1—GENERAL REGULATIONS UNDER THE COMMODITY EXCHANGE ACT

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

Authority: 7 U.S.C. 2, 2a, 4, 4a, 6, 6a, 6b, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6j, 6k, 6l, 6m, 6n, 6o, 7, 7a, 8, 9, 12, 12a, 12c, 13a, 13a–1, 16, 19, 21, 23, and 24, unless otherwise stated.

2. Regulation 1.35 is proposed to be amended by adding paragraph (a–2) to read as follows:

§ 1.35 Records of cash commodity, futures, and option transactions.

(a–2)(1) *Futures commission merchants, introducing brokers, and members of contract markets.* Upon request of the contract market, the Commission, or the United States Department of Justice, each futures commission merchant, introducing broker, and member of a contract market shall obtain from its customers and provide to the requesting body documentation of cash transactions underlying exchanges of futures for cash commodities or exchange of futures in connection with cash commodity transactions.

(2) *Customers.* Each customer of a futures commission merchant, introducing broker, or member of a contract market shall create, retain, and produce upon request of the futures commission merchant, the introducing broker, the contract market member, the contract market, the Commission, or the United States Department of Justice documentation of cash transactions

[9] The proposed document retention would fall within the five-year retention requirement of Commission Regulation 1.31(a), 17 CFR 1.31(a). Regulation 1.31(a) provides that all books and records required to be kept by the Act or by these regulations shall be kept for a period of five years from the date thereof and shall be readily accessible during the first 2 years of the 5-year period. All such books and records shall be open to inspection by any representative of the Commission or the U.S. Department of Justice.

underlying exchanges of futures for cash commodities or exchanges of futures in connection with cash commodity transactions.

(3) *Contract markets.* Every contract market shall adopt rules with require its members to provide documentation of cash transactions underlying exchanges of futures for cash commodities or exchanges of futures in connection with cash commodity transactions upon request of the contract market.

(4) *Documentation.* For the purposes of this paragraph, documentation means those documents customarily generated in accordance with cash market practices which demonstrate the existence and nature of the underlying cash transactions, including, but not limited to, contracts, confirmation statements, telex printouts, invoices, and warehouse receipts or other documents of title.

* * * * *

Issued in Washington, DC on November 9, 1988 by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 88-26474 Filed 11-15-88; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 655

Labor Certification Process for the Temporary Employment of Aliens in Agriculture in the United States; Adverse Effect Wage Rate Methodology; Correction

AGENCY: Employment and Training Administration, Labor.

ACTION: Proposed rule; correction.

SUMMARY: The Department of Labor is correcting an error in the preamble of the proposed rule for the adverse effect wage rate methodology for the temporary alien agricultural labor certification (H-2A) program. The proposed rule appeared in the Federal Register on October 28, 1988 (53 FR 43722).

FOR FURTHER INFORMATION CONTACT: Mr. Thomas M. Bruening; Telephone: 202-535-0163 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department of Labor has published a proposed rule for the adverse effect wage rate methodology for the temporary alien agricultural labor certification (H-2A) program. The proposed rule appeared in the Federal Register on October 28, 1988 (53 FR 43722). The proposed rule contained an error, which is discussed briefly below and is corrected by this document.

Dated: November 10, 1988.

Ann McLaughlin,

Secretary of Labor.

The following correction is made in the preamble to the proposed rule for the adverse effect wage rate methodology for the labor certification process for the temporary employment of aliens in agriculture in the United States (H-2A program), published in the Federal Register at 53 FR 43722 (FR Doc. 88-24954), on October 28, 1988.

In the third full paragraph in the first column on page 43723, the following words shall be deleted, "That court recently rules [*sic*] that the new explanation was unaccepted because it was based, in part, on information not in the rule-making record on June 1. While the DOL disagrees with the ruling and continues to litigate that issue,".

For an additional correction to this document see the Corrections section of this issue.

[FR Doc. 88-26409 Filed 11-15-88; 8:45 am]

BILLING CODE 4510-30-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL-3475-9]

Approval and Promulgation of Implementation Plans; Illinois

AGENCY: U.S. Environmental Protection Agency (USEPA).

ACTION: Proposed rulemaking.

SUMMARY: USEPA proposes to disapprove a revision to the Illinois State Implementation Plan (SIP) for ozone. The revision provides an alternative compliance schedule for Printpack, Incorporated (Printpack) which is located in Elgin, Illinois. This SIP revision would allow Printpack additional time to reformulate to low-solvent adhesives for its adhesive laminating equipment.

USEPA today is proposing to disapprove this SIP revision because the requested compliance date extension is inconsistent with relevant portions of the Clean Air Act and USEPA policy.

DATE: Comments on this revision and on the proposed USEPA action must be received by December 16, 1988.

ADDRESSES: Copies of the SIP revision are available at the following addresses for review: (It is recommended that you telephone Uylaine E. McMahan, at (312) 886-6031, before visiting the Region V office.):

U.S. Environmental Protection Agency, Region V, Air and Radiation Branch, 230 South Dearborn Street, Chicago, Illinois 60604.

Illinois Environmental Protection Agency, Division of Air Pollution Control, 2200 Churchill Road, Springfield, Illinois 62706.

Comments on this proposed rule should be addressed to: (Please submit an original and three copies, if possible.) Gary Gulezian, Chief, Regulatory Analysis Section, Air and Radiation Branch (5AR-26), U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinois 60604.

FOR FURTHER INFORMATION PLEASE CONTACT: Uylaine E. McMahan, (312) 886-6031.

SUPPLEMENTARY INFORMATION:

Background

On November 21, 1983, the Illinois Environmental Protection Agency (IEPA) submitted a proposed revision to its ozone SIP for Printpack. This SIP revision is in the form of a February 5, 1981, Opinion and Order of the Illinois Pollution Control Board (IPCB) PCB 80-148. It grants a variance from the existing SIP requirements until December 31, 1985, and provides a legally enforceable compliance schedule.

Under the existing federally approved SIP, Printpack's paper coating operation is subject to the 2.9 pounds of VOC per gallon emission limitation contained in IPCB Rule 205(n)(1)(C) of Chapter 2: Air Pollution of the IPCB Rules and Regulations. Final compliance is required by December 31, 1982.

In lieu of the compliance date contained in the federally approved SIP, the State is proposing an extended compliance schedule for Printpack.

Printpack manufactures flexible packaging for use primarily by the food industry. Printpack is located in the Northeastern Illinois urban ozone nonattainment area, which has obtained an extension to December 31, 1987, to attain the ozone national ambient air quality standard. USEPA may approve compliance date extensions for sources in such areas, if the State demonstrates that the extension is as expeditious as practicable and will not prevent the area from attaining the ozone standard as expeditiously as practicable, but no later than the end of 1987.

On August 15, 1984, the IEPA submitted Printpack's documentation of its efforts to convert to low-solvent adhesives. Additional information was

submitted by Printpack on November 7, 1984. This documentation included:

1. Internal research and development reports which cover the period from January 1979 to January 1984, which describe Printpack's continuing efforts and progress in developing low solvent adhesives;

2. Reports which describe numerous trials to develop low-solvent adhesives;

3. A description of the company's correspondence with numerous suppliers of adhesives coatings; and

4. Information demonstrating progress made by the company in substantially reducing VOC emissions between 1981 and 1984, as a result of their research and development efforts.

This documentation does not satisfy the Clean Air Act and USEPA's policy on compliance date extensions. In particular, the State has not adequately researched the compliance status of other similar sources to determine if compliance by the original deadline was reasonable.

In the March 20, 1984, **Federal Register** (49 FR 10277), USEPA proposed to disapprove this proposed SIP revision because the Illinois Ozone SIP lacked an approved attainment demonstration for the Chicago nonattainment area. Since the publication of the March 20, 1984, Notice of Proposed Rulemaking, IEPA has submitted a revised ozone attainment demonstration which USEPA proposed to approve on August 15, 1984 (49 FR 32601). However, USEPA recently proposed to disapprove the State attainment demonstration (52 FR 26404), July 14, 1987). For this reason USEPA believes that the State has not adequately demonstrated that this extension will not interfere with timely attainment of the ozone standard and RFP in the intermin.

Proposed Actions

USEPA is proposing that Printpack's schedule to achieve final compliance by December 31, 1985, is not approvable because it does not conform with the requirements of the Clean Air Act and policy on compliance schedules. First, the State has not shown that the requested compliance date is as expeditious as practicable. In addition, this source is located in the Chicago nonattainment area which lacks an approved attainment demonstration. A more detailed discussion of the rationale for proposing disapproval of the State submission and of the Clean Air Act and USEPA policy related to compliance date extensions appears in Appendix A of the proposed rulemaking published on November 8, 1988 at 53 FR 45103.

USEPA is providing a 30-day comment period on this notice of supplemental proposed rulemaking. Public comments received on or before December 16, 1988, will be considered in USEPA's final rulemaking. All comments will be available for inspection during normal business hours at the Region V office at the front of this notice.

Under 5 U.S.C. 605(b), the Administrator has certified that SIP approvals do not have a significant economic impact on a substantial number of small entities because it applies only to Printpack.

Under Executive Order 12291, today's action is not "Major". It has been submitted to the Office of Management and Budget (OMB) for review.

Authority: 42 U.S.C. 7401–7642.

Dated: March 31, 1987.

Robert Springer,

Acting Regional Administrator.

Editorial Note: This document was received by the Office of the Federal Register, November 10, 1988.

[FR Doc. 88–26424 Filed 11–15–88; 8:45 am]

BILLING CODE 6560–50–M

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40 CFR Part 52

[FRL 3475–8]

Approval and Promulgation of Implementation Plans; Ohio

AGENCY: U.S. Environmental Protection Agency (USEPA).

ACTION: Proposed rulemaking.

SUMMARY: USEPA announces proposed rulemaking to disapprove a site-specific State Implementation Plan (SIP) revision to the ozone portion of the Ohio SIP. This SIP revision would allow the ATEC Industries, Incorporated (ATEC) architectural aluminum extrusion coating line (KOO1) in Mahoning County, Ohio to meet the volatile organic compounds (VOC) limitation of 3.5 pounds of VOC per gallon of coating, minus water (3.5 lbs of VOC/gal), as required by Ohio Administrative Code (OAC) 3745–21–09 (U)(1)(a)(iii), on a monthly volume-weighted average in lieu of the daily volume-weighted average reqired by OAC Rule 3745–21–09 (B). USEPA's action is based upon one revision request and several amendments that were submitted by the State.

USEPA is proposing to disapprove this revision because the State did not demonstrate that it is infeasible to use add on controls to comply with the reasonably available control technology (RACT) emission limit on a daily basis and that an averaging period shorter than 1 month is not practicable.

DATE: Comments on this revision and on the proposed USEPA action must be received by December 16, 1988.

ADDRESSES: Copies of the SIP revision are available at the following addresses for review: (It is recommended that you telephone Uylaine E. McMahan, at (312) 886–6031, before visiting the Region V office.)

U.S. Environmental Protection Agency, Region V, Air and Radiation Branch, 230 South Dearborn Street, Chicago, Illinois 60604.

Ohio Environmental Protection Agency, Office of Air Pollution Control, 361 East Broad Street, Columbus, Ohio 43216.

Coments on this proposed rule should be addressed to: (Please submit an original and three copies, if possible.) Gary Gulezian, Chief, Regulatory Analysis Section, Air and Radiation Branch (5AR–26), U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Uylaine E. McMahan, (312) 886–6031.

SUPPLEMENTARY INFORMATION: On June 17, 1985, July 30, 1985, and October 25, 1985, the Ohio Environmental Protection Aency (OEPA) submitted a revision request, with several amendments to its ozone SIP for ATEC. This revision consists of (1) a monthly volume-weighted average limitation (3.5 lbs. of VOC/gal), and (2) a never-to-be-exceeded (5.5 lbs of VOC/gal for any coating used) limit for an architectural aluminum extrusion coating line (KOO1) located at ATEC in Mahoning County, Ohio, which is an urban nonattainment area for the national ambient air quality standard (NAAQS) ozone. OEPA also submitted a request to revise the attainment status designation for Mahoning County from nonattainment to attainment for the ozone NAAQS. This redesignation request is under USEPA's review, and USEPA will propose action on it in the near future.

Under the existing federally approved SIP, each architectural aluminum extrusion coating line is subject to the VOC limitation containe din OAC Rule 3745–21–09 (U)(1)(iii) [3.5 lbs of VOC/gal] and is subject to the daily volume-weighted average compliance requirements contained in OAC Rule 3745–21–09 (B). USEPA approved these rules as meeting the RACT requirements of the Clean Air Act on October 31, 1980 (45 FR 72122), and June 29, 1982 (47 FR 28097).

In lieu of the daily volume-weighted average limitation required by the SIP, the State is proposing that the coatings used in this line (KOO1), which applies

a wide variety of coatings to various types of architectural aluminum extrusions, shall not exceed 3.5 lbs of VOC/gal as a monthly volume-weighted average, and 5.5 lbs of VOC/gal for any coating used.

USEPA's January 20, 1984, policy memorandum entitled "Averaging Times for Compliance with VOC Emission Limits" contains the criteria for evaluating VOC requests for extended averaging which are as follows:

Criterion 1

Extended averaging can be permitted where the source operations are such that daily VOC emissions cannot be determined, or where the application of RACT for each emission point is not economically or technically feasible on a daily basis.

The first point is not an issue is this case because ATEC has never claimed that it is not possible to determine daily emissions. As to the second point, control could be obtained either from the use of complying low solvent coatings or by add-on controls. OEPA submitted documentation from two coating suppliers to demonstrate that complying aluminum coatings are not currently available. However, USEPA believes this information is inconclusive.

OEPA believes that add-on control is not economically reasonable for this source because the cost per ton of controlling the noncomplying coatings (which exceed the SIP allowable by less than 10 tons of VOC per year) would be excessive. In particular, OEPA noted that (1) only about 20 percent of the paints being used exceed 3.5 lbs of VOC/gal and, therefore, add-on controls would not be needed for most operations, (2) less than 20 percent of the VOC emissions are emitted from the paint bake oven, and control equipment on the oven would not bring ATEC into compliance on a daily basis, and (3) control of the spray booth emissions would require a change in the parts loading area to enclose the spray area. Additionally, control of the spray booth emissions would also require a large volume of air to be treated due to the large size of parts being painted. However, OEPA has not provided any documentation of the costs for add-on control for this source.

If the State demonstrates conclusively that complying low-solvent coatings are unavailable, then the USEPA would consider an alternative RACT determination for the existing coatings. USEPA is proposing to disapprove this revision because such a demonstration has not been submitted.

A detailed discussion on the extent of such an investigation is contained in Appendix A of the proposed rulemaking published on November 9, 1988 at 53 FR 45285.

Criterion 2

The area must not lack an approved SIP and there must not be any measured violations of the ozone standard.

ATEC is located in Mahoning County, which has an approved 1979 ozone SIP and has had no measured violations of the ozone NAAQS from 1982 through 1985. Therefore, this SIP revision request is consistent with this criterion.

Criterion 3

A demonstration must be made that the use of monthly averaging (greater than 24-hour averaging) will not jeopardize either ambient standards attainment or the reasonable further progress (RFP) plan for the area. This must be accomplished by showing that the maximum daily increase in emissions associated with monthly averaging is consistent with the approved ozone SIP for the area.

OEPA has demonstrated that the growth margin for the Youngstown area is able to accommodate the maximum daily increase in emissions caused by this revision.

Criterion 4

Averaging times must be as short as practicable and in no case longer than 30 days.

OEPA did not submit an adequate demonstration that it is not feasible for ATEC to meet the proposed limit using a shorter averaging period (e.g., 7 days or 15 days).

USEPA has reviewed this variance and has determined that it does not meet all of USEPA's criteria for monthly averaging. Therefore, USEPA is proposing disapproval of this variance.

USEPA is providing a 30-day comment period on this notice of proposed rulemaking. Public comments received on or before December 16, 1988, will be considered in USEPA's final rulemaking. All comments will be available for inspection during normal business hours at the Region V office listed at the front of this notice.

Under 5 U.S.C. 605(b), I certify that this SIP revision, if disapproved, will not have a significant economic impact on a substantial number of small entities because it applies to only one source, ATEC, and does not impose any new requirement on this source.

Under Executive Order 12291, this action is not "Major". It has been submitted to the Office of Management and Budget (OMB) for review.

Authority: 42 U.S.C. 7401–7642.

Dated: March 31, 1987.

Valdas V. Adamkus,

Regional Administrator.

Editorial Note: This document was received by the Office of the Federal Register November 10, 1988.

[FR Doc. 88-26425 Filed 11-15-88; 8:45am]

BILLING CODE 6560-50-M

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40 CFR Part 52

[FRL-3476-1]

Approval and Promulgation of Implementation Plans; Ohio

AGENCY: U.S. Environmental Protection Agency (USEPA).

ACTION: Proposed rulemaking.

SUMMARY: USEPA is proposing to disapprove a site-specific revision to the Ohio State Implementation Plan (SIP) for ozone. This revision is a request for monthly averaging for volatile organic compound (VOC) emissions for an architectural aluminum extrusion coating line (K001) at Astro Shapes, Incorporated (Astro Shapes). This facility is located in Mahoning County, Ohio.

USEPA is proposing to disapprove this SIP revision, because it has not been demonstrated that (1) complying coatings are unavailable, (2) that the increase in daily emissions are consistent with the SIP for Youngstown, and (3) that the application of reasonably available control technology (RACT) is infeasible on a less than monthly basis.

DATE: Comments on this revision and on the proposed USEPA action must be received by December 16, 1988.

ADDRESSES: Copies of the SIP revision are available at the following addresses for review: (It is recommended that you telephone Uylaine E. McMahan, at (312) 886-6031, before visiting the Region V Office.

U.S. Environmental Protection Agency, Regional V, Air and Radiation Branch, 230 South Dearborn Street, Chicago, Illinois 60604.

Ohio Environmental Protection Agency, Office of Air Pollution Control, 361 East Broad Street, Columbus, Ohio 43216.

Comments on this proposed rule should be addressed to: (Please submit an original and three copies, if possible) Gary Gulezian, Chief, Regulatory Analysis Section, Air and Radiation Branch (5AR-26), U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Uylaine E. McMahan, Air and Radiation Branch (5AR-26), U.S. Environmental Protection Agency, Region V, Chicago, Illinois 60604, (312) 886-6031.

SUPPLEMENTARY INFORMATION: On May 15, 1986, the Environmental Protection Agency (OEPA) submitted a proposed revision to its ozone SIP, allowing monthly averaging for an architectural aluminum extrusion coating line (K001). This operation is located at the Astro Shapes facility in Mahoning County,[1] Ohio, a nonattainment area for ozone.

On July 17, 1986, USEPA notified OEPA that the May 15, 1986, submittal requesting a monthly average for Astro Shapes was deficient, as stated in USEPA's technical support document (TSD) dated July 2, 1986. OEPA submitted supplemental information on August 28, 1986, to support this revision.

Existing SIP Requirements

Under the existing federally approved SIP, the architectural aluminum extrusion coating line (K001) is subject to the control requirements contained in Ohio Administrative Code (OAC) Rule 3745-21-09(U)(1)(a)(iii), which limits the VOC content of extreme performance coatings to 3.5 pounds of VOC per gallon of coating, minus water. OAC Rule 3745-21-04(C)(28) requires compliance with the limit by December 31, 1982. Compliance is to be determined on a 24-hour basis. USEPA approved these rules as meeting the RACT [2] requirement of the Clean Air Act on October 31, 1980 (45 FR 72122), and June 29, 1982 (47 FR 28097).

Extended Averaging Time Criteria

USEPA's January 20, 1984, policy memorandum, entitled "Averaging Times for Compliance With VOC Emission Limits", contains the following criteria for evaluating VOC requests for extended averaging:

Criterion 1

Extended averaging can be permitted where the source operations are such that daily VOC emissions cannot be determined, or where the application of RACT for each emission point is not economically or technically feasible on a daily basis.

Criterion 2

Sources in areas lacking approved SIP's or in areas with approved SIP's but showing measured violations, cannot be considered for longer term averages until the SIP has been revised documenting ambient standards attainment and maintenance of reasonable further progress (RFP) (reflecting the maximum daily emissions from the source with long-term averaging).

Criterion 3

A demonstration must be made that the use of long-term averaging (greater than 24-hour averaging) will not jeopardize either ambient standards attainment or the RFP plan for the area. This must be accomplished by showing that the maximum daily increase in emissions associated with monthly averaging is consistent with the approved ozone SIP.

Criterion 4

Averaging times must be short as practicable, and in no case longer than 30 days.

Analysis

For monthly averaging to be approved, it must be demonstrated that it is infeasible to meet a daily VOC RACT emission limit, e.g., through the use of add-on control or low solvent technology. If the State demonstrates conclusively that complying low-solvent coatings are available, then the USEPA would consider an alternative RACT determination for the existing coatings. In addition, it must be demonstrated that a monthly averaging period is the shortest period that is practicable and that the increase in daily emissions is consistent with the SIP. OEPA has demonstrated that add-on controls for this source would be economically unreasonable, but it has not been demonstrated that the source has completely analyzed the possibility of low solvent coatings.

A detailed discussion of the extent of such an analysis appears in Appendix A of the proposed rulemaking published on November 9, 1988 at 53 FR 45285.

Further, it has not been demonstrated that the application of RACT is infeasible on a less than monthly basis, and that the maximum increase in daily emissions associated with monthly averaging is consistent with the approved SIP for the Youngstown area. USEPA is proposing to disapprove this SIP revision for these reasons.

USEPA is providing a 30-day comment period on this notice of proposed rulemaking. Public comments received on or before December 16, 1988, will be considered in USEPA's final rulemaking. All comments will be available for inspection during normal business hours at the Region V Office address provided at the front of this notice.

Under 5 U.S.C. 605(b), I certify that this SIP disapproval will not have a significant economic impact on a substantial number of small entities, because the effect of this disapproval is to leave in effect existing emission limitations. Therefore, there is no change or any impact on any source or community. Additionally, it applies to only one corporation, Astro Shapes.

Under Executive Order 12291, this action is not "Major". It has been submitted to the Office of Management and Budget (OMB) for review.

Authority: 42 U.S.C. 7401-7642.

Dated: February 10, 1987.

Valdas V. Adamkus,

Regional Administrator.

Editorial Note: This document was received by the Office of the Federal Register November 10, 1988.

[FR Doc. 88-26426 Filed 11-15-88; 8:45 am]

BILLING CODE 6560-50-M

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40 CFR Part 52

[FRL-3477-1]

Approval and Promulgation of Implementation Plans; Ohio

AGENCY: U.S. Environmental Protection Agency (USEPA).

ACTION: Proposed rulemaking.

SUMMARY: USEPA is proposing to disapprove a site-specific revision to the Ohio State Implementation Plan (SIP) for ozone. This revision is a relaxation of reasonably available control technology (RACT) for volatile organic compounds (VOC) involving the Paper Products Company (PPC) roll coating line. This facility is located in Hamilton County, Ohio, an area designated as nonattainment for ozone.

USEAP is today proposing to disapprove this SIP because (1) it has not been demonstrated that it is technically or economically infeasible for PPC to meet the RACT limit, and (2) the State has not shown that this variance is consistent with an approvable attainment demonstration for the Cincinnati area.

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[1] OEPA submitted a request to revise the attainment status designation, at 40 CFR 81.336, for Mahoning County for nonattainment to attainment for the ozone national ambient air quality standard (NAAQS). Mahoning County, at this time, is designated a nonattainment area. However, there have been no measured violations of the ozone NAAQs from 1982 through 1985.

[2] A definition of RACT is contained in a December 9, 1976, memorandum from Roger Strelow, former Assistant Administrator for Air and Waste Management. RACT is defiend as the lowest emission limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility.

DATE: Comments on this revision and on the proposed USEPA action must be received by December 16, 1988.

ADDRESSES: Copies of the SIP revision are available at the following addresses for review: (It is recommended that you telephone Uylaine E. McMahan, at (312) 886-6031, before visiting the Region V office.)

U.S. Environmental Protection Agency, Region V, Air and Radiation Branch, 230 South Dearborn Street, Chicago, Illinois 60604.

Ohio Environmental Protection Agency, Office of Air Pollution Control, 361 East Broad Street, Columbus, Ohio 43216.

Comments on this proposed rule should be addressed to: (Please submit an original and three copies, if possible.) Gary Gulezian, Chief, Regulatory Analysis Section, Air and Radiation Branch (5AR-26), U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Uylaine E. McMahan, Air and Radiation Branch (5AR-26), U.S. Environmental Protection Agency, Region V, Chicago, Illinois 60604, (312) 886-6031.

SUPPLEMENTARY INFORMATION: On July 16, 1986, the Ohio Environmental Protection Agency (OEPA) submitted a proposed relaxation of RACT for a roll coating line at PPC, located in Hamilton County, Ohio. The roll coating line produces paperboard used in the food industry. The proposed relaxation of RACT includes the following conditions:

1. The source shall not apply more than 10 gallons of coatings in any one day.
2. PPC must keep monthly records for all coating material used by the source.
3. PPC must submit annual reports on source emissions.

The variance contains no limits on emissions or emission rates.

On October 2, 1986, USEPA notified that the July 16, 1986, submittal was deficient (see USEPA's September 15, 1986, technical support document (TSD)). The OEPA has not responded to USEPA's October 2, 1986, letter.

Current VOC SIP

Under the existing federally approved SIP, each roll coating line is subject to the control requirements contained in OAC Rule 3745-21-09(F), and the compliance schedule contained in OAC Rule 3745-21-04(C)(5). These rules require PPC to meet a limit of 2.9 pounds of VOC per gallon of coating, excluding water, by April 1, 1982, USEPA approved these rules as meeting the RACT requirements of the Clean Air Act (CAA) on October 31, 1980 (45 FR 72122), and June 29, 1982 (47 FR 20897).

Deficiencies in the RACT Relaxation

An exemption from the VOC regulations for this source constitutes a site-specific relaxation of RACT (i.e., a source-specific redefinition of RACT). In order for such a relaxation to be approved by USEPA, PPC must demonstrate that compliance with the applicable limit is technically or economically infeasible.

PPC believes that it is technically infeasible to meet the emission limits of 2.9 pounds of VOC per gallon of coating (excluding water) through the use of complying coatings. According to the supplier of the vinyl resin used to formulate the coating used for PPC's paperboard product, it is technically infeasible to formulate a high solids coating using this resin due to solubility constraints. The other available options are waterbased coatings and coatings using an exempt solvent.

Although it may be technically feasible to formulate a complying coating using the vinyl resin and an exempt solvent (methlyene chloride), the manufacturer of the application equipment used by PPC believes that use of this solvent would probably make the existing equipment impossible to use. Therefore, PPC believes the only remaining alternative approach is waterbased coatings. However, any waterbased coating used by PPC for its bakery trays must be approved by the Food and Drug Administration (FDA). According to the resin supplier, there are very few water-based resins and polymers available that are FDA approvable. PPC claims that it is continually testing new water-based coatings as it becomes aware of them; but so far, nothing meets all of the criteria.

USEPA has reviewed this site-specific revision for PPC and determined that the company has not provided any documentation to demonstrate that it has been looking for and testing water-based coatings. In addition, PPC must provide documentation showing either that add-on control is not cost-effective (on an annualized dollars per ton of VOC controlled basis), or that the added cost of such equipment would make it more profitable to shut down the line than to remain operating. A detailed discussion of the extent of an acceptable investigation of the feasibility of meeting a SIP limit using complying coatings or other controls is contained in Appendix A of the proposed rulemaking published on November 9, 1988 at at 53 FR 45285.

Air Quality Considerations

PPC is located in Hamilton County and is part of the Cincinnati ozone demonstration area. The area is designated nonattainment for ozone and currently does not have an approved attainment demonstration.

The OEPA believes that approval of this revision generally will not interfere with attainment or maintenance of the ozone NAAQS due to the small quantity of noncomplying emissions (average of 11.6 kilograms per day in 1985); however, because the variance does not limit PPC to any specific level of emissions, it is not possible to determine the effect of this revision on air quality in the Cincinnati area. This determination would have to be based on the highest emitting coating that could be used.

A State seeking to revise an USEPA approved emission limit for a source in a nonattainment area should demonstrate that the requested revision would not interfere with attainment of the ozone standard by December 31, 1987, or with RFP in the interm. If, as here, the requested revision is an uncompensated relaxation of an emission limit, the State can meet this burden by, among other means, demonstrating that the unrevised SIP provides for a sufficient "cushion" to accommodate the relaxation. In other words, the State could demonstrate that the unrevised SIP provides a greater level of control than is necessary to ensure RFP and timely attainment. The State has not attempted to show that the demonstration of attainment that it submitted for Hamilton County account in this way for this relaxation of the emission limit.

Based upon the above information, USEPA is proposing to disapprove this site-specific SIP revision.

USEPA is providing a 30-day comment period on this notice of proposed rulemaking. Public comments received on or before December 16, 1988, will be considered in USEPA's final rulemaking. All comments will be available for inspection during normal business hours at the Region V office address provided at the front of this notice.

Under Executive Order 12291, this action is not "Major". It has been submitted to the Office of Management and Budget (OMB) for review.

Under 5 U.S.C. 605(b), the Administrator has certified that SIP approvals do not have a significant economic impact on a substantial number of small entities. (See 46 FR 8709).

Authority: 42 U.S.C. 7401-7642.

Dated: December 31, 1986.

Valdas V. Adamkus,

Regional Administrator.

Editorial Note. This document was received by the Office of the Federal Register November 10, 1988.

[FR Doc. 88-26427 Filed 11-15-88; 8:45 am]

BILLING CODE 6560-50-M

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40 CFR Part 180

[PP 5E3160/P467; FRL-3477-5]

Pesticide Tolerances for Dimethyl Tetrachloroterephthalate

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes that a tolerance be established for the combined residues of the herbicide dimethyl tetrachloroterephthalate and its metabolites (referred to in this document as "DCPA") in or on the raw agricultural crop group *Brassica* (cole) leafy vegetables. The proposed regulation to establish a maximum permissible level for residues of the herbicide in or on the commodities within the group was requested in a petition submitted by the Interregional Research Project No. 4 (IR-4).

DATE: Comments, identified by the document control number [PP 5E3160/P467], must be received on or before December 16, 1988.

ADDRESSES: By mail, submit written comments to:

Public Docket and Freedom of Information Section, Field Operations Programs (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

In person, bring comments to: Rm. 246, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (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 record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 246 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail:

Hoyt Jamerson, Emergency Response and Minor Use Section (TS-767C), Registration Division, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Office location and telephone number: Rm. 716C, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703)-557-2310.

SUPPLEMENTARY INFORMATION: The Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, has submitted pesticide petition 5E3160 to EPA on behalf of Dr. Robert H. Kupelian, National Director, IR-4 Project and the Agricultural Experiment Station of Florida.

This petition requested that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act, propose the establishment of a tolerance for combined residues of the herbicide dimethyl tetrachloroterephthalate (DCPA) and its metabolites monomethyl tetrachloroterephthalate (MTP) and tetrachloroterephthalic acid (TPA), all calculated as dimethyl tetrachloroterephthalate, in or on the raw agricultural crop group *Brassica* (cole) leafy vegetables, as defined in 40 CFR 180.34(f)(9)(v)(A), at 5.0 parts per million (ppm).

Tolerances are currently established for residues of the herbicide in or on the following raw agricultural commodities in the crop group *Brassica* (cole) leafy vegetables: Broccoli, Brussels sprouts, cabbage, and cauliflower at 1 ppm; collards and kale at 2 ppm; and mustard greens at 5 ppm. Broccoli, cabbage and mustard greens are the representative commodities of the proposed crop group. With the establishment of the crop group tolerance, tolerances would be established at a uniform level for residues of the herbicide at 5 ppm in or on broccoli, Brussels sprouts, cabbage, cauliflower, collards, kale, and mustard greens and, additionally, in or on the remaining commodities within the crop group including kohlrabi, Chinese broccoli, Chinese cabbage, Chinese mustard cabbage, broccoli raab, and rape greens at 5 ppm. Although the crop group tolerance for residues at 5 ppm will apply to all members of the *Brassica* leafy vegetable crop group for purposes of uniformity, actual residues based on registered use patterns are not expected to exceed existing tolerances already established for the specific commodities listed above. The incremental risk resulting from the proposed use of DCPA on the remaining commodities in the group will not significantly increase dietary risk.

The data submitted in the petition and other relevant material have been evaluated. The pesticide is considered useful for the purpose for which the tolerance is sought. The toxicological data considered in support of the proposed tolerance include:

1. A 2-year rat feeding study with a systemic no-observed-effect level (NOEL) of 50 mg/kg/day (1,000 ppm, highest dose tested). The study is not acceptable under persent EPA Guidelines.

2. A 2-year dog feeding study with a NOEL greater than 250 mg/kg (10,000 ppm).

3. A rat teratology study with maternal and fetotoxic NOELs of 2,000 mg/kg/day (highest dose tested).

Data considered desirable but lacking include: a chronic feeding study and a teratology study, each in a second species; oncogenicity studies in two species; a reproduction study; and mutagenicity studies.

DCPA and its metabolites appear to have low acute and chronic toxicity based on the limited studies that have been submitted to support the currently registered pesticide products. However, the Agency's recent evaluation of DCPA raised concerns about the chronic toxicological effects of two manufacturing impurities, hexachlorobenzene (HCB) and 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD). The Agency performed a preliminary risk assessment based on the assumption that the impurities are found in DCPA residues in the same proportion as they are found in the technical product. The agency calculates the potential dietary oncogenic risk from registered uses of DCPA at 2×10^{-6} for HCB and 1×10^{-8} for 2,3,7,8-TCDD.

The provisional acceptable daily intake (PADI), based on the 2-year rat feeding study (NOEL of 50 mg/kg/day, or 1,000 ppm) and using a 100-fold safety factor, is calculated to be 0.5 mg/kg/day. The theorectical maximum residue contribution (TMRC) from existing tolerances for a 1.5-kg daily diet is calculated to be 0.006574 mg/kg/day; the current action for *Brassica* leafy vegetables will increase dietary exposure by 0.0000012 mg/kg/day, 0.02 percent.

The nature of the residues is adequately understood and an adequate analytical method, gas-liquid chromatography, is available in the *Pesticide Analytical Manual* (PAM), Vol. II, for enforcement purposes. There are currently no actions pending against

the continued registration of this chemical.

Based on the above information considered by the Agency and the fact that there are no animal feed items involved, there will be no secondary residues in meat, milk, poultry, or eggs; the tolerance established by amending 40 CFR 180.185 would protect the public health. Therefore, it is proposed that the tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this notice in the **Federal Register** that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 5E3160/P4671]. All written comments filed in response to this petition will be available in the Public Document and Freedom of Information Section, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Recording and recordkeeping requirements.

Dated: October 31, 1988.

Edwin F. Tinsworth,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR Part 180 be amended as follows:

PART 180—[AMENDED]

1. The authority citation for Part 180 continues to read as follows:

Authority: 21 U.S.C. 346a.

2. Section 180.185(a) is amended by deleting the entries for the commodities broccoli, Brussels sprouts, cabbage, cauliflower, collards, kale, and mustard greens and by adding and alphabetically inserting the entry for the raw agricultural commodity crop group *Brassica* (cole) leafy vegetables, to read as follows:

§ 180.185 Dimethyl tetrachloroterephthalate; tolerances for residues.

(a) * * *

Commodities	Parts per million
* * * * *	
Vegetables, leafy, *Brassica* (code)	5
* * * * *	

[FR Doc. 88-26428 Filed 11-15-88; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 88-520, RM-6516]

Radio Broadcasting Services; Woodstock and Broadway, VA

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition by Ruarch Associates licensee of Station WAZR(FM), Channel 240A at Woodstock, Virginia, proposing the substitution of Channel 241B1 for Channel 240A at Woodstock, and the modification of its license to specify operation on the higher class channel, as a first wide coverage are FM service. A site restriction of 23.4 kilometers (14.5 miles) southwest of the community is required. The restricted site coordinates are 38-45-29 and 78-43-36. In addition, in order to accomplish this proposal Channel 226A must be substituted for Channel 238A at Broadway, Virginia.

DATES: Comments must be filed on or before December 29, 1988, and reply comments on or before January 13, 1989.

ADDRESS: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioners, or their counsel or consultant, as follows: Howard W. Simcox, Jr., Esquire, Borsari & Paxson, 2100 M Street NW., Suite 610, Washington, DC 20037 (Counsel for petitioner).

FOR FURTHER INFORMATION CONTACT: Patricia Rawlings, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 88-520, adopted October, 11, 1988, and released November 8, 1988. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, (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 1.1231 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.

Steve Kaminer,

Deputy Chief, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 88-26465 Filed 11-15-88; 8:45 am]

BILLING CODE 6712-01-M

Notices

Federal Register
Vol. 53, No. 221
Wednesday, November 16, 1988

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

Forms Under Review by Office of Management and Budget

November 10, 1988.

The Department of Agriculture has submitted to OMB for review the following proposals for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35) since the last list was published. This list is grouped into new proposals, revisions, extensions, or reinstatements. Each entry contains the following information:

(1) Agency proposing the information collection; (2) title of the information collection; (3) form number(s), if applicable; (4) how often the information is requested; (5) who will be required or asked to report; (6) an estimate of the number of responses; (7) an estimate of the total number of hours needed to provide the information; (8) an indication of whether section 3504(h) of Pub. L. 96-511 applies; (9) name and telephone number of the agency contact person.

Questions about the items in the listing should be directed to the agency person named at the end of each entry. Copies of the proposed forms and supporting documents may be obtained from: Department Clearance Officer, USDA, OIRM, Room 404-W Admin. Bldg., Washington, DC 20250, (202) 447-2118.

Comments on any of the items listed should be submitted directly to: Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, Attn: Desk Officer for USDA.

If you anticipate commenting on a submission but find that preparation time will prevent you from doing so promptly, you should advise the OMB Desk Officer of your intent as early as possible.

Revision

• *Farmer's Home Administration*

7 CFR 1980-E, Business and Industrial Loan Program
FmHA 449-2, -4, -22; 1980-68, -70
Recordkeeping; On occasion; Quarterly
State or local governments; Businesses or other for-profit
17,562 responses; 71,893 hours; not applicable under section 3504(h)
Jack Holston (202) 382-9736

Extension

• *Agricultural Stabilization and Conservation Service*

CFR 1423 Processed Commodities Warehouse Standards
CCC-56, CCC-29, 29-1, 29-2, 29-3; CCC-32, CCC-32-1, 32-2; CCC-560, CCC-55, CCC-513, CCC-56-1, 56-2
On occasion
Business or other for-profit; Small businesses or organizations; 2,528 responses; 2,275 hours; not applicable under section 3504(h)
Barry Klein (202) 447-4647.

New

• *Rural Electrification Administration*

Detail of Investment in Affiliated Companies
REA Form 479d
Annually
Small businesses or organizations; 1,000 responeses; 500 hours; not applicable under section 3504(h)
Monte Heppe, Jr. (202) 382-8530.

Larry K. Roberson,
Action Departmental Clearance Officer.

[FR Doc. 88-26490 Filed 11-15-88; 8:45 am]
BILLING CODE 3410-01-M

Office of the Secretary

Establishment of Agricultural Technical Advisory Committee for Trade in Processed Foods

ACTION: Notice.

Notice is hereby given that Secretary of Agriculture, after consultation with the United States Trade Representative, proposes to establish an Agricultural Technical Advisory Committee for Trade in Processed Foods.

The purpose of this committee is to provide advice to the Secretary and the Trade Representative with respect to the trade policy of the United States pursuant to section 135(c) of the Trade Act of 1974 (Pub. L. 93-618), as amended by the Trade Agreements Act of 1979 (Pub. L. 96-39). Meetings of this committee will be open only to members of the committee in accordance with section 135(f)(2) of the Act unless otherwise determined.

The establishment of this committee is in the public interest in connection with the duties of the Department imposed by the Trade Act of 1974, as amended by the Trade Agreements Act of 1979.

Comments may be submitted to Eileen M. Rainey, Assistant to the Administrator for Advisory Committees, Foreign Agricultural Service, U.S. Department of Agriculture, Room 5066 South Building, Washington, DC 20250 until December 1, 1988.

John J. Franke, Jr.,
Assistant Secretary for Administration.

Issued at Washington, DC, this 8th day of November, 1988.

[FR Doc. 88-26414 Filed 11-15-88; 8:45 am]
BILLING CODE 3410-10-M

CIVIL RIGHTS COMMISSION

Nevada Advisory Committee; Agenda and Notice of Public Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that the Nevada Advisory Committee to the Commission will convene at 10:00 a.m. and adjourn at 12:00 noon on December 2, 1988, at the University of Nevada, Las Vegas, Wright Hall, Gold Room #112, 4505 Maryland Parkway, Las Vegas, Nevada 89154. The purpose of the meeting is to discuss the draft of the Committee's casino employment study and to review data on casino employment collected from the U.S. Equal Employment Opportunity Commission.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson, Elizabeth C. Nozero or Philip Montez, Director of the Western Regional Division (213) 894-3437, (TDD 213/894-0508). Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter, should contact the Regional Division office at least five

(5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, November 8, 1988.

Melvin L. Jenkins,

Acting Staff Director.

[FR Doc. 88-26387 Filed 11-15-88; 8:45 am]

BILLING CODE 6335-01-M

DEPARTMENT OF COMMERCE

Agency Form Under Review by the Office of Management and Budget (OMB)

DOC has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Minority Business Development Agency.

Title: Minority Vendor Profile System.

Form Number: Agency—MBDA 136; OMB-0640-0002.

Type of Request: Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection.

Burden: 100 respondents; 5,000 reporting hours.

Average Hours Per Response: .5 hours or 30 minutes.

Needs and Uses: This form is used to collect information on minority business capabilities for referral to procurement officials interested in extending contract bidding opportunities to minority firms. Respondents are minority owners of business firms capable of and interested in selling goods and services to government agencies and other businesses.

Affected Public: Businesses or other for-profit institutions, and small businesses or organizations.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Francine Picoult, 395-7340.

Copies of the above information collection proposal can be obtained by calling or writing DOC Clearance Officer, Edward Michals, 202/377-3271, Department of Commerce, Room H6622, 14th and Constitution Avenue NW., Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent to Francine Picoult, OMB Desk Officer, Room 3208 New Executive Office Building, Washington, DC 20503.

Dated: November 10, 1988.

Edward Michals,

Department of Clearance Officer, Office of Management and Organization.

[FR Doc. 88-26469 Filed 11-15-88; 8:45 am]

BILLING CODE 3510-CW-M

Export Now Advisory Committee; Open Meeting

A meeting of the Export Now Advisory Committee will be held on January 12, 1989, 10:00 a.m.—1:00 p.m. at the U.S. Department of Commerce, Room 4830, 14th Street and Constitution Avenue NW., Washington, DC 20230. The meeting will be open to the public with a limited number of seats available. Any member of the public may submit written comments concerning the Committee's affairs at any time before or after the meeting.

The Committee was established by the Secretary of Commerce on February 25, 1988 to advise Department officials on the objectives and conduct of the Export Now Program, including methods of increasing public awareness of the advantages of exporting, improving Federal coordination with state, local and private sector export activities, and implementing programs of education and training to increase the export effectiveness of all segments of the U.S. economy.

The purpose of the meeting is to report on the status of the Export Now Program and to receive advice from the public on the conduct and future implementation of the program. A more specific agenda will be available to the public at the beginning of the meeting.

For further information or copies of the minutes, contact Lew W. Cramer or John Hayes, Export Now Program, Herbert C. Hoover Building, Room 1066, 14th Street and Constitution Avenue NW., Washington, DC 20230, (202) 377-2073.

Date: November 10, 1988.

Robert H. Brumley,

General Counsel.

[FR Doc. 88-26447 Filed 11-15-88; 8:45 am]

BILLING CODE 3510-CW-M

Foreign-Trade Zones Board

[Docket 36-88]

Greater New Haven Chamber of Commerce; Application for Subzone; Miles Pharmaceutical Plant, West Haven, CT

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Greater New Haven Chamber of Commerce, requesting special-purpose subzone status for the pharmaceutical plant of Miles, Inc., in West Haven, Connecticut. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-91u), and the regulations of the Board (15 CFR Part 400). It was formally filed on November 7, 1988. The applicant has an application pending with the Board for a general-purpose foreign-trade zone in North Haven, Connecticut (FTZ Doc. 16-88, 53 FR 9132, 3/21/88).

The Miles plant (51 acres) is located at 400 Morgan Lane in West Haven. The facility employs some 1,500 persons and is used to produce a number of pharmaceutical products such as antibiotics, antifungals, anti-infectives, and beta blockers. Miles sources many of the bulk active ingredients and materials abroad, such as nifdipine, azlocillin, nitrendipine, ciprofloxacin, desonide, diethylstilbestrol ipsapiron, mezocillin sodium, mycospor, niclocide, nimodipine, nisoldipine, praziquantel, biltricide, applicators, and gauze. The foreign material accounts for some 65 percent of direct costs. Some of the products are exported.

Zone procedures would exempt Miles from Customs duty payments on foreign materials used in its exports. On its domestic sales, the company will be able to choose the same duty rate that applies to finished pharmaceutical products. Although the active ingredients have the same duty rate as the finished products under the current tariff schedule, the applicant indicates that under the Harmonized Tariff System, which goes into effect on January 1, 1989, the ingredients will have rates ranging from 7.4 to 81. percent, whereas the end products will have rates of 6.2 or 6.3 percent. The application indicates that zone savings would help improve the plant's international competitiveness.

In accordance with the Board's regulations, an examiners committee has been appointed to investigate the application and report to the Board. The committee consists of: Dennis Puccinelli (Chairman), Foreign-Trade Zones Staff, U.S. Department of Commerce, Washington, DC 20230; Edward A. Goggin, Assistant Regional Commissioner, U.S. Customs Service, Northeast Region, 100 Summer Street, Boston, Massachusetts 02110; and Colonel Thomas A. Rhen, Division Engineer, U.S. Army Engineer Division New England, 420 Trapelo Road, Waltham, Massachusetts 02254.

Comments concerning the proposed subzone are invited in writing from interested parties. They should be

addressed to the Board's Executive Secretary at the address below and postmarked on or before December 28, 1988.

A copy of the application is available for public inspection at each of the following locations.

Port Director's Office, U.S. Customs Service, Federal Building, 150 Court Street, New Haven, Connecticut 06511

Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, Room 2835, 14th and Pennsylvania Avenue NW., Washington, DC 20230.

Dated: November 8, 1988.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 88-26472 Filed 11-15-88; 8:45 am]

BILLING CODE 3510-DS-M

International Trade Administration

[A-583-008]

Certain Circular Welded Carbon Steel Pipes and Tubes From Taiwan; Preliminary Results of Antidumping Duty Administrative Review and Tentative Determination to Revoke in Part

AGENCY: International Trade Administration, Import Administration, Commerce.

ACTION: Notice of preliminary results of antidumping duty administrative review and tentative determination to revoke in part.

SUMMARY: In response to requests by the petitioner and two respondents, the Department of Commerce has conducted an administrative review of the antidumping duty order on certain circular welded carbon steel pipes and tubes from Taiwan. The review covers four manufacturers/exporters of this merchandise to the United States and the period May 1, 1986 through April 30, 1987. The review indicates the existence of dumping margins for one manufacturer and zero dumping margins for a second manufacturer. Two respondents had no shipments.

As a result of the review, the Department has preliminarily determined to assess dumping duties equal to the calculated differences between United States price and foreign market value. The Department has tentatively determined to revoke the antidumping duty order with respect to Yieh Hsing. Interested parties are invited to comment on these preliminary results and tentative determination to revoke in part.

EFFECTIVE DATE: November 16, 1988.

FOR FURTHER INFORMATION CONTACT: Anne D'Alauro or Maureen Flannery, Office of Antidumping Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 377-2923.

SUPPLEMENTARY INFORMATION:

Background

On October 20, 1988, the Department of Commerce ("the Department"), published in the **Federal Register** (53 FR 41218) the final results of its last administrative review of the antidumping duty order on certain circular welded carbon steel pipes and tubes from Taiwan. The petitioner and two respondents requested in accordance with § 353.53a(a) of the Commerce Regulations that we conduct an administrative review for the period May 1, 1986 through April 30, 1987. We published a notice of initiation of the antidumping duty administrative review on June 19, 1987 (52 FR 23330). The Department has now conducted that administrative review in accordance with section 751 of the Tariff Act of 1930 ("the Tariff Act").

On July 25, 1988, the petitioner withdrew its request for review with respect to Kao Hsing Chang Iron and Steel Corp., Ltd. The Department has not honored the petitioner's withdrawal of their request since this request was received 404 days after initiation of the review and after the receipt of Kao Hsing Chang's response.

Scope of the Review

Imports covered by the review are shipments of certain circular welded carbon steel pipes and tubes. The Department defines such merchandise as welded carbon steel pipes and tubes of circular cross section, with walls not thinner than 0.065 inches, and 0.375 inches or more but not over 4.5 inches in outside diameter, which are currently classifiable under items 610.3231, 610.3234, 610.3241, 610.3242, 610.3243 and 610.3252 of the Tariff Schedules of the United States Annotated ("TSUSA"), and under item 7306.30.50 of the Harmonized Tariff Schedule ("HTS").

The review covers four manufacturers/exporters of certain Taiwan circular welded carbon steel pipes and tubes.

United States Price

In calculating United States price the Department used purchase price, as defined in section 772 of the Tariff Act. Purchase price was based on the packed f.o.b. or c. & f. price to unrelated purchasers in the United States. We made adjustments, where applicable, for foreign inland freight, ocean freight, brokerage and handling charges, warehouse charges, taxes not collected by reason of the exportation to the United States, and duty drawback. No other adjustments were claimed or allowed.

Foreign Market Value

In calculating foreign market value for Yieh Hsing Enterprise Co., Ltd., the Department used home market sales, as defined in section 773 of the Tariff Act, since there were sufficient sales of such or similar merchandise in the home market. We used constructed value, as defined in section 773 of the Tariff Act, as the basis for calculating foreign market value for An Mau Steel Co., Ltd., since there were no sales of such or similar merchandise in the home market or to third countries.

Home market price was based on the packed delivered price to unrelated customers in the home market. Where applicable, we made adjustments for inland freight, and differences in the credit expenses and the physical characteristics of the merchandise. No other adjustments were claimed or allowed.

We calculated constructed value as the sum of materials and fabrication costs, general expenses, profit, and the cost of packing. Since An Mau's actual general expenses were less than ten percent of the sum of materials and fabrication costs, we used the ten percent statutory minimum for general expenses, as provided by section 773 of the Tariff Act. We examined the industry profit rate since An Mau does not sell the same general class or kind of merchandise in the home market or to third countries. Since that profit rate less than eight percent of the sum of materials costs, fabrication costs, and general expenses, we used the eight percent statutory minimum, as provided by section 773 of the Tariff Act.

Preliminary Results of the Review and Tentative Determination to Revoke in Part

As a result of our comparison of United States price to foreign market value, we preliminarily determine that the following margins exist:

Manufacturer/exporter	Time period	Weighted-average margin (percent)
An Mau Steel	05/01/86-04/30/87	0.89
Far East Machinery	05/01/86-04/30/87	[1] 0.00
Kao Hsing Chang Iron and Steel	05/01/86-04/30/87	[1] 0.00

Manufacturer/exporter	Time period	Weighted-average margin (percent)
Yieh Hsing Enterprise	05/01/86-04/30/87	0.00

[1] No shipments during the review period; margin from last review in which there were shipments.

Interested parties may request disclosure and/or an administrative protective order within 5 days of the date of publication of this notice and may request a hearing within 8 days of publication. Any hearing, if requested, will be held 35 days after the date of publication, or the first workday thereafter. Pre-hearing briefs and/or written comments from interested parties may be submitted not later than 25 days after the date of publication. Rebuttal briefs and rebuttals to written comments, limited to issues raised in those comments, may be filed not later than 32 days after the date of publication. The Department will publish the final results of the administrative review including the results of its analysis of any such comments or hearing.

The Department shall determine, and the Customs Service shall assess, antidumping duties on all appropriate entries. Individual differences between United States price and foreign market value may vary from the percentage stated above for An Mau. The Department will issue appraisement instructions directly to the Customs Service.

Further, as provided for by 19 CFR 353.48(b), a cash deposit of estimated antidumping duties based on the above margin shall be required for An Mau. Because there was no margin for Yieh Hsing, Far East Machinery, and Kao Hsing Chang Iron and Steel, no cash deposit shall be required for those companies. For any future entries of this merchandise from a new exporter, not covered in this or prior administrative reviews, whose first shipments occurred after April 30, 1987 and who is unrelated to any reviewed firm, a cash deposit of .89 percent shall be required. These deposit requirements are effective for all shipments of certain Taiwanese circular welded carbon steel pipes and tubes entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review.

Yieh Hsing has requested partial revocation of the order and, as provided for in § 353.54(e) of the Commerce Regulations, has agreed in writing to an immediate suspension of liquidation and reinstatement of the order under circumstances specified in the written agreement. Yieh Hsing has had no sales at less than fair value for two years. Therefore, we tentatively determine to revoke in part the order on certain circular welded carbon steel pipes and tubes from Taiwan with respect to Yieh Hsing. If this partial revocation is made final, it will apply to all unliquidated entries of this merchandise manufactured by Yieh Hsing and entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice.

This administrative review, tentative determination to revoke in part, and notice are in accordance with sections 751(a)(1) and (c) of the Tariff Act (19 U.S.C. 1675(a)(1) and (c)) and 19 CFR 353.53a and 353.54.

Jan W. Mares,

Assistant Secretary for Import Administration.

Date: November 8, 1988.

[FR Doc. 88-26470 Filed 11-15-88; 8:45 am]

BILLING CODE 3510-DC-M

[C-357-052]

Non-Rubber Footwear From Argentina; Final Results of Countervailing Duty Administrative Review

AGENCY: International Trade Administration, Import Administration, Commerce.

ACTION: Notice of final results of countervailing duty administrative review.

SUMMARY: On April 27, 1988, the Department of Commerce published the preliminary results of its administrative review of the countervailing duty order on non-rubber footwear from Argentina. We have now completed that review and determine the total bounty or grant during the period January 1, 1986 through December 31, 1986 to be zero for 24 firms 3.13 percent *ad valorem* for all other firms.

EFFECTIVE DATE: November 16, 1988.

FOR FURTHER INFORMATION CONTACT: Lorenza Olivas or Bernard Carreau, Office of Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 377-2786.

SUPPLEMENTARY INFORMATION:

Background

On April 27, 1988, the Department of Commerce ("the Department") published in the **Federal Register** (53 FR 15094) the preliminary results of its administrative review of the countervailing duty order on non-rubber footwear from Argentina (44 FR 3474, January 17, 1979). The Department has now conducted that administrative review in accordance with section 751 of the Tariff Act of 1930 ("the Tariff Act").

Scope of Review

Imports covered by this review are shipments of Argentine footwear described in Part 1A of Schedule 7 of the Tariff Schedules of the United States Annotated, excluding items 700.5100 through 700.5400, 700.5700 through 700.7100, and 700.9000. These produces are currently classifiable under the Harmonized Tariff Schedule (HTS) item number listed in the Appendix to this notice.

The review covers the period January 1, 1986 through December 31, 1986 and three programs: (1) A rebate of indirect taxes; (2) post-export financing; and (3) pre-export financing.

Analysis of Comments Received

We gave interested parties an opportunity to comment on the preliminary results. We received written comments from the Argentine Footwear Industry Federation ("the Federation").

Comment 1: The Federation argues that the appropriate benchmark for measuring the benefits from pre- and post-export financing is the yearly average of only the regulated interest rates, not the average of both the regulated and the unregulated rates. The Federation points out that, according to the Subsidies Appendix (49 FR 18016) (1984), the Department's practice of using a national average commercial interest rate to measure the benefit from short-term preferential loan programs was adopted to avoid the administrative burden of having to compute company-specific benchmarks. The Federation maintains that it is not requesting the Department to use company-specific benchmarks. Rather, because non-rubber footwear producers provided evidence that they were able to secure standard commercial loans at the regulated interest rates, it is asking the Department to compute the benchmark using only those interest rates that were available to the specific exporters covered by this review.

Department's Position: We disagree. The benchmark rate should reflect the predominant alternative sources of short-term financing available to an average firm in Argentina. Since unregulated interest rate loans make up a significant portion of the lending in Argentina, it is appropriate to include them in the national average

benchmark. (*See Oil Country Tubular Goods from Argentina; Final Results of Countervailing Duty Administrative Review* (53 FR 846, January 9, 1987); and *Roses and Other Cut Flowers from Colombia; Final Results of Countervailing Duty Administrative Review* (52 FR 248, December 28, 1987).)

Comment 2: The Federation requests that the Department correct certain clerical errors in its calculations of the benefits from the pre- and post-export financing programs in the preliminary results.

Department's Position: With regard to Mocassino, we have revised our calculations in those instances where we used the incorrect loan value to determine the pre-export financing benefit. We have also weight-averaged Cerro's pre-export financing benefits based on its non-rubber footwear exports to the United States.

In our preliminary results, we based our benchmark rate on a six-month average of the regulated and unregulated interest rates because the level of pre- and post-export lending to most of the footwear producers was disproportionately spread between the first and second half of the year. Since the monthly regulated and unregulated rates did not vary greatly during the review period, we have now used a yearly average benchmark. (*See Final Affirmative Countervailing Duty Determinations and Countervailing Duty Orders: Certain Welded Carbon Steel Pipe and Tube Products from Argentina,* (53 FR 37619, September 27, 1988).)

Adjusting for all these changes, we determine the benefit to be 2.57 percent *ad valorem* for pre-export financing and 0.56 percent *ad valorem* for post-export financing.

Comment 3: The Federation argues that the Department should grant a zero duty deposit rate to new companies that did not export to the United States during the period of review. The new exporters have individually certified that they have not received, and will not apply for, either pre- or post-export financing, the two programs preliminarily found countervailable by the Department in this review. Similarly, the Department should grant a zero duty deposit to three companies found to have received benefits during the review period that have also certified they will not receive either pre- or post-export financing in the future.

Department's Position: Generally, to be considered for a zero rate for purposes of cash deposit of estimated coutervailing duties, a company must have exported during the review period. If a company has not exported during the review period, we have no "track record" on which to rely in determining the appropriate cash deposit rate. Therefore, until the new companies demonstrate otherwise, the "all other" rate is our best estimate of the countervailable benefits received by these companies. This has long been our practice, not only for new companies, but also for all unknown exporters. (*See e.q., Certain Textile Mill Products from Mexico; Final Results of Countervailing Duty Administrative Review* (52 FR 45010, November 24, 1987); *cf. Asahi Chemical Industry Co. v. United States,* 548 F. Supp. 1261, 1267 (Ct. Int'l Trade 1982) (*Asahi*), holding reasonable the Department's use of most recent price and value information to establish margins when there were no entries during the period of review.)

Our policy regarding the companies that did export during the review period is to set a cash deposit rate that reflects our best estimate of the current benefit that those companies receive from countervailable programs. We normally change the cash deposit rate if a program-wide change has occurred before the publication of our preliminary results, or if some other change has occurred that we are able to verify before publishing the preliminary results. In this case, neither has occurred with respect to the new companies or the companies found to have received benefits during the period of review. Therefore, we conclude that the cash deposit rate should be the same as the assessment rate for all companies.

Comment 4: The Federation contends that the cash deposit requirements of the Commerce Regulations do not apply to new exporters because new exporters were not subject to an administrative review. Therefore, it is not logical for the Department to assign the "all other" rate to new exporters. If the Department believes it must set a cash deposit rate for new exporters, it should base that rate on any relevant facts collected during the review, including the renunciation certifications. In this way, the duty deposit rate will realistically correspond to the established facts.

Department's Position: We disagree with the Federation's contention that the cash deposit rate set in an administrative review does not apply to new exporters. Section 701 of the Tariff Act provides for the imposition of countervailing duties on *all* merchandise imported into the United States, the production or exportation of which receives a subsidy. Consequently, in an administrative review, we review exports of all merchandise except exports of merchandise from companies that have been excluded. We cannot exclude a company from a countervailing duty order once the order is issued. Requests for company exclusions must be submitted within 30 days of publication of a ntoice to initiate an investigation, and the decision as to the exclusion must be made in the Department's final determination (19 CFR 355.38). No company has been excluded from this order. All Argentine firms exporting non-rubber footwear to the United States are subject to the results of this review, including the new exporting firms. Consequently, the "all other" rate for duty deposit purposes applies to the merchandise exported to the United States by all firms, whether or not the firms exported during the period of review. (*Cf. Asahi.*)

Comment 5: The Federation claims that the Department's selection of the "all other" rate as the duty deposit rate for the new exporters is arbitrary and capricious. Since the Trade and Tariff Act of 1984 provides for the automatic assessment of countervailing duties in the amount of the estimated duty required at the time of entry, the duty deposit rate could become the final assessed countervailing duty rate if a review is not requested. The countervailing duties actually assessed on current entries by the new exporters could reflect a "benefit" that bears no relation whatsoever to reality.

Due process is denied the new exporters if the duty deposits required for 1988 and 1989 entries are based on outdated or erroneous information for 1986.

Department's Position: We disagree with the Federation's claim that our selection of the "all other" rate as the duty deposit rate for new exporters is arbitrary and capricious. (*See* our positions on Comments 3 and 4.) The Federation has the opportunity in January 1989 to request a review of 1988 entries, and in January 1990, of 1989 entries. If we receive review requests for those years, we will collect updated information. Whether we conduct reviews or follow the automatic liquidation procedure, we believe that due process is fully served.

Final Results of Review

After considering all of the comments received, we determine the total bounty or grant to be zero for the 24 firms listed below and 3.13 percent *ad valorem* for all other firms for the period January 1, 1986 through December 31, 1986.

The following firms received no benefits during the period of review:

1. Alarsu S.A.
2. Alikon

3. Alpargatas S.A.I.C.
4. Armeny S.A.
5. Balassi E Hijos S.A.
6. Barttolome Blengio y Cia
7. Bonsoir S.R.L.
8. Borcal S.A.
9. Camboriu S.R.I.
10. Casa Corazon Cueros S.R.L.
11. Costa S.A.
12. Creaciones Ketal S.R.L.
13. Dinor S.A.
14. E-Meu S.R.L.
15. Fabrica De Calzado M.B. S.A.
16. Jose Cabrabs E Hijos
17. Jose Gravagna S.A.
18. La Scarpa S.A.
19. Linea Vanguard S.A.
20. Macri Calz S.A.
21. Mocasineria Morganti S.R.L.
22. Orlando Asan
23. Pell-Cuer S.R.L.
24. Vogue Shoes S.R.L.

The Department therefore will instruct the Customs Service to liquidate, without regard to countervailing duties, entries of this merchandise from the 24 firms listed above and to assess countervailing duties of 3.13 percent of the f.o.b. invoice price on shipments of this merchandise from all other firms exported on or after January 1, 1986 and on or before December 31, 1986.

Further, as provided by section 751(a)(1) of the Tariff Act, the Department will instruct the Customs Service to waive cash deposits of estimated countervailing duties on shipments of this merchandise from the 24 firms listed above and to collect a cash deposit of estimated countervailing duties of 3.13 percent of the f.o.b. invoice price on shipments from all other firms entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice. This deposit requirement shall remain in effect until publication of the final results of the next administrative review.

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 355.10.

Jan W. Mares,

Assistant Secretary, Import Administration.

Date: November 8, 1988.

Appendix—Non-Rubber Footwear HTS Classifications

6115.91.00.00	6115.93.20.00
6209.90.40.00	6401.92.30.00
6401.92.60.00	6401.99.80.00
6402.11.00.00	6402.19.10.00
6402.19.50.00	6402.30.30.00
6402.30.50.00	6402.91.40.00
6402.91.50.00	6402.99.05.00
6402.99.10.00	6402.99.15.00
6402.99.70.00	6402.99.80.00
6403.11.30.00	6403.11.60.00
6403.19.15.00	6403.19.45.00
6403.19.60.00	6403.20.00.00
6403.30.00.00	6403.40.30.00
6403.40.60.00	6403.51.30.00
6403.51.60.00	6403.51.0.00
6403.59.15.00	6403.59.30.00
6403.59.60.00	6403.59.90.00
6403.91.30.00	6403.91.60.00
6403.91.90.00	6403.99.20.00
6403.99.40.00	6403.99.60.00
6403.99.75.00	6403.99.90.00
6404.11.20.00	6404.19.15.00
6404.19.20.00	6404.19.25.00
6404.19.30.00	6404.19.35.00
6404.19.509.00	6404.19.60.00 [1]
6404.19.70.00 [1]	6404.19.35.00
6404.19.50.00	6404.19.60.00
6404.19.70.00	6404.20.20.00
6404.20.40.00	6404.20.60.00
6405.10.00.00	6405.20.30.00
6405.20.60.00	6405.20.90.00
6405.90.90.00	6406.10.05.00
6406.10.10.00	6406.10.20.00
6406.10.45.00	6812.50.10.00
9021.19.80.00	

[FR Doc. 88-26471 Filed 11-15-88; 8:45 am]

BILLING CODE 3510-DS-M

[1] Except footwear which is over 50 percent by weight of rubber or plastics or over 50 percent by weight of fibers and rubber or plastics with at least 10 percent by weight being rubber or plastics.

Caribbean Basin Business Promotion Council; Open Meetings

AGENCIES: International Trade Administration and the Office of the U.S. Trade Representative.

SUMMARY: This is the fourth meeting of the Caribbean Basin Business Promotion Council (Council). The Council consists of 30 private sector members and nine U.S. Government representatives. The Council was established to advise the Secretary of Commerce on matters pertinent to implementation of the Caribbean Basin Initiative (CBI). The Council's advice will also be forwarded to the interagency CBI Task Force.

Prior to the meeting of the full Council, there will be an open meeting of the 936 Subcommittee which consists of several members of the Caribbean Business Promotion Council.

Time and Place: The 936 Subcommittee will meet at 1:00 p.m. on Tuesday, November 29, 1988 in the Escorial Room of the Intercontinental Hotel, 100 Chopin Plaza, Miami, Florida. Immediately following that meeting, the entire Caribbean Basin Business Promotion Council will meet from 2:00 p.m. to approximately 5:00 p.m. on Tuesday, November 29, 1988 in the Escorial Room of the Intercontinental Hotal, 100 Chopin Plaza, Miami, Florida.

Proposed Agenda—936 Subcommittee

A discussion of Puerto Rico's Caribbean Development (936) Program, methods by which the Council can further promote the program, and ways to support its continued implementation.

Proposed Agenda—Caribbean Basin Business Promotion Council

Members' country visits reports and a general discussion on identifying Council's goals for 1989.

Public Participation: The meetings will be open to public participation and a period will be set aside for oral comments or questions. Any member of the public may submit written comments concerning the Subcommittee and Council's affairs at any time before or after the meetings. Limited seating is available to the public.

FOR FURTHER INFORMATION CONTACT: Paul D. Bucher, Caribbean Basin Information Center, U.S. Department of Commerce, Main Commerce Building, Room 3203, Washington, DC 20230. Telephone (202) 377-0703. Copies of the minutes of the Council's meetings will also be available at the above office 30 days after the meetings.

Date: November 10, 1988.

Gordon Studebaker,

Director, CBI Center.

[FR Doc. 88-26468 Filed 11-15-88; 8:45 am]

BILLING CODE 3510-FP-M

Applications for Duty-Free Entry of Scientific Instruments; Louisiana State University and A&M College et al.

Pursuant to section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89-651; 80 Stat. 897; 15 CFR Part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with § 301.5(a)(3) and (4) of the regulations and be filed within 20 days with the Statutory Import Programs Staff, U.S. Department of Commerce, Washington, DC 20230. Applications may be examined between 8:30 a.m. and 5:00 p.m. in Room 1523, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC.

Docket No.: 88-211. *Applicant:* Louisiana State University and A&M College, Department of Biochemistry, 314 A.R. Choppin Hall, Baton Rouge, LA 70803. *Instrument:* 252-CF-Plasma Desorption T-O-F Mass Spectrometer,

Model BIN-20K. *Manufacturer:* Bio-Ion Nordic AB, Sweden. *Intended Use:* The instrument will be used to examine carbohydrates and peptides in the mass range of 1000 to 15 000 for mass estimation. In addition, the instrument will be used for instructing graduate students and postdoctoral fellows in its use. *Application Received by Commissioner of Customs:* May 17, 1988.

Docket No.: 88-311. *Applicant:* Vanderbilt University Medical Center, 1161 21st Avenue South, Nashville, TN 37232. *Instrument:* Two (2) Radioisotope Hot Cells. *Manufacturer:* Von Gahlen International, Inc., The Netherlands. *Intended Use:* The instrument will be used to determine the clinical utility of the diagnostic imaging modality known as Positron Emission Tomography (PET). The PET process concentrates on biochemical and metabolic processes to characterize normal and abnormal cellular activity. This type of analysis may enable more precise determination of the extent and type of brain tumor and tissue blood flow and energy metabolism within the heart. The objectives of the investigations will be to determine the instrument's potential as a diagnostic tool in the following areas of medicine: brain tumors, coronary artery disease, epilepsy, dementia (Alzheimer's disease), and trauma. *Application Received by Commissioner of Customs:* September 29, 1988.

Docket No.: 89-001. *Applicant:* The University of Texas at Austin, Department of Chemistry, Welch Hall, 26th & Speedway, Austin, TX 78712. *Instrument:* Mass Spectrometer, Model VG ZAB-2E. Manufacturer: VG Instruments, United Kingdom. *Intended Use:* The instrument will be used to determine the molecular weight and chemical structure for inorganic and organic compounds with masses in range up to and in excess of 10 000 dalton. *Application Received by Commissioner of Customs:* October 3, 1988.

Docket No.: 89-002. *Applicant:* The Johns Hopkins University, 3400 N. Charles Street, Baltimore, MD 21218. *Instrument:* Rapid Kinetics Instrument, SFM 3/PC. *Manufacturer:* Biologic Co., France. *Intended Use:* The instrument will be used for determining kinetics of protein association and dissociation by subunits of human hemoglobin, and for reactions with other molecules. The objectives of these studies are to understand basic mechanisms that will lead to the design of artificial blood substitutes that could be used in civilian disasters, blood banking deficits or military defense. *Application Received by Commissioner of Customs:* October 12, 1988.

Docket No.: 89-003. *Applicant:* The Catholic University of America, 620 Michigan Avenue, NE., Washington, DC 20064. *Instrument:* DMDP High Resolution Spectrometer, Model 2000 with Accessories. *Manufacturer:* SOPRA, France. *Intended Use:* The instrument will be used for a wide range of studies including collision-induced Rayleigh light scattering spectra studies to determine the structural relaxation times in liquids composed of complex molecules, and raman spectra very close to the exciting line will be studied in solutions containing DNA to discover if the prediction of low lying resonances in DNA is true. The instrument will also be used in the training of graduate students in physics, chemistry and biology. *Application Received by Commissioner of Customs:* October 12, 1988.

Docket No.: 89-004. *Applicant:* North Shore University Hospital, 300 Community Drive, Manhasset, NY 11030. *Instrument:* Electron Microscope, Model JEM 100CX. *Manufacturer:* JEOL Ltd., Japan. *Intended Use:* The instrument will be used in the following research projects:

1. Studies on diabetic glomerular disease in an animal model.
2. Stereological analysis of monocytes in leukemic patients and normal individuals.
3. Studies on intestinal structure, fluid transport and malnutrition.

The objectives of thes studies will be to evaluate quantitative structural alterations in absorptive epithelial cells that may play a role in the mechanism of the fluid transport inhibition, to investigate the role of vesicle mediated exchanges in intestinal fluid transport regulation by determining the extent of endocytosis utilizing extracellular tracers, to determine the effect of malnutrition on structural alterations occurring during fluid transport alterations. In addition, the instruments will be used for post-graduate training of Anatomic Pathology medical residents and M.D. Fellows in laboratory research. *Application Received by Commissioner of Customs:* October 19, 1988.

Docket No.: 89-005. *Applicant:* Florida Department of Business Regulation, Division of Pari Mutuel Wagering, Bureau of Laboratory Services, 725 South Bronough Street, Tallahassee, FL 32399-1039. GC/Mass Spectrometer/DS, MAT 90. *Manufacturer:* Finnigan MAT, West Germany. *Intended Use:* The instrument will be used to develop new methodology to determine whether any drugs or medication are present in the body fluids of racing animals and to develop and validate new methodology in order to detect and positively identify micro-quantities of drugs or medications present in the body fluids of animals. Compounds of interest will include synthetic drugs and those of bio-organic origin (e.g., steroids). A great deal of effort will be spent attempting to identify unknown compounds and drugs from confiscated items such as hypodermic needles or syringes, in which only a drop of thin film of drug remains in the barrel or needle. *Application Received by Commissioner of Customs:* October 19, 1988.

Docket No.: 89-006. *Applicant:* Louisiana State University Medical Center, School of Medicine in Shreveport, Department of Anatomy, P.O. Box 33932/1501 Kings Highway, Shreveport, LA 71130-3932. *Instrument:* Electron Microscope, Model CM 10. *Manufacturer:* N.V. Philips, The Netherlands. *Intended Use:* The instrument will be used for a wide range of research projects which include but are not limited to the following:

(1) Identification of the various subtypes of T-lymphocytes in the mammary gland during pregnancy and lactation.

(2) Identification of the mechanism of tranist of leukocytes through epithelia.

(3) Experiments designed to ascertain transferrin localization in erythroid cells during the critical period in which iron is being released from transferrin.

(4) Studies of vascular smooth muscle and peripheral nerve ultrastructure.

(5) Visualization of the membranes of the epithelial cells and bacteria as they translocate the gut membranes.

(6) Research to delineate the three-dimensional arrangement of cytoskeletal elements in the supranuclear Golgi region of the goblet cell.

In addition, the instrument will be used by students in the anatomy Graduate Program to conduct various research projects. *Application Received by Commissioner of Customs:* October 20, 1988.

Docket No.: 89-007. State University of New York at Albany, 1400 Washington Avenue, Albany, NY 12222. *Instrument:* Cryo-Stop-Flow Spectrofluorimeter, Model SF-41. *Manufacturer:* Hi-Tech, United Kingdom. *Intended Use:* The instrument will be used for detailed studies of the reversible binding and activating characteristics of copper(I) compounds containing organic polyamine organic ligands. These include studies to determine oxygen affinities and carbon monoxide affinities, i.e., thermodynamic parameters (by temperature dependent

studies), rates (kinetics) of oxygen binding, detailed mechanisms of the binding process as a function of the particular materials (compound), ability to oxidize organic compounds and mechanism of such processes.

Application Received by Commissioner of Customs: October 20, 1988.

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 88-26473 Filed 11-15-88; 8:45 am]

BILLING CODE 3510-DS-M

Minority Business Development Agency

Business Development Center Applications; Tennessee

AGENCY: Minority Business Development Agency, Commerce.

ACTION: Notice.

SUMMARY: The Minority Business Development Agency (MBDA) announces that it is soliciting competitive applications under its Minority Business Development Center (MBDC) Program to operate an MBDC for a 3-year period, subject to available funds. The cost of performance for the first 12 months is estimated at $216,776 for the project performance of 04/1/89 to 03/31/90. The MBDC will operate in the Memphis, Tennessee, Metropolitan Statistical Area (MSA). The first year cost for the MBDC will consist of $184,260 in Federal Funds and a minimum of $32,516 in non-Federal funds (which can be a combination of cash, in-kind contribution and fees for services).

The funding instrument for the MBDC will be a cooperative agreement and competition is open to individuals, non-profit and for-profit organizations, local and state governments, American Indian tribes and educational institutions.

The MBDC will provide management and technical assistance to eligible clients for the establishment and operation of businesses. The MBDC program is designed to assist those minority businesses that have the highest potential for success. In order to accomplish this, MBDA supports MBDC programs that can: Coordinate and broker public and private sector resources on behalf of minority individuals and firms; offer them a full range of management and technical assistance; and serve as a conduit of information and assistance regarding minority business.

Applications will be judged on the experience and capability of the firm and its staff in addressing the needs of minority business individuals and organizations; the resources available to the firm in providing management and technical assistance; the firm's proposed approach to performing the work requirements included in the application; and the firm's estimated cost for providing such assistance. It is advisable that applicants have an existing office in the geographic region for which they are applying. The MBDC will operate for a 3-year period with periodic reviews culminating in annual evaluations to determine if funding for the project should continue. Continued funding will be at the discretion of MBDA based on such factors as an MBDC's satisfactory performance, the availability of funds, and Agency priorities.

CLOSING DATE: The closing date for applications December 14, 1988. Applications must be postmarked on or before December 14, 1988.

ADDRESS: Atlanta Regional Office, Minority Business Development Agency, U.S. Department of Commerce, Suite 505, Atlanta, Georgia 30309, 404/347-3438.

FOR FURTHER INFORMATION CONTACT: Carlton L. Eccles, Regional Director of The Atlanta Regional Office.

SUPPLEMENTARY INFORMATION: Questions concerning the preceding information, copies of application kits and applicable regulations can be obtained at the above address.

(Catalog of Federal Domestic Assistance, 11.800 Minority Business Development)

Note.—A pre-application conference to assist all interested applicants will be held at the U.S. Department of Commerce, Minority Business Development Agency, 1371 Peachtree Street, NE., Suite 505, Atlanta, Georgia, Tuesday, November 29, 1988, at 10:00 a.m.

Carlton L. Eccles,

Regional Director, Atlanta Regional Office.

[FR Doc. 88-26406 Filed 11-15-88; 8:45 am]

BILLING CODE 3510-21-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Announcement of an Import Limit for Certain Cotton Textile Products Produced or Manufactured in the German Democratic Republic, East Germany

November 10, 1988.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs establishing a limit for the new agreement year.

EFFECTIVE DATE: January 1, 1989.

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854)

FOR FURTHER INFORMATION CONTACT: Jerome Turtola, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-4212. For information on the quota status of this limit, refer to the Quota Status Reports posted on the bulletin boards of each Customs port. For information on embargoes and quota re-openings, call (202) 377-3715.

SUPPLEMENTARY INFORMATION: A copy of the current bilateral textile agreement between the Governments of the United States and the German Democratic Republic is available from the Textiles Division, Economic Bureau, U.S. Department of State, (202) 647-1998.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedules of the United States Annotated (see **Federal Register** notice 53 FR 44937, published on November 7, 1988).

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements

Committee For The Implementation of Textile Agreements

November 10, 1988

Commissioner of Customs,
Department of the Treasury,
Washington, D.C. 20229.

Dear Mr. Commissioner: Under the terms of section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); pursuant to the Bilateral Cotton Textile Agreement, effected by exchange of notes dated December 10, 1986 and February 27, 1987, between the Governments of the United States and the German Democratic Republic; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on January 1, 1989, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton textile products in Category 334, produced or manufactured in Germany and exported during the twelve-month period beginning on

January 1, 1989 and extending through December 31, 1989, in excess of 19,500 dozen.

Imports charged to the category limit for the period January 1, 1988 through December 31, 1988 shall be charged against the level of restraint to the extent of any unfilled balance. In the event the limit established for that period has been exhausted by previous entries, such goods shall be subject to the level set forth in this directive.

The restraint limit set forth above is subject to adjustment in the future according to the provisions of the current bilateral agreement between the Governments of the United States and the Democratic Republic.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 88-26455 Filed 11-15-88; 8:45 am]

BILLING CODE 3510-DR-M

Announcement of Import Limits for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in the Arab Republic of Egypt

November 10, 1988.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs establishing limits for the new agreement year.

EFFECTIVE DATE: January 1, 1989.

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

FOR FURTHER INFORMATION CONTACT: Janet Heinzen, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-4212. For information on the quota status of these limits refer to the Quota Status Reports posted on the bulletin boards of each Customs port. For information on embargoes and quota re-openings, call (202) 377-3715.

SUPPLEMENTARY INFORMATION: A copy of the current bilateral agreement between the Governments of the United States and the Arab Republic of Egypt is available from the Textiles Division, Economic Bureau, U.S. Department of State, (202) 647-1998.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Catergories with the Harmonized Tariff Schedule of the United States Annotated (see **Federal Register** notice 53 FR 44937, published on November 7, 1988).

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee For The Implementation of Textile Agreements

November 10, 1988

Commissioner of Customs,
Department of the Treasury,
Washington, D.C. 20229.

Dear Mr. Commissioner: Under the terms of Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); and the Arrangement Regarding International Trade in Textiles done in Geneva on December 20, 1973, as further extended on July 31, 1986; pursuant to the Bilateral Textile Agreement, effected by exchange of notes dated December 7 and 28, 1977, as amended and extended, between the Governments of the United States and the Arab Republic of Egypt; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on January 1, 1989, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton and man-made fiber textile products in the following categories, produced or manufactured in Egypt and exported during the twelve-month period which begins on January 1, 1989 and extends through December 31, 1989, in excess of the following levels of restraint:

Category	Twelve-month restraint limit
218-220, 224-227, 313-317 and 326, as a group.	56,683,000 square meters equivalent.
Sublevels in the group:	
218	2,508,000 square meters.
219	14,421,000 square meters.
220	14,421,000 square meters.
224	14,421,000 square meters.
225	14,421,000 square meters.
226	14,421,000 square meters.
227	14,421,000 square meters.
313	23,073,600 square meters.
314	14,421,000 square meters.
315	14,421,000 square meters.
317	14,421,000 square meters.
326	2,508,000 square meters.
Limits not in a group:	
300/301	5,315,253 kilograms of which not more than 788,587 kilograms shall be in Category 301.
339	536,230 dozen.

Imports charged to the category limits for the period January 1, 1988 through December 31, 1988 shall be charged against those levels of restraint to the extent of any unfilled balances. In the event the limits established for that period have been exhausted by previous entries, such goods shall be subject to the levels set forth in this directive.

The limits set forth above are subject to adjustment in the future according to the provisions of the current bilateral agreement between the Governments of the United States and the Arab Republic of Egypt.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 88-26454 Filed 11-15-88; 8:45 am]

BILLING CODE 3510-DP-M

Amendment of Import Limits for Certain Wool Textile Products Produced or Manufactured in Uruguay

November 10, 1988.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs amending limits.

EFFECTIVE DATE: January 1, 1989.

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854)

FOR FURTHER INFORMATION CONTACT: Naomi Freeman, International Trade Specialist, Office of Textile and Apparel, U.S. Department of Commerce, (202) 377-4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port. For information on embargoes and quota re-openings, call (202) 377-3715.

SUPPLEMENTARY INFORMATION: Based upon the implementation of the Harmonized Commodity Code on January 1, 1989, the current limits for Categories 433, 435 and 442 are being amended.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States Annotated

(see **Federal Register** notice 53 FR 44937, published on November 7, 1988). Also see 53 FR 24121, published on June 27, 1988.

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

November 10, 1988.

Commissioner of Customs,
Department of the Treasury,
Washington, D.C. 20229.

Dear Mr. Commissioner: This directive amends, but does not cancel, the directive issued to you on June 22, 1988 by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of cotton and wool textile products, produced or manufactured in Uruguay and exported during the period July 1, 1988 through June 30, 1989.

Effective on January 1, 1989, the limits for wool textile products in the following categories are being increased:

Category	Amended twelve-month restraint limit [1] (dozen)
433	15,487
435	45,172
442	29,560

[1] The limits have not been adjusted to account for any imports exported after June 30,1988.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 88-26456 Filed 11-15-88; 8:45 am]

BILLING CODE 3510-DR-M

DEPARTMENT OF DEFENSE

Department of the Army

Military Traffic Management Command; Military/Industry Mobile Homes Symposium; Open Meeting

Announcement is made of meeting of the Military/Industry Mobile Homes Symposium. This meeting will be held on November 28, 1988 at Headquarters, Military Traffic Management Command, 5611 Columbia Pike, Falls Church, Virginia, and will convene at 0930 hours and adjourn at approximately 1500 hours.

Proposed Agenda

The purpose of the symposium is to provide an open discussion and free exchange of ideas with the public on procedural changes to Personal Property Traffic Management Regulation, DOD 4500.34-R, and the handling of other matters of mutual interest concerning the Department of Defense Personnal Property Shipment and Storage Program.

All interested persons desiring to submit topics to be discussed should contact the Commander, Military Traffic Management Command, ATTN: MT-PPM, at telephone number 756-1600, between 0800-1530 hours. Topics to be discussed should be received on or before November 18, 1988.

Dated: October 31, 1988.

Kenneth L. Denton,

Department of the Army, Alternate Liason Officer for the Federal Register.

[FR Doc. 88-26416 Filed 11-15-88; 8:45 am]

BILLING CODE 3710-08-M

U.S. Army Laboratory Command; Availability of a High-Q Stress-Compensated Crystal Device for Exclusive Licensing

In accordance with 37 CFR 404.7, announcement is made of the availability of a high-Q stress-compensated crystal device for exclusive licensing. An inventor at the U.S. Army Electronics Technology and Devices Laboratory (USAETDL) has been granted a patent on a new type of quartz crystal resonator. The rights to the resonator belong to the United States Government.

In addition to the desirable properties of temperature and stress compensation exhibited by the well known SC-cut, this new resonator (provisionally designated the SK-cut) is designated to have the highest possible Q for a quartz crystal resonator, almost double that of the SC-cut. Such an improvement in Q implies the potential for over 20dB reduction in close-in phase noise with this device. Laboratory tests of prototype resonators have been completed.

Under the authority of section 11 (a)(2) of the Federal Technology Transfer Act of 1986 (Pub. L. 99-502) and section 207 of Title 35, United States Code, the Department of the Army as represented by USAETDL wishes to exclusively license rights to the new resonator to a party interested in manufacturing and selling the resonator.

FOR FURTHER INFORMATION CONTACT: Mr. John A. Kosinski, U.S. Army Electronics Technology and Devices Laboratory, ATTN: SLCET-MA, Fort Monmouth, NJ 07703-5000; (201) 544-2843

John O. Roach, II,

Army Liaison Officer with the Federal Register.

[FR Doc. 88-26388 Filed 11-15-88; 8:45 am]

BILLING CODE 3710-08-M

U.S. Army Laboratory Command; Availability of a Method of Making a Low Aging Piezoelectric Resonator for Exclusive Licensing

In accordance with 37 CFR 404.7, announcement is made of the availability of a method of making a low aging piezoelectric resonator for exclusive licensing. An inventor at the U.S. Army Electronics Technology and Devices Laboratory (USAETDL) has been granted a patent on a technique for reducing contaimination transfer within the enclosure of a precision resonator. The rights to the technique belong to the United States Government.

The new technique involves appropriate application of a d.c. electric field to the resonator and package in order to reduce unwanted transfer of residual contaminants within the resonator enclosure. The technique may readily be applied to existing package types.

Under the authority of section 11 (a)(2) of the Federal Technology Transfer Act of 1986 (Pub. L. 99-502) and section 207 of Title 35, United States Code, the Department of the Army as represented by USAETDL wishes to exclusively license rights to the new method to a party interested in employing the method in the manufacture and sale of piezoelectric resonators.

FOR FURTHER INFORMATION CONTACT: Mr. John A. Kosinski, U.S. Army Electronics Technology and Devices Laboratory, ATTN: SLCET-MA, Fort Monmouth, NJ 07703-5000; (201) 544-2843

John O. Roach, II,

Army Liaison Officer with the Federal Register.

[FR Doc. 88-26389 Filed 11-15-88; 8:45 am.]

BILLING CODE 3710-08-M

DEPARTMENT OF EDUCATION

[CFDA No.: 84.117E]

Notice Inviting Applications for New Awards for Field-Initiated Studies Under the Educational Research Grant Program for Fiscal Year 1989

Purpose: To support field-initiated studies designed to advance educational theory and practice.

Weighting for Selection Criteria: The program regulations at 34 CFR 700.20(b)(4) authorize the Secretary to distribute an additional 25 points among the criteria described in the regulations at § 700.22 to bring the total to a maximum of 100 points. The Secretary will distribute the reserved 25 points as follows: 15 additional points to the criterion at § 700.22(f) (Significance), bringing the total for this criterion to 30 points; and 10 additional points to the criterion at § 700.22(g) (Technical soundness), bringing the total for this criterion to 25 points.

Deadline for Transmittal of Applications: March 3, 1989

Applications Available: December 2, 1988

Available Funds: $500,000

Estimated Range of Awards: $30,000 to $70,000

Estimated Average Size of Awards: $50,000

Estimated Number of Awards: 10

Project Period: 12 to 18 months

Applicable Regulations: (a) The regulations for the Educational Research Grant Program, 34 CFR Part 700. Final regulations for this program were published in the **Federal Register** on July 18, 1988 (53 FR 27108). (b) The Education Department General Administrative Regulations, 34 CFR Parts 74, 75, 77, and 78.

For Applications or Information Contact: Ms. Delores Monroe, Office of Research, Office of Educational Research and Improvement, U.S. Department of Education, 555 New Jersey Avenue NW., Washington, DC 20208-5646. Telephone Number (202) 357-6223.

Program Authority: 20 U.S.C. 1221e.

Dated: November 10, 1988.

Patricia M. Hines,

Acting Assistant Secretary for Educational Research and Improvement.

[FR Doc. 88-26506 Filed 11-15-88; 8:45 am]

BILLING CODE 4000-01-M

National Advisory Council on Educational Research and Improvement; Meeting, Education

AGENCY: National Advisory Council on Educational Research and Improvement.

ACTION: Full council meeting of the National Advisory Council on Educational Research and Improvement.

SUMMARY: This notice sets forth the schedule and agenda of a forthcoming meeting of the National Advisory Council on Educational Research and Improvement. This notice also describes the functions of the Council. Notice of this meeting is required under section 10(a)(2) of the Federal Advisory Committee Act.

DATE: December 8 and 9, 1988.

ADDRESS: The Council will meet on December 8 from 10:30 a.m. to 4 p.m. at the President's Room of the University of Miami Faculty Club, 1550 Brescia Avenue, Coral Gables, Florida 33124. The Council will continue its meeting in the same location from 9 a.m. to 3:30 p.m. on December 9.

FOR FURTHER INFORMATION CONTACT: Mary Grace Lucier, Executive Director, National Advisory Council on Educational Research and Improvement, 330 C Street SW., Room 4076, Washington, DC 20202-7579, (202) 732-1205.

SUPPLEMENTARY INFORMATION: The Council is authorized by section 405 of the 1972 Education Amendments, Pub. L. 92-318, as amended by the Higher Education Amendments of 1986 (Pub. L. 99-498, 20 U.S.C. 1221e). The Council advises the President, the Secretary of Education, and the Congress on policies and activities carried out by the Office of Educational Research and Improvement.

Meetings of the Council are open to the public. The agenda for December 8 includes briefings on the initiatives undertaken by the Dade County School System to assist students at risk and to prevent dropping out, and reports on efforts to prevent drug abuse and illiteracy. On December 9 members will discuss character education, academic and career counseling and issues in bilingual education.

Records are kept of all Council Proceedings and are available for public inspection at the Office of the National Advisory Council on Educational Research and Improvement, 330 C Street SW., Room 4076, Washington, DC 20202-7579, from the hours of 9 a.m. to 5 p.m. Monday through Friday.

Dated: November 10, 1988.

Mary Grace Lucier,

Executive Director.

[FR Doc. 88-26444 Filed 11-15-88; 8:45 am]

BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY

Office of Fossil Energy

National Petroleum Council; Open meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770), notice is hereby given of the following meeting:

Name: National Petroleum Council.

Date and Time: December 13, 1988, 9 a.m.

Place: The Madison Hotel, Dolley Madison Ballroom, 15th & M Streets, NW., Washington, DC.

Contact: Margie D. Biggerstaff, U.S. Department of Energy, Office of Fossil Energy (FE-1), Washington, DC 20585, Telephone: 202/586-4695.

Purpose: To provide advice, information, and recommendations to the Secretary of Energy on matters relating to oil and gas or the oil and gas industry.

Tentative Agenda

—Call to order by Edwin L. Cox, Chairman, National Petroleum Council.

—Remarks by the Honorable John S. Herrington, Secretary of Energy.

—Report of the NPC Committee on Petroleum Storage and Transportation.

—Consideration of administrative matters.

—Discussion of any other business properly brought before the National Petroleum Council.

—Public comment (10-minute rule).

—Adjournment.

Public Participation: The meeting is open to the public. The chairperson of the Council is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Any member of the public who wishes to file a written statement with the Council will be permitted to do so, either before or after the meeting. Members of the public who wish to make oral statements pertaining to agenda items should contact Margie D. Biggerstaff at the address or telephone number listed above. Requests must be received at least five days prior to the meeting and reasonable provision will be made to include the presentation on the agenda.

Transcripts: Available for public review and copying at the Public Reading Room, Room 1E-190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC, between 9:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays.

Issued at Washington, DC on November 9, 1988.

J. Robert Franklin,

Deputy Advisory Committee Management Officer.

[FR Doc. 88-26496 Filed 11-15-88; 8:45 am]

BILLING CODE 6450-01-M

Economic Regulatory Administration

[ERA Docket No. 88-45-NG]

Consolidated Fuel Corp.; Order Granting Blanket Authorization to Import and Export Natural Gas From and to Canada and Mexico

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Notice of order granting blanket authorization to import and export natural gas.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) gives notice that it has issued an order granting Consolidated Fuel Corporation (Consolidated) blanket authorization to import and export natural gas from and to Canada and Mexico. The order issued in ERA Docket No. 88-45-NG authorizes Consolidated to import and export up to a total of 100 Bcf of natural gas from and to Canada and Mexico, over a two-year period beginning on the date of first delivery.

A copy of this order is available for inspection and copying in the Natural Gas Division Docket Room, 3F-056, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586-9478. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m. Monday through Friday, except Federal holidays.

Issued in Washington, DC, November 8, 1988.

Constance L. Buckley,

Acting Director, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 88-26497 Filed 11-15-88; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-3476-9]

Agency Information Collection Activities Under OMB Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected cost and burden; where appropriate, it includes the actual data collection instrument.

FOR FURTHER INFORMATION CONTACT: Sandy Farmer at EPA, (202) 382-2740.

SUPPLEMENTARY INFORMATION:

Office of Water

Title: National Operations and Maintenance Excellence Awards Program Questionnaire (EPA ICR # 1287).

Abstract: This program awards publicly owned treatment works (POTWs) for outstanding operation and maintenance of their plants. POTWs submit questionnaires only if they would like to be considered for an award. An EPA panel selects award-winners based on established criteria. States review questionnaires before forwarding them to EPA.

Burden Statement: The estimated public reporting burden for this collection of information is 2 hours per POTW and 3.2 hours per State each year. This estimate includes the time to read instructions, gather necessary data, and complete and review the questionnaires.

Respondents: States and PTOWs.

Estimated No. of Respondents: 320.

Estimated Total Annual Burden on Respondents: 640 hours.

Frequency of Collection: 1 response per year.

Send comments regarding the burden estimate, or any other aspect of this collection of information, including suggestions for reducing the burden, to:

Sandy Farmer, U.S. Environmental Protection Agency, Information Policy Branch (PM-223), 401 M Street SW., Washington, DC 20460

and

Tim Hunt, Office of Management and Budget, Office of Information and Regulatory Affairs, 726 Jackson Place NW., Washington, DC 20503, (Telephone (202) 395-3084).

OMB Responses to Agency PRA Clearance Requests

EPA ICR # 1221; Milk Cow and Population Survey; was approved 10/19/88; OMB # 2080-0017; expires 10/31/91.

EPA ICR # 1230.04; New Source Review and Prevention of Significant Deterioration Permitting Programs; was approved 10/13/88; OMB # 2060-0003; expires 8/31/89.

EPA ICR # 0824.04; Ocean Dumping Regulation—Reports and Recordkeeping to Obtain Permit, Request Designation, and Report on Permitted Dumping Activities; was approved 10/11/88; OMB # 2040-0008, expires 10/31/91.

EPA ICR # 0002.03; General Pretreatment Regulations For Existing And New Sources; was approved 10/11/88; OMB # 2040-0009, expires 4/30/90.

EPA ICR # 0801; Uniform Hazardous Waste Manifest For Generators, Transporters, and Disposal Facilities; was approved 10/14/88; OMB # 2050-0039, expires 12/31/88.

EPA ICR # 1473; Health Significance of Bacteria Found In Point-Of-Entry Granular Activated Filters; was approved 10/25/88; OBM #2080-0034; expires 3/31/90.

Date: November 2, 1988.

Paul Lapsley,

Director, Information and Regulatory Systems Division.

[FR Doc. 88-26429 Filed 11-15-88; 8:45 am]

BILLING CODE 6560-50-M

[ER-FRL-3475-3]

Chetco River, OR; Ocean Dredged Material Disposal Site; Intent To Prepare an Environmental Impact Statement

AGENCY: U.S. Environmental protection Agency (EPA), Region 10.

ACTION: Notice of intent to prepare an environmental impact statement (EIS) on the final designation of an interim Ocean Dredged Material Disposal Site (ODMDS) located off the Chetco River, Oregon.

PURPOSE: The U.S. EPA, Region 10, in accordance with section 102(2)(c) of the National Environmental Policy Act (NEPA), and with the cooperation of the U.S. Army Corps of Engineers, Portland District, will prepare a draft EIS on the designation of an ODMDS off the Chetco River, Oregon. The EIS will provide the information necessary to designate an ODMDS. This Notice of Intent is issued pursuant to section 102 of the Marine Protection, Research, and Sanctuaries Act (MPRSA) of 1977, and 40 CFR Part 228 (Criteria for the Management of Disposal Sites for Ocean Dumping).

FOR FURTHER INFORMATION AND TO BE PLACED ON THE PROJECT MAILING LIST CONTACT: Mr. John Malek, Ocean Dumping Coordinator, U.S. Environmental Protection Agency, Region 10, 1200 Sixth Avenue WD-138, Seattle, Washington, 98101-3188, Phone (206) 442-1286. Questions regarding

disposal site studies may also be directed to: Mr. Rudd Turner, U.S. Army Engineer District, Planning Division, P.O. Box 2946, Portland, Oregon 97208-2946, Phone (503) 221-6463.

SUMMARY: The Chetco River navigation channel requires periodic maintenance dredging to ensure safe navigation. Disposal of dredged sediments at an interim designated ODMDS has occurred in the past. Studies to support final site designation were conducted by the Corps of Engineers, Portland District, and coordinated with EPA, Region 10. Designation of a final ODMDS site at this location will provide a feasible and environmentally acceptable disposal site for present and anticipated future maintenance work in the area.

Need for Action

The Corps of Engineers, Portland District, has requested that EPA designate an ODMDS offshore the Chetco River, Oregon, for disposal of sediments dredged to maintain the federally authorized navigation project and for disposal of materials during other actions authorized in accordance with section 103 of the MPRSA. EPA has voluntarily committed to prepare EISs in conjunction with ocean dumping site designations. This EIS will provide the necessary information to evaluate alternatives and designate a preferred ODMDS.

Alternatives

1. No action: The no action alternative is defined as not designating an ocean disposal site and termination of ocean disposal for this area.

2. Alternative disposal options in the nearshore, mid-shelf, and shelf break region of the Pacific Ocean, and on the uplands.

Scoping

A scoping meeting is not contemplated. Scoping will be accomplished with affected federal, state, and local agencies, and with interested parties by correspondence, telephone contract, etc.

Estimated Date of Release

The draft EIS will be available in Spring 1989.

Responsible Official

Gary L. O'Neal for Robie G. Russell, Regional Administrator, Region 10.

Dated: November 8, 1988.

Richard E. Sanderson,

Director, Office of Federal Activities.

[FR Doc. 88-26419 Filed 11-15-88; 8:45 am]

BILLING CODE 6560-50-M

[FRL-3477-2]

National Drinking Water Advisory Council; Open Meeting

Under section (10)(a)(2) of Pub. L. 92-423, "The Federal Advisory Committee Act," notice is hereby given that a meeting of the National Drinking Water Advisory Council established under the Safe Drinking Water Act, as amended (Pub. L. 99-339), will be held at 9:00 a.m. on December 1, 1988, and at 8:30 a.m. on December 2, 1988, at the St. James Hotel, 650 24th Street, NW., Washington, DC, in the St. James Room. Council Subcommittees will hold meetings on November 29 and 30, 1988.

The main purpose of this meeting is to update the Council on the status of and comments received on the Proposed Primary Enforcement Responsibility Regulation and the Proposed Lead and Copper Regulation. The Council will receive a briefing on the Draft Primary Drinking Water Regulations for Radionuclides, Synthetic Organic Chemicals and Inorganic Chemicals (Phase II), and Disinfection/Disinfection By-Products. The Council will also hear a panel discussion on the cost implications of Agency regulations on the water supply community.

This meeting will be open to the public. The Council encourages the hearing of outside statements and will allocate a portion of its meeting time for public participation. Oral statements will be limited to ten minutes. It is preferred that there be one presenter for each statement. Any outside parties interested in presenting an oral statement should petition the Council by telephone at (202) 382-2285. The petition should include the topic of the proposed statement, the petitioner's telephone number and should be received by the Council before November 28, 1988.

Any person who wishes to file a written statement can do so before or after a Council meeting. Written statements received prior to the meeting will be distributed to the members before any final discussion or vote is completed. Statements received after a meeting will become part of the permanent meeting file and will be forwarded to the Council members for their information.

Any member of the public wishing to attend the Council meeting, present an oral statement, or submit a written statement, should contact Ms. Charlene E. Shaw, Designated Federal Official, National Drinking Water Advisory Council, Office of Drinking Water (WH-550A), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

The telephone number is: Area Code 202/382-2285.

James R. Elder,

Acting Assistant Administrator for Water.

Date: November 9, 1988.

[FR Doc. 88-26430 Filed 11-15-88; 8:45 am]

BILLING CODE 6560-50-M

[OPP-240083; FRL-3477-6]

State Registration of Pesticides

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received notices of registration of pesticides to meet special local needs under section 24(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, from 32 States. A registration issued under this section of FIFRA shall not be effective for more than 90 days if the Administrator disapproves the registration or finds it to be invalid within that period. If the Administrator disapproves a registration or finds it to be invalid after 90 days, a notice giving that information will be published in the **Federal Register**.

DATE: The last entry for each item is the date the State registration of that product became effective.

FOR FURTHER INFORMATION CONTACT:

Owen F. Beeder, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 410 M Street SW., Washington, DC.

Office location and telephone number: Rm. 716A, CM # 2, 1921 Jefferson Davis Highway, Arlington, VA (703) 557-7893.

SUPPLEMENTARY INFORMATION: This notice only lists the section 24(c) applications submitted to the Agency. The Agency has 90 days to approve or disapprove each application listed in this notice. Applications that are not approved are returned to the appropriate State for action. Most of the registrations listed below were received by the EPA in July and August of 1988. Receipts of State registrations will be published periodically. Of the following registrations, none involve a changed-use pattern (CUP). The term "changed-use pattern" is defined in 40 CFR 162.3(k) as a significant change from a use pattern approved in connection with the registration of a pesticide product. Examples of significant change include, but are not limited to, changes from a nonfood to food use, outdoor to indoor use, ground to aerial application,

terrestial to aquatic use, and nondomestic to domestic use.

Alabama

EPA SLN No. AL 88 0004. Ciba-Geigy Corp., Agriculture Div. Registration is for Triumph 4E Insecticide to be used on golf courses and sod farms to control white grubs, mole crickets, and billbugs. July 13, 1988.

Arizona

EPA SLN No. AZ 88 0019. Hopkins Agricultural Chemical Co. Registration is for Ramik Green to be used on levee and ditch banks, around farm buildings, along fence lines, in orchards, or in other crop or noncrop areas to control rats and mice. July 6, 1988.

EPA SLN No. AZ 88 0020. Mobay Corp. Agricultural Chemicals Division. Registration is for Guthion 2L to be used on cotton to control cotton boll weevils. July 6, 1988.

EPA SLN No. AZ 88 0021. Fairfield American Corp. Registration is for Permanone VC 40 to be used for treatment of rodent nesting and bedding materials to control fleas and other ecto-parasites associated with ground squirrels, chipmunks, and domestic rats and mice. July 6, 1988.

EPA SLN No. AZ 88 0022. Fairfield American Corp. Registration is for Permanone Pyrenone Liquid Dust to be used only in insecticide-bait tubes to control fleas and other ectoparasites associated with ground squirrels, tree squirrels, chipmunks, and wild and domestic rats and mice. July 6, 1988.

EPA SLN No. AZ 88 0023. Fairfield American Corp. Registration is for Pyrenone and Permanone 0.5 Dust to be used only in insecticide-bait tubes or in direct application to rodent burrow openings for control of fleas and other ectoparasites associated with ground squirrels, tree squirrels, chipmunks, and wild and domestic rats and mice. July 6, 1988.

Arkansas

EPA SLN No. AR 88 0003. Fermenta Plant Protection Co. Registration is for DSMA Liquid to be used on cotton, turf, and noncrop areas to control various weeds. August 26, 1988.

California

EPA SLN No. CA 88 0014. Santa Barbara County Agricultural Commissioner. Registration is for Dupont Lannate Insecticide to be used on greenhouse-grown bell peppers to control armyworms. June 28, 1988.

EPA SLN No. CA 88 0016. Rincon-Vitova Insectaries. Registration is for Vinco Formaldehyde Solution to be used on sitotroga eggs to control predatory mites. July 18, 1988.

EPA SLN No. CA 88 0017. Santa Barbara County Agricultural Commissioner. Registration is for Rout Ornamental Herbicide to be used on field-grown gypsophilia to control various weeds. July 8, 1988.

EPA SLN No. CA 88 0018. Contra Costa County Dept. of Agriculture. Registration is for Neamcur 3 to be used on greenhouse-grown roses to control nematodes. July 11, 1988.

EPA SLN No. CA 88 0019. Modoc County Dept. of Agriculture. Registration is for Rovral Fungicide to be used on potatoes to control white mold. July 13, 1988.

EPA SLN No. CA 88 0021. Sutter County Dept. of Agriculture. Registration is for Monitor 4 Liquid Insecticide to be used on several citrus crops to control rindworm complex. August 9, 1988.

Connecticut

EPA SLN No. CT 88 0008. Ciba-Geigy Corp., Agricultural Div. Registration is for Triumph 4E Insecticide to be used on golf courses and sod farms to control armyworms, chinchbugs, clover mites, and sod webworms. July 5, 1988.

EPA SLN No. CT 88 0009. FMC Corp., Agricultural Chemical Group. Registration is for Furadan 4F Insecticide to be used on strawberries to control root weevils. July 12, 1988.

Delaware

EPA SLN No. DE 88 0002. Delaware Dept. of Agriculture Plant Industry Section. Registration is for Menthol to be used on honey-bee hives to control tracheal mites. July 11, 1988.

Florida

EPA SLN No. FL 88 0006. Chevron Chemical Co. Registration is for Orthene 75S Soluble Powder to be used on nonbearing citrus to control imported fire ants. July 19, 1988.

EPA SLN NO. FL 88 0007. Sun Refining and Marketing Co. Registration is for Sunspray 9E to be used on citrus to control several bugs, mites, and scales. July 25, 1988.

EPA SLN NO. FL 88 0008. Hi-Acres, Inc., Fertilizer Div. Registration is for Hi-Acres Soluble Oil Spray to be used on citrus to control spider mites, whiteflies, and certain scale insects. July 25, 1988.

EPA SLN NO. FL 88 0009. Farmbelt Chemicals, Inc. Registration is for Farmbelt 455 Soluble Oil to be used on citrus trees to control certain insect pests. July 25, 1988.

EPA SLN No. FL 88 0011. Platte Chemical Co. Registration is for Clean Crop Spray Oil 9E to be used on various citrus crops to control scales, spider mites, and whiteflies. August 17, 1988.

EPA SLN No. FL 88 0012. Asgrow Florida Co. Registration is for Citrus Oil 455 to be used on various crops of citrus to control scale insects in post bloom. August 25, 1988.

EPA SLN FL 88 0013. Agra Chem Sales Co., Inc. Registration is for Soluble 97 Oil–455 to be used on citrus to control spider mites, whiteflies, and certain scale insects. September 2, 1988.

Georgia

EPA SLN No. GA 88 0005. ICI Americas, Inc., Agricultural Products. Registration is for Relex 2LC Herbicide to be used on pine seedling nurseries to control yellow nutsedge (*Cyperus esculeutus*). July 28, 1988.

EPA SLNB No. GA 88 0007. Ciba-Geigy Corp., Agricultural Div. Registration is D-Z-N Diazinon 50 W to be used on nursery stock to control fire ants. August 10, 1988.

EPA SLN No. GA 88 0008. Ciba-Geigy Corp., Agricultural Div. Registration is D-Z-N Diazinon AG500 to be used on nursery stock to control fire ants. August 10, 1988.

Hawaii

EPA SLN No. HI 88 0006. Rohn and Haas Co. Registration is for Goal 1.6E Herbicide to be used on bearing and nonbearing macadamia nuts plantings to control certain annual broadleaf weeds. July 27, 1988.

Idaho

EPA SLN No. ID 88 0006. Platte Chemical, Inc. Registration is for Clean Crop Dimethoate 400 to be used on lentils to control aphids and lygus bugs. July 11, 1988.

EPA SLN No. ID 88 0008. Wilbur-Ellis Co. Registration is for Sulfur DF to be used on sugar beets to control red spider mites. July 20, 1988.

Indiana

EPA SLN No. IN 88 0004. FMC Corp. Registration is for Dimethoate 267 systemic insecticide to be used on soybeans to control spider mites. July 13, 1988.

EPA SLN No. IN 88 0005. Drexel Chemical Co. Registration is for Drexel Dimethoate 2.67 to be used on soybeans to control spider mites. July 14, 1988.

EPA SLN No. In 88 0006. Platte Chemical Co. Registration is for Clean Crop Dimethoate 267 EC Systemic Insecticide to be used on soybeans to control spider mites. July 14, 1988.

EPA SLN No. In 88–0007. Pennwalt Corp. Registration is for Penncap-M Microencapsulated Insecticide to be

used on soybeans to control spider mites. July 25, 1988.

EPA SLN No. IN 88 0008. J.R. Simplot Co. Registration is for Dimethoate 25 WP to be used on soybeans to control spider mites. July 28, 1988.

EPA SLN No. IN 88 0009. Universal Cooperatives, Inc. Registration is for Dimethoate 267 EC Systemic Insecticide to be used on soybeans to control spider mites. July 29, 1988.

EPA SLN No. IN 88 0010. Gowan Co. Registration is for Prokil Dimethoate W-25 Insecticide to be used on soybeans to control spider mites. July 29, 1988.

EPA SLN No. IN 88 0012. Dow Chemical U.S.A. Registration is for Lorsban 50 W Insecticide to be used on soybeans to control spider mites. August 3, 1988.

Iowa

EPA SLN No. IA 88 0003. FMC Corp. Registration is for Talstar 10 WP to be used on commercial outdoor ornamental plants to control spider mites. July 14, 1988.

EPA SLN No. IA 88 0004. Ciba-Geigy Corp., Agricultural Div. Registration is for Triumph 4E Insecticide to be used on golf courses and sod farms to control numerous turf pests. July 14, 1988.

EPA SLN No. IA 88 0005. Gowan Co. Registration is for Prokil Dimethoate E267 to be used on soybeans to control spider mites. July 14, 1988.

EPA SLN No. IA 88 0006. Drexel Chemical Co. Registration is for Drexel Dimethoate 2.67 to be used on soybeans to control spider mites. July 14, 1988.

EPA SLN No. IA 88 0007. FMC Corp. Registration is for Dimethoate 267 Systemic Insecticide to be used on field corn to control spider mites. July 18, 1988.

EPA SLN No. IA 88 0008. Platte Chemical Co. Registration is for Clean Crop Dimethoate 267 EC Systemic Insecticide to be used on soybeans to control spider mites. July 22, 1988.

EPA SLN No. IA 88 0009. J.R. Simplot Co. Registration is for Dimethoate 25 WP to be used on soybeans to control spider mites. July 26, 1988.

EPA SLN No. IA 88 0010. Aceto Agricultural Chemicals Co. Registration is for Dimethogon 25 WP Dimethoate Insecticide to be used on soybeans to control spider mites. July 26, 1988.

Louisiana

EPA SLN No. LA 88 0006. Rohm and Haas Co. Registration is for Goal 1.6E Herbicide to be used as premergence application on fallow beds to control various weeds. July 7, 1988.

EPA SLN No. LA 88 0007. Rohm and Haas Co. Registration is for Kelthane MF Agricultural Miticide to be used on pecans to control mites. July 20, 1988.

Maine

EPA SLN No. ME 88 0003. Chevron Chemical Co. Registration is for Ortho Diquat Herbicide to be used on potatoes for desiccation to facilitate harvest. August 18, 1988.

Michigan

EPA SLN No. MI 88 0008. Uniroyal Chemical Co. Registration is for Omite 6E to be used on apples to control European red and two-spotted spider mites. August 4, 1988.

EPA SLN No. MI 88 0009. Ciba-Geigy Corp., Agricultural Div. Registration is for Triumph 4E Insecticide to be used on tees, greens, and aprons of golf courses to control various insects. August 4, 1988.

EPA SLN No. MI 88 0010. Dow Chemical U.S.A. Agricultural Products Div. Registration is for Lorsban 50W Insecticide to be used on soybeans to control spider mites. August 4, 1988.

Minnesota

EPA SLN No. MN 88 0001. Metropolitan Mosquito Control District, St. Paul. Registration is for Zoecon Altosid Liquid Larvicide Mosquito Growth Regulator to be used on field sites as a larvicide growth regulator for control of mosquitos. June 6, 1988.

Mississippi

EPA SLN No. MS 88 0007. Ciba-Geigy Corp., Agricultural Div. Registration is for Triumph 4E Insecticide to be used on golf courses and sod fames to control various insects. July 12, 1988.

Missouri

EPA SLN No. MO 88 0004. FMC Corp. Registration is for Talstar 10 WP to be used on field-grown ornamental trees, shrubs, plants, and flowers to control mites. July 11, 1988.

EPA SLN No. MO 88 0005. Coopers Animal Health, Inc. Registration is for Saber™ Insecticide Ear Tags to be used on cattle to control horn flies. September 9, 1988.

Nebraska

EPA SLN No. NE 88 0005. Natural Fibers Corp. Registration is for Poast to be used on milkweed to control arious weeds and grass species. June 27, 1988.

Nevada

EPA SLN No. NV 88 0007. Uniroyal Chemical Co., Inc. Registration is for Comite-Alfalfa to be used on alfalfa grown for seed only to control two-spotted spider mite complex. July 14, 1988.

New Hampshire

EPA SLN No. NH 88 0001. Uniroyal Chemical, Inc. Registration is for Omite-6E to be used on apples to control European red and two-spotted spider mites. July 20, 1988.

New Jersey

EPA SLN No. NJ 88 0002. American Cyanamid Co. Registration is for Cythion Insecticide Malathion ULV Concentrate Insecticide to be applied in cities, towns, and other areas where automobiles, trailers, trucks, and pleasure boats are present to control mosquitoes. July 5, 1988.

EPA SLN No. NJ 88 0003. Fairfield American Corp. Registration is for Derringer Insecticide for use in mosquito abatement districts to control mosquitoes. July 7, 1988.

EPA SLN No. NJ 88 0004. Fairfield American Corp. Registration is for Permanone Tick Repellent to be used on domestic animals to control ticks, mosquitoes, and chiggers. July 20, 1988.

North Carolina

EPA SLN No. NC 88 0007. Ciba-Geigy Corp., Agricultural Div. Registration is for Triumph 4E Insecticide to be used on golf courses and sod farms to control various insects. July 14, 1988.

Ohio

EPA SLN No. OH 88 0003. Drexel Chemical Co. Registration is for Drexel Dimethoate 2.67 to be used on soybeans to control spider mites. August 1, 1988.

EPA SLN No. OH 88 0005. Drexel Chemical Co. Registration is for Drexel Diazinon Insecticide to be used on soybeans to control spider mites. August 1, 1988.

EPA SLN No. OH 88 0006. Dow Chemical U.S.A., Agricultural Products Dept. Registration is for Lorsban 50W Insecticide to be used on soybeans to control spider mites. August 2, 1988.

EPA SLN No. OH 88 0007. Platte Chemical Co., Inc. Registration is for Clean Crop Diazinon 500-Ag to be used on soybeans to control spider mites. August 3, 1988.

EPA SLN No. OH 88 0009. Gowan Co. Registration is for Prokil Dimethoate E267 to be used on soybeans to control two-spotted spider mites. August 16, 1988.

Oregon

EPA SLN No. OR 88 0007. J.T. Eaton & Co., Inc. Registration is for Eaton's Answer for the Control of Pocket Gophers to be used on rangeland, cropland, forest, and noncrop areas to control pocket gophers. August 19, 1988.

EPA SLN No. OR 88 0010. Platte Chemical Co., Inc. Registration is for Clean Crop Diazinon 500-AG to be used on grass and seed fields to control cranberry girdlers. June 24, 1988.

EPA SLN No. OR 88 0012. McLauglin Gormley King Co. Registration is for MGK Big Game Repellent Powder BGR-P to be used on conifer seedlings to control black-tailed deer and Roosevelt elk. June 27, 1988.

EPA SLN No. OR 88 0014. Platte Chemical Co. Registration is for Clean Crop Cheat Stop 90 WDG to be used on deep furrow seeded wheat for preplant preemergence control of downy brome (cheat grass). September 9, 1988.

EPA SLN No. OR 88 0015. Oregon Clover Association. Registration is for Mertect 340-F to be used to control seed-borne northern anthracnose (Kabatiella caulivora). August 31, 1988.

Pennsylvania

EPA SLN No. PA 88 0004. Fairfield American Corp. Registration is for Permanone Tick Repellent to be used on clothing to control ticks, chiggers, and mosquitoes. June 27, 1988.

EPA SLN No. PA 88 0005. Ciba-Geigy Corp., Agricultural Div. Registration is for Triumph 4E Insecticide to be used on golf courses and sod farms to control various insects. July 15, 1988.

EPA SLN No. PA 88 0006. B&W Quality Growers, Inc. Registration is for Kocide 101 to be used on watercrest to control cercospora. August 23, 1988.

South Carolina

EPA SLN No. SC 88 0004. Rohm & Haas Co. Registration is for Goal 1.6E Herbicide to be used on field corn to control witchweed (*Striga asiatica*). July 12, 1988.

EPA SLN No. SC 88 0005. Ciba-Geigy Corp. Agricultural Division. Registration is for Triumph 4E Insecticide to be used on tees, greens, and aprons of golf courses and sod farms to control several insects. August 5, 1988.

Tennessee

EPA SLN No. TN 88 0005. Ciba-Geigy Corp., Agricultural Div. Registration is for Triumph 4E Insecticide to be used on tees, greens, and aprons of golf courses and on sod farms to control several worms, bugs, and mites. August 17, 1988.

Virginia

EPA SLN No. VA 88 0004. Ciba-Geigy Corp., Agricultural Div. Registration is for Triumph 4E Insecticide to be used on golf courses and sod farms to control several insects. July 14, 1988.

EPA SLN No. VA 88 0005. Rhone-Poulenc Ag Co. Registration is for Larvin® Brand 3.2 Thiodicarb Insecticide to be used on soybeans to control several caterpillar worms. August 2, 1988.

EPA SLN No. VA 88 0006. Ciba-Geigy Corp., Agricultural Div. Registration is for Ridomil 2E Fungicide to be used on snap beans to control *pythium*. August 11, 1988.

Washington

EPA SLN No. WA 88 0013. Fermenta Plant Protection Co. Registration is for Bravo 720 to be used on nonbearing strawberries and nursery plants to control common leafspot. June 30, 1988.

EPA SLN No. WA 88 0015. ICI Americas, Inc. Agricultural Products. Registration is for Prefar 4E Herbicide to be used on bulb onions to control various grasses and weeds. July 20, 1988.

EPA SLN No. WA 88 0016. Drexel Chemical Co. Registration is for Dimethoate 4EC to be used on lentils to control alpha and lygus bugs. July 27, 1988.

EPA SLN No. WA 88 0017. Platte Chemical Co., Inc. Registration is for Thiodan 3EC to be used on seed alfalfa to control alfalfa aphids. July 27, 1988.

EPA SLN No. WA 88 0018. Platte Chemical Co., Inc. Registration is for Endocide 3EC to be used on seed alfalfa to control spotted alfalfa aphids. July 27, 1988.

EPA SLN No. WA 88 0019. Platte Chemical Co. Registration is for Clean Crop Cheat Stop 90 WDG to be used on deep furrow seeded winter wheat to control downy brome. August 25, 1988.

EPA SLN No. WA 88 0020. Abbott Laboratories, Chemical and Agricultural Products Div. Registration is for Dipel 2X to be used on hops to control loopers. August 3, 1988.

EPA SLN No. WA 88 0021. Gowan Co. Registration is for Phosphamidon 8 Spray to be used on apples to control green apple aphids. September 6, 1988.

Wisconsin

EPA SLN No. WI 88 0009. Wilbur-Ellis Co. Registration is for Red-Top Diazinon 14G to be used on cranberries to control cranberry girdler. July 18, 1988.

EPA SLN No. WI 88 0011. Rhone Poulenc Ag Co. Registration is for Butyrac 200 to be used on established birdsfoot trefoil grown for seed production to control weeds. August 1, 1988.

EPA SLN No. WI 88 0012. Agtrol Chemical Products. Registration is for Champion Wettable Powder to be used on gingseng to control *Alternaria* leaf and stem blight. August 13, 1988.

EPA SLN No. WI 88 0013. Wilbur-Ellis Co. Registration is for Wilbur-Ellis Snail & Slug Bait to be used on gingseng to control slugs. September 9, 1988.

West Virginia

EPA SLN No. WV 88 0002. B&W Quality Growers, Inc. Registration is for Kocide 101 to be used on watercress to control leaf spot. August 25, 1988.

EPA SLN No. WV 88 0003. Ciba-Geigy Crop., Agricultural Div. Registration is for Triumph 4E Insecticide to be used on golf course trees, greens, and aprons and on sod farms to control various insect pests. August 31, 1988.

(Sec. 24 as amended, 92 Stat. 835 (7 U.S.C. 136).)

Dated: November 4, 1988.

Douglas D. Campt,

Director, Office of Pesticide Programs.

[FR Doc. 88-26431 Filed 11-15-88; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

November 8, 1988.

The Federal Communications Commisson has submitted the following information collecton requirement to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act, as amended (44 U.S.C. 3501 *et seq.*).

Copies of the submission may be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street NW., Suite 140, Washington, DC 20037. For further information on this submission contact Jerry Cowden, Federal Communications Commission, (202) 632-7513. Persons wishing to comment on this information collection should contact Eyvette Flynn, Office of Management and Budget, Room 3235 NEOB, Washington, DC 20503, (202) 395-3785.

OMB Number: 3060-0187

Title: Section 73.3594, Local public notice of designation for hearing

Action: Extension

Respondents: Businesses (including small businesses)

Frequency of Response: On occasion

Estimated Annual Burden: 1,070 responses; 4,280 total hours; avg. 4 hour each.

Needs and Uses: Applicants of any AM, FM, or television broadcast station designated for hearing by the Commisison must give notice of such designation to the public. This notice gives interested parties as opportunity to respond.

Federal Communications Commission.
Donna R. Searcy,
Secretary.
[FR Doc. 88-26467 Filed 11-15-88; 8:45 am]
BILLING CODE 6712-01-M

FEDERAL HOME LOAN BANK BOARD

Arsenal Savings Association, FA, Indianapolis, IN; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 5(d)(6)(A) of the Home Owners' Loan Act, as amended, 12 U.S.C. 1464(d)(6)(A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole receiver for Arsenal Savings Association, FA, Indianapolis, Indiana, on September 26, 1988.

Dated: November 10, 1988.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,
Assistant Secretary.
[FR Doc. 88-26487 Filed 11-15-88; 8:45 am]
BILLING CODE 6720-01-M

Banc Home Savings Association, Midland, TX; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 406(c)(1)(B)(i)(I) of the National Housing Act, as amended, 12 U.S.C. 1729(c)(1)(B)(i)(I) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole receiver for Banc Home Savings Association, Midland, Texas, on October 14, 1988.

Dated: November 10, 1988.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,
Assistant Secretary.
[FR Doc. 88-26478 Filed 11-15-88; 8:45 am]
BILLING CODE 6720-01-M

First Federal Savings and Loan Association of Amarillo, Amarillo, TX; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 5(d)(6)(A) of the Home Owners' Loan Act of 1933, as amended, 12 U.S.C. 1464(d)(6)(A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole receiver for First Federal Savings and Loan Association of Amarillo, Amarillo, Texas, on October 14, 1988.

Dated November 10, 1988.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,
Assistant Secretary.
[FR Doc. 88-26484 Filed 11-15-88; 8:45 am]
BILLING CODE 6720-01-M

Heart O'Texas Savings Association, San Saba, TX; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 406(c)(1)(B)(i)(I) of the National Housing Act, as amended, 12 U.S.C. 1729(c)(1)(B)(i)(I) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole receiver for Heart O'Texas Savings Association, San Saba, Texas, on October 14, 1988.

Dated November 10, 1988.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,
Assistant Secretary.
[FR Doc. 88-26486 Filed 11-15-88; 8:45 am]
BILLING CODE 6720-01-M

Odessa Savings Association, Odessa, TX; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 406(c)(1)(B)(i)(I) of the National Housing Act, as amended, 12 U.S.C. 1729(c)(1)(B)(i)(I) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole receiver for Odessa Savings Association, Odessa, Texas, on October 14, 1988.

Dated: November 10, 1988.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,
Assistant Secretary.
[FR Doc. 88-26489 Filed 11-15-88; 8:45 am]
BILLING CODE 6720-01-M

Olney Savings Association, Olney, TX; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 406(c)(1)(B)(i)(I) of the National Housing Act, as amended, 12 U.S.C. 1729(c)(1)(B)(i)(I) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole receiver for Olney Savings Association, Olney Texas, on October 14, 1988.

Dated: November 10, 1988.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,
Assistant Secretary.
[FR Doc. 88-26485 Filed 11-15-88; 8:45 am]
BILLING CODE 6720-01-M

Petroplex Savings Association, Midland, TX; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 406(c)(1)(B)(i)(I) of the National Housing Act, as amended, 12 U.S.C. 1729(c)(1)(B)(i)(I) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole receiver for Petroplex Savings Association, Midland, Texas, on October 14, 1988.

Dated: November 10, 1988.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,
Assistant Secretary.
[FR Doc. 88-26488 Filed 11-15-88; 8:45 am]
BILLING CODE 6720-01-M

San Angelo Savings Association, San Angelo, TX; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 406(c)(1)(B)(i)(I) of the National Housing Act, as amended, 12 U.S.C. 1729(c)(1)(B)(i)(I) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole receiver for San Angelo Savings Association, San Angelo, Texas, on October 14, 1988.

Dated: November 10, 1988.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,
Assistant Secretary.
[FR Doc. 88-26483 Filed 11-15-88; 8:45 am]
BILLING CODE 6730-01-M

Security Federal Savings and Loan Association, Pampa, TX; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 5(d)(6)(A) of the Home Owners' Loan Act of 1933, as amended, 12 U.S.C. 1464(d)(6)(A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole receiver for Security Federal Savings and Loan Association, Pampa, Texas, on October 14, 1988.

Dated: November 10, 1988.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,

Assistant Secretary.

[FR Doc. 88-26480 Filed 11-15-88; 8:45 am]

BILLING CODE 6720-01-M

Shamrock Federal Savings Bank, Shamrock, TX; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 5(d)(6)(A) of the Home Owners' Loan Act of 1933, as amended, 12 U.S.C. 1464(d)(6)(A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole receiver for Shamrock Federal Savings Bank, Shamrock, Texas, on October 14, 1988.

Dated: November 10, 1988.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,

Assistant Secretary.

[FR Doc. 88-26479 Filed 11-15-88; 8:45 am]

BILLING CODE 6720-01-M

Southern Savings and Loan Association, Brownwood, TX; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 406(c)(1)(B)(i)(I) of the National Housing Act, as amended, 12 U.S.C. 1729(c)(1)(B)(i)(I) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole receiver for Southern Savings Loan Association, Brownwood, Texas, on October 14, 1988.

Dated: November 10, 1988.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,

Assistant Secretary.

[FR Doc. 88-26482 Filed 11-15-88; 8:45 am]

BILLING CODE 6720-01-M

Southwest Savings and Loan Association, Abilene, TX; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 406(c)(1)(B)(i)(I) of the National Housing Act, as amended, 12 U.S.C. 1729(c)(1)(B)(i)(I) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole receiver for Southwest Savings and Loan Association, Abilene, Texas, on October 14, 1988.

Dated November 10, 1988.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,

Assistant Secretary.

[FR Doc. 88-26481 Filed 11-15-88; 8:45 am]

BILLING CODE 6720-01-M

FEDERAL MARITIME COMMISSION

Agreement(s) Filed

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street, NW., room 10325. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 202-010270-030.

Title: Gulf-European Freight Association.

Parties:

Compagnie Generale Maritime (CGM)
Lykes Bros. Steamship Company, Inc.
Gulf Container Line (GCL), B.V.
Sea-Land Service, Inc.
Hapag-Lloyd AG
P&O Containers (TFL) Limited
Nedlloyd Lijnen, B.V.

Synopsis: The proposed modification would set forth rules of general applicability relating to the negotiations of specific service contract charges.

Agreement No.: 202-010656-030.

Title: North Europe Gulf Freight Association.

Parties:

Compagnie Generale Maritime (CGM)
Lykes Bros. Steamship Company, Inc.
Gulf Container Line (GCL), B.V.
Sea-Land Service, Inc.
Hapag-Lloyd AG
P&O Containers (TFL) Limited
Nedlloyd Lijnen, B.V.

Synopsis: The proposed modification would further clarify the parties' authority regarding open rates. Adherence to any agreement reached would be voluntary.

Agreement No.: 202-010656-031.

Title: North Europe Gulf Freight Association.

Parties:

Compagnie Generale Maritime (CGM)
Lykes Bros. Steamship Company, Inc.
Gulf Container Line (GCL), B.V.
Sea-Land Service, Inc.
Hapag-Lloyd AG
P&O Containers (TFL) Limited
Nedlloyd Lijnen, B.V.

Synopsis: The proposed modification would clarify the rights and obligations of members electing not to participate in specific service contracts and to propose rules of general applicability relating to the negotiations of specific service contract charges.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

Dated: November 10, 1988.

[FR Doc. 88-26413 Filed 11-15-88; 8:45 am]

BILLING CODE 6730-01-M

Agreement(s) Filed

The Federal Maritime Commission hereby gives notice that the following agreement(s) has been filed with the Commission pursuant to section 15 of the Shipping Act, 1916, and section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street, NW., Room 10325. Interested parties may submit protests or comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments and protests are found in § 560.7 and/or § 572.603 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Any person filing a comment or protest with the Commission shall, at the same time, deliver a copy of that document to the person filing the agreement at the address shown below.

Agreement No.: 224-200170.

Title: Port of Bellingham Terminal Lease Agreement.

Parties: State of Alaska (State) Port of Bellingham (Lessor).

Filing Party: Hugh M. Wilson, Manager Marine Terminals, Port of Bellingham, 625 Cornwall Avenue, Bellingham, Washington 98227-1737.

Synopsis: The agreement authorizes the lease of approximately six acres of property (Fanhaven Terminal) to State by Lessor for exclusive use of the

terminal ticketing/office area including managers office, staff toilet, and storage area, and the warehouse and port administration areas. The State will have priority use of the staging area, transfer bridge and morring structures. The term of this lease shall be for a period of twenty years from the first day of occupancy of the lease premises.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

Dated: November 10, 1988.

[FR Doc. 88-26476 Filed 11-15-88; 8:45 am]

BILLING CODE 6730-01-M

GENERAL SERVICES ADMINISTRATION

Agency Information Collection Activities Under OMB Review

The GSA hereby gives notice under the Paperwork Reduction Act of 1980 that it is requesting the Office of Management and Budget (OMB) to renew expiring information collection 3090-0006, Statement of Personal History. This form is used to investigate the suitability of guards, cleaners, and other persons applying for employment under GSA contracts.

AGENCY: Law Enforcement Division (PML), GSA.

ADDRESSES: Send comments to Bruce McConnell, GSA Desk Officer, Room 3235, NEOB, Washington, DC, 20503, and to Mary L. Cunningham, GSA Clearance Officer, General Services Administration (CAIR), F Street at 18th, NW., Washington, DC 20405.

Annual Reporting Burden: Individuals responding, 12,000; responses, 1 per year; average hours per response, .41; burden hours, 5,000.

FOR FURTHER INFORMATION CONTACT: Irene M. Arvey, 202-566-0494.

Copy of Proposal: A copy of the proposal may be obtained from the Information Collection Management Branch (CAIR), Room 3014, GS Bldg., Washington, DC 20405, or by telephoning 202-535-7691.

Dated: November 7, 1988.

Emily C. Karam,

Director, Information Management Division (CAI).

[FR Doc. 88-26390 Filed 11-15-88; 8:45 am]

BILLING CODE 6820-23-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Health

National Center for Health Services Research and Health Care Technology Assessment; Briefing Sessions

Name: Development of Assessment Teams—A Briefing Session for Prospective Grant Applicants

Date and Time: December 9, 1988—11:00 a.m. to 4:30 p.m.

Place: Parklawn Building, Conference Room D, 5600 Fishers Lane, Rockville, Maryland.

Supplementary Information: The National Center for Health Services Research and Health Care Technology Assessment (NCHSR) will conduct a briefing session to inform the research community of its interest in supporting Assessment Teams as a means to identify and analyze the outcomes and costs of alternative practice patterns as an extension of the Patient Outcome Assessment Research Program (POARP) during FY 1989.

The session is open to the general public. Expenses involved with attendance at the session will be the responsibility of the attendees.

For further information, please call Mr. Gerald Cohen, (301) 443-2080.

Dated: November 8, 1988.

J. Michael Fitzmaurice,

Director, National Center for Health Services Research and Health Care Technology Assessment.

[FR Doc. 88-26452 Filed 11-15-88; 8:45 am]

BILLING CODE 4160-17-M

Food and Drug Administration

[Docket No. 87D-0119]

In Vitro Diagnostic Devices (IVD's) Intended for Home Use; Draft Points To Consider Regarding Labeling and Premarket Submissions; Availability

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Assessing the Safety and Effectiveness of Home-Use In Vitro Diagnostic Devices (IVD's): Draft Points to Consider Regarding Labeling and Premarket Submissions." The draft document was prepared by FDA's Center for Devices and Radiological Health (CDRH) to assist persons manufacturing, importing, or distributing IVD's intended for home use to comply with FDA's current regulations and thereby ensure that such devices are safe and effective. FDA also is making the draft document available to describe to interested persons the issues involved with marketing IVD's intended for home use. FDA is taking this action under the Federal Food, Drug, and Cosmetic Act.

DATE: Comments received by February 14, 1989, will be considered by FDA in preparing a final points to consider document. The draft document and comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

ADDRESS: Written requests for single copies of the draft points to consider document and any written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. (Send two self-addressed adhesive labels to assist the Branch in processing your requests.)

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7234.

SUPPLEMENTARY INFORMATION: IVD's, as defined in FDA's regulations (21 CFR 809.3(a)), are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. IVD's are intended for use in the collection, preparation, and examination of specimens taken from the human body.

In most cases in the past, a physician supervised the collection of specimens from a patient's body and submitted the specimens to a clinical laboratory with instructions regarding which in vitro tests were to be done. Trained laboratory technicians performed the tests using IVD's. The clinical laboratory reported the test results to the patient's physician who then explained and interpreted the meaning of the test results to the patient.

There has been an increasing interest in recent years in the development of certain IVD's for consumers to purchase and use to perform tests on their own body specimens and interpret the results of their own diagnostic tests.

Accordingly, FDA is making available a document entitled "Assessing the Safety and Effectiveness of Home-Use In Vitro Diagnostic Devices (IVD's): Draft Points to Consider Regarding Labeling and Premarket Submissions." Interested persons may submit to the

Docket Management Branch (address above) written comments on the draft document at any time; however, comments submitted by February 14, 1989, will be considered by FDA in preparing a final points to consider document. The comments submitted will be used to determine whether any revisions of the document are warranted. Two copies of any comments should 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. The draft document and comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 5, 1988.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 88-26405 Filed 11-15-88; 8:45 am]

BILLING CODE 4160-01-M

Advisory Committees; Meetings

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

Meetings: The following advisory committee meetings are announced:

Dental Products Panel

Date, time, and place. December 16, 1988, 9 a.m., Conference Rms. D and E, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 9 a.m. to 10 a.m.; open committee discussion, 10 a.m. to 4 p.m.; Gregory Singleton, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7555.

General function of the committee. The committee reviews and evaluates available data on the safety and effectiveness of dental products and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before December 1, 1988, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will discuss a guide for the preparation and submission of dental endosseous implant premarket approval applications.

Oncologic Drugs Advisory Committee

Date, time, and place. December 19 and 20, 1988, 8:30 a.m., Conference Rms. D and E, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open committee discussion, December 19, 1988, 8:30 a.m. to 4 p.m.; open public hearing, 4 p.m. to 5 p.m., unless public participation does not last that long; open committee discussion, December 20, 1988, 8:30 a.m. to 5 p.m.; David F. Hersey, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695.

General function of the committee. The committee reviews and evaluates available data on the safety and effectiveness of marketed and investigational human drugs for use in cancer patients.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before December 5, 1988, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. On December 19, 1988, the committee will discuss: (1) NDA 19-880 Paraplatin® (carboplatin), Bristol Myers, for treatment of stages III and IV ovarian cancer, and (2) FDA requirements for approval of new drugs for treatment of superficial bladder cancer. On December 20, 1988, the committee will discuss: (1) NDA 19-884 Uromitexan® (mesna), Asta Pharma AG, for use with ifosfamide as a uroprotective agent, and (2) supplemental NDA 17-970/S-018 Nolvadex® (tamoxifen), Stuart Pharmaceutical Co., for treatment of premenopausal advanced breast cancer.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (Subpart C of 21 CFR Part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR Part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

Details on the agenda, questions to be addressed by the committee, and a current list of committee members are available from the contact person before and after the meeting. Transcripts of the open portion of the meeting will be available from the Freedom of

Information Office (HFI-35), Food and Drug Administration, Rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting will be available from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), and FDA's regulations (21 CFR Part 14) on advisory committees.

Dated: November 9, 1988.

Ronald G. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 88-26403 Filed 11-15-88; 8:45 am]

BILLING CODE 4160-01-M

Advisory Committee; Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

MEETING: The following advisory committee meeting is announced:

Vaccines and Related Biological Products Advisory Committee

Date, time, and place. November 18, 1988, 8:30 a.m., Lister Hill Auditorium, Bldg. 38A, National Library of Medicine, National Institutes of Health, 8600 Rockville Pike, Bethesda, MD.

Type of meeting and contact person. Open committee discussion, 8:30 a.m. to 12:30 p.m.; open public hearing, 12:30 p.m. to 1:30 p.m., unless public participation does not last that long; Jack Gertzog, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455.

General function of the committee. The committee reviews and evaluates available data on the safety and effectiveness of marketed and investigational human drugs for use in the diagnosis, prevention, or treatment of human diseases. The committee also reviews and evaluates the quality and relevance of FDA's research program which provides scientific support for the regulation of these products.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person as soon as possible.

Open committee discussion. The committee will discuss a treatment IND request for IMREG (an immunosupportive biologic agent). Seating capacity is limited and seating for the public will be on a first-come basis.

FDA is giving less than 15 days public notice of this Vaccines and Related Biological Products Advisory Committee meeting because it involves an expedited review of a biologic intended for a life-threatening illness, consistent with FDA's new initiative for expediting the review of such products. The next regularly scheduled meeting of the committee is January 30 to February 1, 1989. FDA did not believe it appropriate to wait that long. Attempts were made to schedule a committee meeting later in November or in early December to permit sufficient time for at least a 15-day public notice of the meeting. However, it was not possible to find a date during that period on which a quorum of committee members could meet. The agency decided that it was in the public interest to hold this scientific review on November 18, 1988, even if there was not sufficient time for the customary 15-day public notice.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee work.

Public hearings are subject to FDA's guideline (Subpart C of 21 CFR Part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR Part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

Details on the agenda, questions to be addressed by the committee, and a current list of committee members are available from the contact person before and after the meeting. Transcripts of the open portion of the meeting will be available from the Freedom of Information Office (HFI-35), Food and Drug Administration, Rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting will be available from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), and FDA's

regulations (21 CFR Part 14) on advisory commttees.

Dated: November 14, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88-26556 Filed 11-11-88; 11:47 am]

BILLING CODE 4160-01-M

[Docket No. 88N-0387]

Public Meeting; Seafood Safety as Related to Cooked and Processed Seafood

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting with the seafood industry and other interested persons to discuss a number of agency concerns relating to public health aspects of cooked and processed seafood.

DATES: The meeting will be held Friday, December 16, 1988, 9:30 a.m. to 3 p.m. Interested persons who will be unable to attend the meeting may submit written comments on the issues outlined in this notice by January 16, 1989.

ADDRESSES: The meeting will be held in the auditorium of the Hubert H. Humphrey Bldg., 200 Independence Ave. SW., Washington, DC 20201. Written comments should be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, referencing the Docket No. found in the heading of this notice.

FOR FURTHER INFORMATION CONTACT: John M. Tisler, Center for Food Safety and Applied Nutrition (HFF-326), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0255.

SUPPLEMENTARY INFORMATION: The meeting is being sponsored by FDA, in accordance with 21 CFR 10.65(b), to discuss with the seafood industry and other interested persons the agency's concerns raised by its inspectional and analytical findings relating to cooked and processed seafood.

Issues to be discussed will include:

1. Microbiological contamination of ready-to-eat or heat-and-serve seafood products.
2. Public health concerns relating to these products.
3. Improved processing practices for these products.
4. Strategies for protecting the consumer from associated health risks.

FDA is inviting all interested persons to participate in this meeting. Interested persons who will be unable to attend the meeting may submit to FDA written comments that set forth their views on the issues outlined in this notice.

Dated: November 9, 1988.

Ronald G. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 88-26402 Filed 11-10-88; 8:45 am]

BILLING CODE 4160-01-M

Consumer Participation; Open Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following district consumer exchange meeting:

Dallas District Office, chaired by Gerald E. Vince, District Director. The topic to be discussed is new drug development in the United States.

DATE: Monday, November 28, 1988, 1:30 p.m. to 3:30 p.m.

ADDRESS: Texas Pharmaceutical Association, 1624 East Anderson Lane, Austin, TX 78723.

FOR FURTHER INFORMATION CONTACT: Juan A. Tijerina, Consumer Affairs Officer, Food and Drug Administration, 727 East Durango, Rm. B-406, San Antonio, TX 78206-1200, 512-229-6737.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's district offices, and to contribute to the agency's policymaking decisions on vital issues.

Dated: November 9, 1988.

Ronald G. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 88-26404 Filed 11-15-88; 8:45 am]

BILLING CODE 4160-01-M

Health Resources and Services Administration

Final Funding Priority for Grants for Predoctoral Training in Family Medicine

The Health Resources and Services Administration announces the final funding priority for Grants for Predoctoral Training in Family Medicine which will be applied in the review of applications for Fiscal Year 1989.

Section 786(a) of the Public Health Service Act authorizes the award of grants to assist in meeting the cost of planning, developing and operating or participating in approved predoctoral training programs in the field of family medicine. Grants may include support for the program only or support for both the program and the trainees.

To receive support, programs must meet the requirements of regulations as set forth in 42 CFR Part 57, Subpart Q.

Review Criteria

The review of applications will take into consideration the following criteria:

1. The potential effectiveness of the proposed project in carrying out the education purposes of section 786(a) of the Act;
2. The degree to which the project plan adequately provides for meeting the requirements;
3. The administrative and management ability of the applicant to carry out the proposed project in a cost-effective manner; and
4. The potential of the project to continue on a self-sustaining basis after the period of grant support.

In addition, the following mechanisms may be applied in determining the funding of approved applications:

1. Funding preferernces—Funding of a specific category or group of approved applications ahead of other categories or groups of applications, such as competing continuations ahead of new projects.
2. Funding priorities—favorable adjustment of review scores by HRSA staff when applications meet specified objective criteria.
3. Special considerations—enhancement of priority scores by merit reviewers based on the extent to which applications address special areas of concern.

A proposed funding priority was published in the **Federal Register** of August 15, 1988, (53 FR 30719) for Grants for Predoctoral Training in Family Medicine. One comment was received during the 30 day comment period in support of increasing primary care services to special populations.

Therefore, the funding priority as proposed is retained as follows:

A funding priority will be given to projects in which substantial training experience is in a PHS 332 health manpower shortage area and/or PHS 329 migrant health center, PHS 330 community health center of PHS 781 funded Area Health Education Center or State designated clinic/center serving an underserved populations.

This program is listed at 13.986 in the *Catalog of Federal Domestic Assistance.* It is not subject to the provisions of Executive Order 12372, Integovernmental Review of Federal

Programs (as implemented through 45 CFR Part 100).

Dated: November 9, 1988.

John H. Kelso,

Acting Administrator.

[FR Doc. 88-26401 Filed 11-15-88; 8:45 am]

BILLING CODE 4160-15-M

National Institutes of Health

Division of Research Resources; General Research Support Review Committee; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Minority Biomedical Research Support Subcommittee (MBRSS) of the General Research Support Review Committee (GRSRC), on November 18, 1988, which was published in the **Federal Register**, August 12, 1988, (53 FR 30472-30473).

This meeting was to have met in closed session on November 18, from 8:30 a.m. to 12:00 noon. The meeting will now be open to the public from 8:30 a.m. to 11:00 a.m. in Conference Room 9, Building 31C, National Institutes of Health, to discuss policy matters relating to the Minority Biomedical Research Support Program. The meeting will be closed to the public from 1:00 p.m. to adjournment for the review of grant applications.

Dated: November 10, 1988.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 88-26669 Filed 11-15-88; 10:15 am]

BILLING CODE 4140-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Land Records for Saginaw Chippewa Indian-Owned Lands in the State of Michigan

ACTION: Notice; Transfer of custody.

SUMMARY: This notice is published in accordance with 25 CFR 150 and in exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs under 209 DM 8.1. As of January 1, 1989, the official custody of all Saginaw Chippewa land records and title documents pertaining to Indian-owned trust or restricted lands under the jurisdiction of the Minneapolis Area Office, Minneapolis, Minnesota, and the Michigan Agency, Sault Ste. Marie, Michigan, whether within or outside the boundaries of the Isabella or Saginaw Chippewa Indian Reservation is transferred from the Central Office, Washington, DC, to the Aberdeen Land Titles and Records Office, Bureau of Indian Affairs, 115 4th Avenue SE., Aberdeen, South Dakota 57401. The Aberdeen Land Titles and Records Office is thereafter the official office of record for the recording and maintenance of these records.

EFFECTIVE DATE: January 1, 1989.

FOR FURTHER INFORMATION CONTACT: Quentin M. Jones, Land Records Officer, Division of Real Estate Services, Bureau of Indian Affairs, 18th and C Streets NW., Washington, DC 20245.

W.P. Ragsdale,

Acting Assistant Secretary—Indian Affairs.

[FR Doc. 88-26391 Filed 11-15-88; 8:45 am]

BILLING CODE 4310-02-M

Bureau of Land Management

[ID-943-09-4214-10; I-18246]

Termination of Recreation and Public Purpose Classification; Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Classification termination.

SUMMARY: This order terminates a Bureau of Land Management classification affecting 120 acres of public land near Portneuf, Idaho. After termination of the classification, the underlying lands will immediately become available for disposal through a pending public sale action.

EFFECTIVE DATE: November 16, 1988.

FOR FURTHER INFORMATION CONTACT: Nancy Bloyer, BLM, Idaho State Office, 3380 Americana Terrace, Boise, Idaho 83706, 208-334-1471.

By virtue of the authority vested in the Secretary of the Interior by the Recreation and Public Purposes Act of June 14, 1926, as amended; 43 U.S.C. 869; 869-4; it is ordered as follows:

1. Pursuant to the regulations in 43 CFR 2091.7-1(b)(1) and the authority delegated to me by BLM Manual Section 1203 (48 FR 85), the classification decision of February 28, 1983, which classified 120 acres of public land as suitable for recreation and public purposes under the Act of June 14, 1926, as amended; 43 U.S.C. 869; 869-4, under serial number I-18246, is hereby revoked insofar as it affects the following-described lands:

Boise Meridian

T. 7 S., R. 35 E.

Sec. 28, W½SW¼, SE¼SW¼.

The area described contains 120 acres in Bannock County.

2. Upon termination of the classification, the underlying lands will immediately become available for disposal through a pending public sale action under section 203 of the Federal Land Policy and Management Act of 1976.

Delmar D. Vail,

State Director.

Dated: November 9, 1988.

[FR Doc. 88-26408 Filed 11-15-88; 8:45 am]

BILLING CODE 4310-66-M

[UT-040-09-4830-12]

Cedar City District Advisory Council; Meeting

Notice is hereby given in accordance with Pub. L. 92-463, that a meeting of the Cedar City District Advisory Council will be held Friday, December 2, 1988. The meeting will begin at 9:30 a.m. in the BLM office at 176 East DL Sargent Drive, Cedar City, Utah. The agenda will include: Dixie Resource Area land use planning; riparian policy; Recreation 2000 program; and updates on the Desert Tortoise program.

All Advisory Council meetings are open to the public. Interested persons may make oral statements at 9:45 a.m., or submit written comments for the Council's consideration. Anyone wishing to make an oral statement must notify the District Manager, 176 East DL Sargent Drive, Cedar City, Utah 84720 by November 30, 1988. Depending on the number of persons wishing to make a statement, a per person time limit may be established by the District Manager or the Council Chairman.

Date: November 7, 1988.

David F. Everett,

Acting District Manager.

[FR Doc. 88-26394 Filed 11-15-88; 8:45 am]

BILLING CODE 4310-00-M

[NM-040-09-4212-08]

Kansas Supplemental Planning Analysis; Availability and Public Meeting

AGENCY: Bureau of Land Management, Interior, Tulsa District, Oklahoma.

ACTION: Notice of availability/notice of public meeting.

SUMMARY: The Bureau of Land Management (BLM), Oklahoma Resource Area of the Tulsa District, has prepared a Supplement to the 1987 document Planning for Proposed Disposal of Public Lands in Kansas. This Supplemental Planning Analysis (SPA) addresses the disposal of Federally owned surface estate managed by the BLM within the State of Kansas. The

known BLM managed Federal surface estate within Kansas consists of 1,023.49 acres, located on 21 isolated tracts, within 15 Kansas Counties. The Proposed Action analyzed by the SPA is the transfer of public lands with fish and wildlife values to the Kansas Department of Wildlife and Parks (KDWP), and the transfer into private ownership of those tracts of public lands meeting the provisions of the Color-of-Title Act of December 22, 1928 (45 Stat. 1069; 43 U.S.C. 1068, 1068a).

Availability: The subject document has been sent to all persons on the SPA mailing list. Additional copies of the SPA are available upon request from the Resource Area Manager at the address below.

Public Meeting: A public meeting/open house will be held to provide the public an opportunity to comment on the proposed action. BLM representatives will receive both oral and written comments at this public meeting/open house. The public meeting/open house will be held December 14, 1988, in Great Bend, Kansas at the Best Western Angus Inn, Second floor meeting room, 2920 10th Street, from 3:00 p.m. to 7:00 p.m.

Comments: In addition to the public meeting/open house, written comments and suggestions concerning the proposed action will be received until close of business, December 21, 1988, at the Oklahoma Resource Area Office.

ADDRESS: Comments and suggestions concerning this Proposed Action should be sent to: Area Manager, Bureau of Land Management, Oklahoma Resource Area, 200 W. Fifth Street, Room 548, Oklahoma City, Oklahoma 73102.

FOR FURTHER INFORMATION CONTACT: Brian Mills, Oklahoma Resource Area, (405) 231-5491.

Dated: November 9, 1988.

Monte G. Jordan,

Associate State Director.

[FR Doc. 88-26407 Filed 11-15-88; 8:45 am]

BILLING CODE 4310-FB-M

[AZ 020-41-5410-ZAFA; AZA-23560]

Receipt of Conveyance of Mineral Interest Application; Arizona

ACTION: Notice of receipt of conveyance of mineral interest application, AZA-23560.

Notice is hereby given that pursuant to section 209 of the Act of October 21, 1976, 90 Stat. 2757, ANAM, Inc., has applied to purchase the mineral estate described as follows:

Gila and Salt River Meridian, Arizona

T. 6 S., R. 12 E.,
Sec. 33, S½S½;
Sec. 34, S½.
T. 7 S., R. 11 E.,
Sec. 25, all.
T. 7 S., R. 12 E.,
Sec. 3, lots 1, 2, S½NE¼.
T. 7 S., R. 13 E.,
Sec. 12, S½;
Sec. 13, E½;
Sec. 27, SW¼SW¼.
T. 7 S., R. 14 E.,
Sec. 17, E½, S½NW¼, SW¼;
Sec. 21, N½NW¼;
Sec. 26, S½NW¼, S½;
Sec. 27, W½;
Sec. 28, E½, SW¼;
Sec. 29, N½, N½SW¼, SE¼SW¼, SE¼;
Sec. 30, NE¼NE¼;
Sec. 31, lots 1 to 4, incl., SE¼SW¼, S½ SE¼;
Sec. 32, W½;
Sec. 33, W½, SE¼,
Sec. 35, N½N½, SE¼NE¼, SW¼NW¼.
T. 8 S., R. 13 E.,
Sec. 8, E½;
Sec. 9, S½;
Sec. 11, E½;
Sec. 12, SW¼NW¼, W½SW¼, SE¼ SW¼;
Sec. 13, N½N½;
Sec. 14, SW¼, S½SE¼;
Sec. 15, E½SW¼, W½SE¼;
Sec. 22, all;
Sec. 23, E½NE¼, SW¼NE¼, N½NW¼, SW¼NW¼, S½;
Sec. 25, all;
Sec. 26, N½;
Sec. 27, all.
T. 8 S., R. 14 E.,
Sec. 2, S½;
Sec. 5, all;
Sec. 6, lot 6, NE¼SW¼;
Sec. 7, E½;
Sec. 8, all;
Sec. 11, N½;
Sec. 14, all;
Sec. 18, lots 1, NE¼, NE¼NW¼;
Sec. 20, W½;
Sec. 22, SE¼;
Sec. 23, S½S½;
Sec. 24, E½, SW¼;
Sec. 26, N½N½;
Sec. 27, NE¼;
Sec. 29, N½NW¼;
Sec. 30, NE¼, N½SE¼.

Containing 15,207.25 acres, more or less.

Additional information concerning this application may be obtained from the Area Manager, Phoenix Resource Area, Phoenix District Office, 2015 West Deer Valley Road, Phoenix, Arizona 85027.

Upon publication of this notice in the **Federal Register**, the mineral interests described above will be segregated to the extent that they will not be open to appropriation under the public land laws, including the mining laws. The segregative effect of the application shall terminate either upon issuance of a patent or other document of conveyance of such mineral interests, upon final rejection of the application or two years from the date of filing of the application, October 5, 1988, whichever occurs first.

Henri R. Bisson,

District Manager.

Date: October 27, 1988.

[FR Doc. 88-26395 Filed 11-15-88; 8:45 am]

BILLING CODE 4310-32-M

[CA-020-09-4050-90; CA20656]

Realty Action; Classification of Public Lands in Lassen County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action; classification of Public Lands under the Recreation and Public Purposes Act, in Lassen County, CA, (CA20656).

SUMMARY: The following described public lands are hereby classified as suitable for lease under the Recreation and Public Purposes Act of June 14, 1926, as amended (43 U.S.C. 869 *et seq.*):

T. 30N., R. 13E., M.D.M., California

Section 17; W½ N½ NW¼ NE¼, W½ E½ N½ NW¼ NE¼.

Total: 15 acres.

These lands are proposed to be leased to the Lassen County Board of Supervisors for 20 years, with option to renew the lease, for the construction and operation of a flying site and landing field for radio controlled model airplanes. The lease shall be subject to the standard terms and conditions of a Recreation and Public Purposes Act Lease as contained on BLM Form 2912-1. In addition, the lease will contain special stipulations designed to mitigate environmental impacts and to protect valid existing rights.

These stipulations will require the lessee to: (1) Develop the site in accordance with the Plan of Development and Site Plan; (2) close livestock control gates or install cattle guards if needed; (3) paint all buildings in colors that blend with the area and to maintain all structures in good repair; (4) locate facilities at least 100 feet from a nearby county road; (5) cause no interference with existing road right-of-way CA 12431, and to maintain that portion of CA 12431 that runs through the lease; (6) carry liability insurance covering all use at the site; (7) design and install sanitary facilities in accordance with local health codes; (8) remove all trash or refuse from the site; (9) reclaim and rehabilitate the site in the event the lease is relinquished or terminated.

The above described public lands are hereby segregated from all other forms of disposal, entry or appropriation under the public land laws, including locations under the mining laws, but not to leasing under the mineral leasing laws. Any minerial leases issued would contain a no surface occupancy clause. The segregative effect of this notice shall automatically expire 18 months after publication of this notice, if no application is filed or if no lease is issued. If a lease is issued, the segregation will continue for the term of the lease, unless this notice is amended or revised.

Comments: For a period of 45 days after publication of this notice in the Federal Register, comments may be sent to the District Manager, Bureau of Land Management, 705 Hall St., Susanville, CA 96130. Comments will be evaluated by the California State Director of the Bureau of Land Management, who may affirm, vacate or modify this classification.

Information: For additional information on this matter call or write the Eagle Lake Area Manager, Bureau of Land Management, 2545 Riverside Drive, Susanville, CA 91630. Telephone (916) 257-0456.

Richard H. Stark, Jr.,

Eagle Lake Area Manager.

November 2, 1988.

[FR Doc. 88-26392 Filed 11-15-88; 8:45 am]

BILLING CODE 4310-40-M

[ID-943-09-4212-13; I-23055]

Realty Action; Issuance of Land Exchange Conveyance Document; Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Exchange of public and private lands.

SUMMARY: The United States has issued an exchange conveyance document to Larry M. Bull, Jr., Pocatello, Idaho 83204, for the following-described lands under section 206 of the Federal Land Policy and Management Act of 1976:

Boise Meridian

T. 7 S., R. 35 E.,
Sec. 23, SW¼SE¼;
Sec. 26, N½NW¼, NW¼NE¼.
Comprising 160.00 acres of public land.

In exchange for these lands, the United States acquired the following-described lands:

Boise Meridian

T. 7 S., R. 35 E.,
Sec. 36, SE¼SW¼, SW¼SE¼,
Sec. 35, NE¼NW¼, NW¼NE¼.
Comprising 160.00 acres of private land.

The purpose of the exchange was to acquire the non-federal lands for use in wildlife habitat and riparian management. The public interest was well served through completion of this exchange.

The values of the federal public land and the non-federal land in the exchange were both appraised at the equal value of $32,000.00.

John Davis,

Deputy State Director for Operations.

Dated: November 4, 1988.

[FR Doc. 88-26393 Filed 11-15-88; 8:45 am]

BILLING CODE 4310-GG-M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-242]

Certain Dynamic Random Access Memories, Components Thereof and Products Containing Same; Change of Commission Investigative Attorney

Notice is hereby given that, as of this date, Deborah D. Sorkin, Esq., of the Office of Unfair Import Investigations will be the Commission investigative attorney in the above-cited investigation instead of Gary J. Rinkerman, Esq.

The Secretary is requested to publish this Notice in the Federal Register.

Lynn I. Levine,

Director, Office of Unfair Import Investigations.

Dated: November 10, 1988.

[FR Doc. 88-26492 Filed 11-15-88; 8:45 am]

BILLING CODE 7020-02-M

[Investigation No. 337-TA-276]

Certain Erasable Programmable Read Only Memories, Components Thereof, Products Containing Such Memories, and Processes for Making Such Memories; Change of Commission Investigative Attorney

Notice is hereby given that, as of this date, Deborah D. Sorkin, Esq., of the Office of Unfair Import Investigations will be the Commission investigative attorney in the above-cited investigation instead of Gary J. Rinkerman, Esq.

The Secretary is requested to publish this Notice in the Federal Register.

Lynn I. Levine,

Director, Office of Unfair Import Investigations.

Dated: November 10, 1988.

[FR Doc. 88-26493 Filed 11-15-88; 8:45 am]

BILLING CODE 7020-02-M

[332-265]

United States-Israel Free-Trade Agreement; Probable Effects on U.S. Industry and Consumers of Certain Remaining U.S. and Israel Tariff Reductions

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation and scheduling of hearing.

SUMMARY: Following receipt on September 28, 1988, of a request from the U.S. Trade Representative made at the direction of the President, the Commission instituted investigation No. 332-265 under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)) to—

1. Advise the President, with respect to each article contained in the attached annex 1, as to the probable economic effect on domestic industries in the United States producing like or directly competitive products, and on consumers, of the removal of the duties on these products of Israel in six equal annual stages commencing on January 1, 1990, compared with the probable economic effect of the elimination of these duties without staging on January 1, 1995, the latest date for duty elimination provided in the implementing legislation for the Agreement.

2. Report on the likely economic benefits to U.S. exporters of products in the attached annex 2 of a similar six-stage elimination of the Israeli duties over the period in question. Annex 2 lists the products in terms of the headings in the Israeli tariff schedule prior to Israel's adoption of the Harmonized System.

EFFECTIVE DATE: November 8, 1988.

FOR FURTHER INFORMATION CONTACT:

(1) Agricultural products, Mr. Doug Newman (202-252-1328)

(2) Textiles and apparel, Mr. Larry Butler (202-252-1470)

(3) Chemical products, Mr. Edward Matusik (202-252-1356)

(4) Minerals and metals, Ms. Ann Reed (202-252-1428)

(5) Machinery and equipment, Mr. John Cutchin (202-252-1396)

(6) General manufactures, Mr. Richardo Witherspoon (202-252-1489)

All of the above are in the Commission's Office of Industries. For information on legal aspects of the investigation contact Mr. William Gearhart of the Commission's Office of the General Counsel at 202-252-1091.

Background

The Agreement on the establishment of a Free Trade Area between the Government of the United States of America and the Government of Israel, entered into in April 1985, provides that all products of Israel imported into the United States and all products of the United States imported into Israel which conform to the conditions specified in the Agreement shall be free of duty by January 1, 1995.

Duties on a large number of articles were removed immediately upon implementation of the Agreement on September 1, 1985. For virtually all remaining articles, staged removal of the duty began on September 1, 1985. For a short list of articles, however, the Agreement specified that the most-favored-nation rate would continue to apply until January 1, 1990, and that the rates to be applied on and after January 1, 1990, shall be determined after consultation between the Governments of Israel and the United States. Nevertheless, effective January 1, 1995, these articles are to be free of duty. Any reduction of these duties prior to January 1, 1995, however, requires Congressional approval.

Preparatory to entering into consultations with the Government of Israel on the U.S. and Israel rates of duty to be applied on the articles in Annex 1 and Annex 2 when imported on and after January 1, 1990, the USTR requested the assistance of the Commission in providing probable economic effects advice.

Public Hearing

A public hearing in connection with the investigation will be held in the Commission Hearing Room, 500 E Street SW., Washington, DC, beginning at 9:30 a.m. on January 24, 1989, and continuing as required on January 25. All persons shall have the right to appear by counsel or in person, to present information, and to be heard. Persons wishing to appear at the public hearing should file requests to appear and should file prehearing briefs (original and 14 copies) with the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436, not later than 5:00 p.m., January 10, 1989. Post-hearing briefs are required by February 7, 1989.

Written Submissions

In lieu of or in addition to appearances at the public hearing, interested persons are invited to submit written statements concerning the investigation. Written statements should be received by the close of business on February 7, 1989. Commercial or financial information which a submitter desires the Commission to treat as confidential must be submitted on separate sheets of paper, each clearly marked "Confidential Business Information" at the top. All submissions requesting confidential treatment must conform with the requirements of § 201.6 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.6). All written submissions, except for confidential business information, will be made available for inspection by interested persons. All submissions should be addressed to the Secretary at the Commission's office in Washington, DC.

Hearing-impaired individuals are advised that information on this matter can be obtained by contacting our TDD terminal on (202) 252-1810.

By order of the Commission.

Kenneth R. Mason,

Secretary.

Issued: November 10, 1988.

ANNEX 1.—U.S. TARIFF ITEMS

HTS No.	Brief description	Col. 1 duty rate
0603.10.60	Fresh cut roses	8% ad val.
0711.20.20	Olives, not pitted, provisionally preserved	7.7¢/kg.
0711.20.40	Olives, pitted or stuffed, provisionally preserved	11.3¢/kg.
0712.20.20	Onion powder or flour	35% ad val.
0712.20.40	Dried onions, other than power or flour	25% ad val.
0712.90.40	Dried garlic	35% ad val.
0712.90.75	Dried tomatoes	13% ad val.
2002.10.00	Tomatoes, whole or in pieces, prepared or preserved otherwise than by vinegar or acetic acid	14.7% ad val.
2002.90.00	Tomatoes, other than whole or in pieces, prepared or preserved otherwise than by vinegar or acetic acid	13.6% ad val.
2005.70.10	Olives, in brine, green, not pitted	7.7¢/kg.
2005.70.20	Olives, in brine, green, pitted or stuffed, placed packed	11¢/kg.
2005.70.25	Olives, in brine, green pitted or stuffed, other than placed packed	11.3¢/kg.
2005.70.50	Olives, in brine, not green canned not pitted	11.6¢/kg.
2005.70.60	Olives, in brine, not green, canned other than pitted	11.9¢/kg.
2005.70.70	Olives, in brine, not green, other than canned, in airtight containers of glass or metal	11.6¢/kg.
2005.70.75	Olives, in brine, not green, other than canned, other than in airtight containers of glass or metal	5.1¢/kg.
2005.70.80	Olives, prepared or preserved other than in brine	11¢/kg.
2009.11.00	Organge juice, frozen	9.25¢/liter
2009.19.20	Orange juice, other than frozen, not concentrated	5.3¢/liter
2009.19.40	Orange juice, other than frozen, concentrated	9.25¢/liter
2009.20.20	Grapefruit juice, not concentrated	5.3¢/liter
2009.20.40	Grapefruit juice, concentrated	9.25¢/liter
2009.30.40	Citrus fruit juice, n.e.s.i., not concentrated	5.3¢/liter
2009.30.60	Citrus fruit juice, n.e.s.i., concentrated	9.25¢/liter
2103.20.40	Tomato sauces other than ketchup	13.6% ad val.
2827.51.10	Sodium Bromide	6.6¢/kg.
2903.59.05	Dibromoethyldibromocyclohexane	13.5% ad val.
2903.69.25	Pentabromoethylbenzene; and Tribromocumene	9.1% ad val.
2907.19.50	Other monophenols	7.2% ad val.
2907.22.50	Other polyphenols	7.2% ad val.
2907.29.50	Polyphenols, n.e.s.	7.2% ad val.
2907.30.00	Phenol-alcohols	7.2% ad val.
2908.10.25	Tetrabromobisphenol A	1.5¢/kg. +19.4% ad val.
2908.10.30	Other halogenated phenol or phenol-alcohol derivatives, n.e.s.	13.5% ad val.
2908.20.20	Halogenated phenol or phenol-alcohols with sulfo groups, their salts and esters, n.e.s.	13.5% ad val.
2908.90.40	Other specified derivatives of phenol and phenol-alcohols	13.5% ad val.

ANNEX 1.—U.S. TARIFF ITEMS—Continued

U.S. Tariff Items

HTS No.	Brief description	Col. 1 duty rate
2909.30.07	Decabromodiphenyl oxide; and Octabromodiphenyl oxide	20% ad val.
2917.39.17	Tetrabromophthalic anhydride	20% ad val.
2925.19.10	Ethylenebistetrabromophthalimide	15% ad val.
7113.11.10	Silver rope or chain	7% ad val.
7113.19.10	Precious Metal rope or chain, other than silver	7% ad val.
7113.19.21	Gold rope necklaces and neck chains	6.5% ad val.
7113.19.25	Gold Mixed link necklaces and neck chains	6.5% ad val.
7113.19.29	Gold necklaces and neck chains, nes	6.5% ad val.
7113.20.10	Rope or chain of base metal clad with precious metal	7% ad val.
7113.20.21	Rope necklaces and neck chains clad with precious metal	6.5% ad val.
7113.20.25	Mixed link necklaces and neck chains clad with gold	6.5% ad val.
7113.20.29	Necklaces and neck chains, nes, clad with gold	6.5% ad val.

Annex 2—Israel Tariff Items[1]

Israel Customs Tariff (CCN-based nomeclature)

01040000	02011010	02011020
02020000	02030000	02050000
03011000	03011500	03014020
03014090	03019900	03029900
03030000	04010000	04021000
04023000	04029000	04030000
04040000	04059900	04060000
04070000	05159900	06019900
06029900	06030000	06049900
07013000	07014000	07019900
07020000	07039900	07042000
07044000	07044990	08011000
08019911	08019919	08019920
08021000	08031000	08041000
08042000	08059900	08061000
08069900	08071000	08079900
08080000	08090000	08100000
08120000	09040000	10040000
11021000	11029900	11050000
11080000	12012000	12013000
12013500	12014000	12015000
12019900	12100000	15010000
15020000	15031000	15039900
15071031	15071032	15071034
15121000	15122000	15129900
15130000	16010000	16020000
16030000	16042090	16049900
16050000	17041000	17042000
17043000	17045000	18069910
18069990	19030000	19071000
19079900	19089900	20019900
20024010	20024090	20029900
20030000	20050000	20061000
20063000	20069900	20079900
21030000	21042000	21049900
21052000	21059910	21059990
21071000	21071500	21072000
21073000	21077000	21078000
21079900	22040000	22051000
22059900	22070000	22080000
22091000	22099900	23010000
23040000	23060000	23072000
23073000	23079900	24010000
24023000	27101510	27101590
27102500	27103000	27105090
27106000	27109990	27110000
27120000	27130000	27160000
29021040	29041010	29041020
29111000	29151000	29253000
30039910	30039990	30041000
30042010	30042090	30043000
30044000	30045000	30049900
31021000	32130000	33069900
34039990	36061000	36069900
37039999	37089900	38111090
38160000	39011053	39013520
39013540	39017000	39017590
39019900	39021019	39021021
39021029	39021033	39021036
39021039	39021040	39021069
39021090	39024000	39024500
39025010	39025059	39025060
39025591	39025592	39029990
39039941	39039949	39071010
39071300	39071420	39071430
39071449	39074460	39071471
39071479	39071481	39071489
39071490	39075100	39075621
39076530	39076540	39079920
39079930	39079941	39079990
40090000	40100000	40113099
40114090	40119900	40132010
40132091	40141090	41021090
41029920	41029990	41039900
41049900	41059900	41080000
41100000	42022000	42023000
42029900	44151500	44152000
44159900	44189900	44230000
48012090	48019910	48019990
48071090	48078000	48079910
48153000	48159990	48169900
41189900	41192000	48212000
48219900	49109900	64019900
64029900	64030000	64040000
68049990	68090000	68109900
70089900	70171090	79172000
70181010	73103500	73183010
73184090	73203090	73204010
73204090	73209990	73219900
73359900	74031120	74079900
74103000	74150000	74160000
76029990	76049990	76069900
76089900	82049900	82059900
82062000	83151090	84069990
84115091	84116090	84120000
84151000	84172000	84205090
84224000	84612000	84612500
84614000	84619900	84631021
85011089	85012140	85012189
85019990	85029900	85049900
85131090	85151000	85179900
85193590	85197090	85197500
85202020	85226099	85233000
85234090	85239929	85239990
85269990	86080000	87051000
90177090	90261020	90269900
90283690	97034000	98055000
98059900		

[1] Annex 2 lists the products in terms of the headings in the Israeli tariff schedule prior to Israel's adoption of the Harmonized System. Contact Ms. Monica Lane of the Commission's Office of Industries (202–252–1296) for complete descriptions of the articles listed and the Israel rates of duty.

[FR Doc. 88–26494 Filed 11–15–88; 8:45 am]

BILLING CODE 7020-02-M

[TA-131(b)-13, TA-503(a)-17, and 332-266]

Probable Economic Effect of Providing Duty-Free Treatment for Watches Under the Generalized System of Preferences

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation and scheduling of hearing.

SUMMARY: Following receipt on October 18, 1988, of a request from the U.S. Trade Representative made in part at the direction of the President, the Commission instituted investigation Nos. TA-131(b)-13, TA-503(a)-17, and 332-266 under sections 503(a) and 131(b) of the Trade Act of 1974 (19 U.S.C. 2463(a) and 2151(b)), and section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g))—

(1) Pursuant to sections 503(a) and 131(b) of the Trade Act, and the authority of the President delegated to the U.S. Trade Representative by sections 4(c) and 8(c) and (d) of Executive Order 11846, as amended, to advise the President, with respect to the

watches provided for in each 8-digit subheading under the Harmonized Tariff Schedule of the United States (HTS) heading 9101 and 9102, as to the probable economic effect on U.S. industries producing or assembling watches and U.S. industries producing or assembling watch bands, straps or bracelets and on U.S. consumers of the elimination of U.S. import duties under the U.S. Generalized System of preferences (GSP). Separate advice will be provided for the watch manufacturing and assembly industry and the watch band, strap and bracelet manufacturing and assembly industry and for each of two geographic areas (the United States and U.S. insular possessions). In providing its advice, the USTR requested the Commission to assume that benefits of the GSP would not apply to imports that would be excluded from receiving such benefits by virtue of the "competitive need" limitations specified in section 504(c) of the Act.

The Commission will provide, to the degree possible, data on the following factors for the most recent three year period for each of the aforementioned U.S. industries: Annual production, capacity, capacity utilization, domestic shipments, exports, inventories, employment, wages, and financial experience (including prices). Data will also be provided, to the extent possible, on the following factors for current and potential foreign producers: current and potential production capacity and capacity utilization, domestic shipments, and exports to U.S. and other markets.

(2) Pursuant to section 332(g) of the Tariff Act and at the direction of the President, to advise the President, with respect to whether articles like or directly competitive with the watches described in each 8-digit subheading of headings 9101 and 9102 of the HTS were being produced in the United States on January 3, 1985 for purposes of section 504(d) of the Trade Act.

EFFECTIVE DATE: November 7, 1988.

FOR FURTHER INFORMATION CONTACT: Ms. Linda Linkins (202-252-1499), Office of Industries. For information on legal aspects of the investigation contact Mr. William Gearhart of the Commission's Office of the General Counsel at 202-252-1091.

Background

The USTR announced the items which have been sent to the Commission for probable economic effect advice in the **Federal Register** of October 7, 1988 (53 FR 39576).

Public Hearing

A public hearing in connection with the investigation will be held in the Commission Hearing Room, 500 E Street SW., Washington, DC 20436, beginning at 9:30 a.m. on January 10, 1989. All persons shall have the right to appear by counsel or in person, to present information, and to be heard. Persons wishing to appear at the public hearing should file requests to appear and should file prehearing briefs (original and 14 copies) with the Secretary, United States International Trade Commission, 500 E St., SW., Washington, DC 20436, not later than noon, December 29, 1988. Posthearing briefs must be filed by January 17, 1989.

Written Submissions

In lieu of or in addition to appearances at the public hearing, interested persons are invited to submit written statements concerning the investigation. Written statements should be received by the close of business on January 17, 1989. Commercial or financial information which a submitter desires the Commission to treat as confidential must be submitted on separate sheets of paper, each clearly marked "Confidential Business Information" at the top. All submissions requesting confidential treatment must conform with the requirements of § 201.6 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.6). All written submissions, except for confidential business information, will be made available for inspection by interested persons. All submissions should be addressed to the Secretary at the Commission's office in Washington, DC.

Hearing-impaired individuals are advised that information on this matter can be obtained by contacting our TDD terminal on (202) 252-1810.

By order of the Commission.

Kenneth R. Mason,

Secretary.

Issued: November 10, 1988.

[FR Doc. 88-26495 Filed 11-15-88; 8:45 am]

BILLING CODE 7020-02-M

DEPARTMENT OF JUSTICE

Lodging of Consent Decree; Cumberland, KY

In accordance with the policy of the Department of Justice, 28 CFR 50.7, notice is hereby given that on August 3, 1988, a proposed consent decree in *United States v. City of Cumberland, Kentucky, et al.*, Civ. No. 87-265, was lodged with the United States District Court for the Eastern District of Kentucky. The action was brought pursuant to the Clean Water Act, 33 U.S.C. 1251 *et seq.* and alleged violations by the City of its National Pollutant Discharge Elimination System (NPDES) permit. The complaint prayed for civil penalties and injunctive relief.

The consent decree requires the City to pay a civil penalty of $7,500, to employ two Class II operators or one, Class II operator and one Class II operator trainee, to submit a revised Municipal Compliance Plan (MCP) which will contain a schedule to bring the City into compliance with its NPDES permit by February 28, 1990, to obtain a portable chlorinator and chlorinate all bypasses, to initiate and complete construction in accordance with the schedule in the revised MCP and to pay stipulated penalties for violations of the schedule.

The Department of Justice will receive comments relating to the proposed consent decree for a period of 30 days from the date of this publication. Comments should be addressed to the Assistant Attorney General of the Land & Natural Resources Division, Department of Justice, Washington, DC. All comments should refer to *United States v. City of Cumberland*, D.O.J. Ref. 90-5-1-1-2949.

The proposed consent decree may be examined at the office of the United States Attorney, Fourth Floor, Federal Building, Limestone and Barr Streets, Lexington, Kentucky 40507 and at the Region IV Office of the Environmental Protection Agency, 345 Courtland Street, NE., Atlanta, Georgia 30365. Copies of the proposed decree can be obtained by mail from the Environmental Enforcement Section, Land & Natural Resources Division, United States Department of Justice, Washington, DC 20530. Any request for a copy should be accompanied by a check in the amount of $2.80 for copying costs payable to the "Treasurer of the United States."

Roger J. Marzulla,

Assistant Attorney General, Land and Natural Resources Division.

[FR Doc. 88-26396 Filed 11-15-88; 8:45 am]

BILLING CODE 4410-10-M

Antitrust Division

National Cooperative Research Act of 1984; Bell Communications Research, Inc.

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 et seq. ("the Act"), Bell

Communications Research, Inc. ("Bellcore") has filed written notifications, on behalf of Bellcore and FUJITSU LIMITED and FUJITSU LABORATORIES, LTD. (hereinafter collectively known as "FUJITSU") simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties of the joint venture and (2) the nature and objectives of the joint venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to section 6(b) of the Act, the identities of the parties to the joint venture, and its general areas of planned activities, are given below.

Bellcore is a Delaware corporation with its principal place of business at 290 W. Mt. Pleasant Avenue, Livingston, New Jersey 07039.

FUJITSU is a Japanese corporation with its registered office at 1015, Kamikodanaka, Nakahara-ku, Kawasaki-shi, Kanagawa-ken 211, Japan.

Bellcore and FUJITSU entered into an agreement on August 10, 1988 to collaborate on research to gain further knowledge and understanding of technologies for telecommunication services, systems, interfaces and equipments, with application to exchange and exchange access services, including;

(a) Concepts of new communication services,

(b) Case studies of new services based on the above concepts and studies of man-machine interfaces for accessing them,

(c) Studies of interfaces between terminals and communications systems, and

(d) Opto-electronic devices.

This agreement replaces the one entered into between Bellcore and FUJITSU on November 13, 1986. This notification supplements the notification submitted to the Department of Justice and Federal Trade Commission on December 22, 1986 the notice of which was published in the **Federal Register** on February 13, 1987.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 88-26397 Filed 11-15-88; 8:45 am]

BILLING CODE 4410-07-M

National Cooperative Research Act of 1984; Bell Communications Research, Inc.

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 et seq. ("the Act"), Bell Communications Research, Inc. ("Bellcore") has filed written notifications, on behalf of Bellcore and Graphics Communication Technologies, Ltd., (hereinafter known as "GCT") simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties of the joint venture and (2) the nature and objectives of the joint venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to section 6(b) of the Act, the identities of the parties to the joint venture, and its general areas of planned activities, are given below.

Bellcore is a Delaware corporation with its principal place of business at 290 W. Mt. Pleasant Avenue, Livingston, New Jersey 07039.

GCT is a Japanese corporation with its principal place of business at Column M.A. 6-11-1, Minami-Aoyama, Minato-ku, Tokyo 107, Japan.

Bellcore and GCT entered into an agreement effective September 1, 1988 to collaborate on research to understand the application of video compression algorithms and new technology and equipment in the area of Low Bit-Rate Video Codecs for exchange and exchange access service, and specifically for ISDN, demonstrating the feasibility of research concepts by means of experimental prototypes and experimental systems of such technology and equipment, and undertaking research to provide a basis of related submissions to public standards organizations.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 88-26398 Filed 11-15-88; 8:45 am]

BILLING CODE 4410-01-M

National Cooperative Research Act of 1984; X/Open, Ltd.

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 et seq. ("the Act"), X/Open, Ltd. ("X/Open") has filed a written notification simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to the venture and (2) the nature and objectives of the venture. The notification was filed for the purpose of involing the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to section 6(b) of the Act, the identities of the parties to the venture and X/Open's general areas of planned activities, are given below.

X/Open is a nonprofit international organization consisting at present of many of the world's leading manufacturers of computer systems. X/Open was organized in England and began operations as Kirkstock Limited in 1984. It was incorporated on May 28, 1987, Kirkstock became X/Open on June 24, 1987 and began business on September 10, 1987.

The purpose of X/Open is to research, establish and publish standards for the development of computer software in order to promote software compatibility among different hardware systems. Its efforts seek to achieve customer acceptance of the computer systems and software of many different vendors worldwide. By responding to user demands for greater efficiency and ease of use among different computer systems. X/Open's activities are aimed at promoting the maximum use of computer systems resources in the United States and abroad by providing users with consistent functional utility in a wide number of applications irrespective of system vendor. X/Open's ultimate goal is the broad portability of software application programs throughout a broad range of different hardware systems. This goal would be achieved through the establishment and industry acceptance of a common user interface and a common programmer interface among a large number of hardware systems, thereby enhancing the choices available to computer systems users and increasing the market opportunities and creative efforts of software developers.

X/Open engages in research, compilation and testing of design and operational features of a wide variety of systems and programs as part of analyzing and recommending optimum multi-vendor, user-friendly, software compatibility standards.

X/Open presently consists of the following 15 firms: AT&T Informations Systems Inc., Companie des Machines Bull, Digital Equipment Corporation, Fujitsu Limited, Hewlett-Packard Company, International Business Machines Corporation, International Computers Limited. NCR Corporation, Nixdorf Computer AG, Nokia Data System AB, N.V. Philips' Gloeilampenfabrieken, Olivetti International S.A., Siemens

Aktiengesellschaft, Sun Microsystems, and Unisys Corporation.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 88-26399 Filed 11-15-88; 8:45 am]

BILLING CODE 4410-01-M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Arts in Education Advisory Panel; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), as amended, notice is hereby given that a meeting of the Arts in Education Advisory Panel (Arts in Schools Basic Education Grants Section) to the National Council on the Arts will be held on December 1, 1988, from 9:15 a.m.—5:00 p.m. in Room 714 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW. Washington, DC 20506.

A portion of this meeting will be open to the public on December 1, 1988, from 1:45 p.m.-5:00 p.m. The topic for discussion will be policy.

The remaining sessions of this meeting on December 1 from 9:15 a.m.-1:45 p.m. are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the *Federal Register* of February 13, 1980, these sessions will be closed to the public pursuant to subsection (c)(4), (6) and (9)(B) of section 552b of Title 5, United States Code.

If you need special accommodations due to a disability, please contact the Office for Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW., Washington, DC 20506, 202/682-5532, TTY 202/682-5496 at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Advisory Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call 202/682-5433.

November 9, 1988.

Yvonne M. Sabine,

Director, Council and Panel Operations, National Endowment for the Arts.

[FR Doc. 88-26498 Filed 11-15-88; 8:45 am]

BILLING CODE 7537-01-M

Arts in Education Advisory Panel; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), as amended, notice is hereby given that a meeting of the Arts in Education Advisory Panel (State Arts in Education Grants Section) to the National Council on the Arts will be held on December 7-8, 1988, from 8:00 a.m.—8:00 p.m. and December 9, 1988, from 8:00 a.m.—5:00 p.m. in Room M09 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

A portion of this meeting will be open to the public on December 9, 1988, from 2:00 p.m.—5:00 p.m. The topic for discussion will be policy.

The remaining sessions of this meeting on December 7-8 from 8:00 a.m.—8:00 p.m. and December 9 from 8:00 a.m.—2:00 p.m. are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the **Federal Register** of February 13, 1980, these sessions will be closed to the public pursuant to subsection (c)(4), (6) and (9)(B) of section 552b of Title 5, United States Code.

If you need special accommodations due to a disability, please contact the Office for Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW., Washington, DC 20506, 202/682-5532, TTY 202/682-5496 at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Advisory Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call 202/682-5433.

November 9, 1988.

Yvonne M. Sabine,

Director, Council and Panel Operations, National Endowment for the Arts.

[FR Doc. 88-26499 Filed 11-15-88; 8:45 am]

BILLING CODE 7537-01-M

Dance Advisory Panel; Amended Notice of Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), as amended, notice is hereby given that a meeting of the Dance Advisory Panel (Presenters Section) to the National Council on the Arts which was to have been held on November 17-18, 1988, from 9:00 a.m.—8:00 p.m. and November 19, 1988, from 9:00 a.m.—6:00 p.m. in Room 730 of the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506 has been changed. It will be held on November 29-30 from 9:00 a.m.—8:00 p.m. and December 1, 1988, from 9:00 a.m.—6:00 p.m.

The portion of the meeting which was to be open to the public on November 19, 1988, from 4:00—6:00 p.m. for a policy and guidelines discussion has been changed. The open portion of this meeting will be held on December 1, 1988, from 4:00—6:00 p.m.

The remaining sessions of this meeting on November 29-30, 1988, from 9:00 a.m.—8:00 p.m. and December 1, 1988, from 9:00 a.m.—4:00 p.m. are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the **Federal Register** of February 13, 1980, these sessions will be closed to the public pursuant to subsections (c) (4), (6) and (9) (b) of section 552b of Title 5, United States Code.

If you need special accommodations due to a disability, please contact the Office for Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue NW., Washington, DC 20506, 202/682-5532, TTY 202/682-5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained form Ms. Yvonne M. Sabine, Advisory Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call 202/682-5433.

Yvonne Sabine,

Director, Council and Panel Operations, National Endowment for the Arts.

[FR Doc. 88-26500 Filed 11-15-88; 8:45 am]

BILLING CODE 7537-01-M

Humanities Panel; Meeting

AGENCY: National Endowment for the Humanities.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the provisions of the Advisory Committee Act (Pub. L. 92-463, as amended) notice is hereby given that the following meetings of the Humanities Panel will be held at the Old

Post Office, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Stephen J. McCleary, Advisory Committee Management Officer, National Endowment for the Humanities, Washington, DC 20506, telephone 202/786-0322.

SUPPLEMENTARY INFORMATION: The proposed meetings are for the purpose of panel review, discussion, evaluation and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended including discussion of information given in confidence to the agency by grant applicants. Because the proposed meetings will consider information that is likely to disclose: (1) Trade secrets and commercial or financial information obtained from a person and privileged or confidential; (2) information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy; or (3) information the disclosure of which would significantly frustrate implementation of proposed agency; pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings, dated January 15, 1978, I have determined that these meetings will be closed to the public pursuant to subsectons (c)(4), (6) and (9)(B) of section 552 of Title 5, United States Code.

(1) *Date:* December 1, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 316-2.
Program: The meeting will review Summer Stipends applications in European History, submitted to the Division of Fellowships and Seminars, for projects beginning after May 15, 1989.

(2) *Date:* December 2, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 430.
Program: This meeting will review Summer Stipends applications in Archaeology; Ancient, Medieval, and Renaissance History, submitted to the Division of Fellowships and Seminars, for projects beginning after May 15, 1989.

(3) *Date:* December 2, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 316-2.
Program: This meeting will review Summer Stipends applications in American History I, submitted to the Division of Fellowships and Seminars, for projects beginning after May 15, 1989.

(4) *Date:* December 2, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 315.
Program: This meeting will review Summer Stipends applications in Sociology, Psychology, and Education, submitted to the Division of Fellowships and Seminars, for projects beginning after May 15, 1989.

(5) *Date:* December 5, 1988.
Time: 8:30 a.m. to 5:00 p.m.
Room: 415.
Program: This meeting will review State and Regional Exemplary Award proposals submitted by state humanities councils, submitted to the Division of State Programs, for projects beginning after April 1, 1989.

(6) *Date:* December 5, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 315.
Program: This meeting will review Summer Stipends applications in Music and Dance, submitted to the Division of Fellowships and Seminars, for projects beginning after May 15, 1989.

(7) *Date:* December 5, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 316-2.
Program: This meeting will review Summer Stipends applications in Anthropology, Folklore, and New World Archaeology, submitted to the Division of Fellowships and Semianrs, for projects beginning after May 15, 1989.

(8) *Date:* December 6, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 315.
Program: This meeting will review Summer Stipends applications in American Literature, submitted to the Division of Fellowships and Seminars, for projects beginning after May 15, 1989.

(9) *Date:* December 6, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 316-2.
Program: This meeting will review Summer Stipends applications in Philosophy I, submitted to the Division of Fellowships and Seminars, for proejcts beginning after May 15, 1989.

(10) *Date:* December 7, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 316-2.
Program: This meeting will review Summer Stipends applications in Art History, submitted to the Division of Fellowships and Seminars, for projects beginning after May 15, 1989.

(11) *Date:* December 8, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 315.
Program: This meeting will review Summer Stipends applications in Communication, Rhetoric, Theater, and Film, submitted to the Division of Fellowships and Seminars, for projects beginning after May 15, 1989.

(12) *Date:* December 8, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 316-2.
Program: This meeting will review Summer Stipends applications in Political Science, Law and Jurisprudence, submitted to the Division of Fellowships and Seminars, for projects beginning after May 15, 1989.

(13) *Date:* December 9, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 316-2.
Program: This meeting will review Summer Stipends applications in British Literature, submitted to the Division of Fellowships and Seminars, for projects beginning after May 15, 1989.

(14) *Date:* December 9, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 315.
Program: This meeting will review Summer Stipends applications in Ameircan History II, submitted to the Division of Fellowships and Seminars, for projects beginning after May 15, 1989.

(15) *Date:* December 12, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 315.
Program: This meeting will review Summer Stipends applications in Philosophy II, submitted to the Division of Fellowships and Seminars, for projects beginning after May 15, 1989.

(16) *Date:* December 12, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 316-2.
Program: This meeting will review Summer Stipends applications in African, Asian, and Latin American History and Politics, submitted to the Division of Fellowships and Seminars, for projects beginning after May 15, 1989.

(17) *Date:* December 13, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 315.
Program: This meeting will review Summer Stipends applications in Modern American and Modern British Literature, submitted to the Division of Fellowships and Seminars, for projects beginning after May 15, 1989.

(18) *Date:* December 13, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 316-2.
Program: This meeting will review Summer Stipends applications in Classical, Medieval, and

Renaissance Languages and Literature, submitted to the Division of Fellowships and Seminars, for projects beginning after May 15, 1989.

(19) *Date:* December 14, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 316–2.
Program: This meeting will review Summer Stipends applications in Hispanic Languages and Literatures; Linguistics submitted to the Division of Fellowships and Seminars, for projects beginning after May 15, 1989.

(20) *Date:* December 15, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 315.
Program: This meeting will review Summer Stipends applications in Religious Studies, submitted to the Division of Fellowships and Seminars, for projects beginning after May 15, 1989.

(21) *Date:* December 15, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 316–2.
Program: This meeting will review Summer Stipends applications in Foreign Languages and Literatures; Comparative Literature, submitted to the Division of Fellowships and Seminars, for projects beginning after May 15, 1989.

(22) *Date:* December 16, 1988.
Time: 8:30 a.m. to 5:30 p.m.
Room: 316–2.
Program: This meeting will review Summer Stipends applications in French and Italian Languages and Literatures; Theory and Criticism, submitted to the Division of Fellowships and Seminars, for projects beginning after May 15, 1989.

Stephen J. McCleary,
Advisory Committee Management Officer.
[FR Doc. 88–26435 Filed 11–15–88; 8:45 am]
BILLING CODE 7536–01–M

Inter-Arts Advisory Panel; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act Pub. L. 92–463), as amended, notice is hereby given that a meeting of the Inter-Arts Advisory Panel (Folk Arts Section) to the National Council on the Arts will be held on December 7–9, 1988, from 9:00 a.m.–5:30 p.m. and on December 10, 1988, from 9:00 a.m.–3:30 p.m. in Room 716 of the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the Agency by grant applicants. In accordance with the determination of the Chairman published in the **Federal Register** of February 13, 1980, these sessions will be closed to the public pursuant to subsections (c)(4), (6) and (9)(B) of section 552b of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Advisory Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call (202) 682–5433.

November 9, 1988.
Yvonne M. Sabine,
Director, Council and Panel Operations, National Endowment for the Arts.
[FR Doc. 88–26501 Filed 11–15–88; 8:45 am]
BILLING CODE 7537–01–M

Literature Advisory Panel; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that a meeting of the Literature Advisory Panel (Literary Publishing Section) to the National Council on the Arts will be held on December 8–9, 1988, from 9:00 a.m.–6:00 p.m. and on December 10, 1988, from 9:00 a.m.–2:30 p.m. in Room 714 of the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

A portion of this meeting will be open to the public on December 10, 1988, from 1:00–2:30 p.m. The topic for discussion will be policy and guidelines.

The remaining sessions of this meeting on December 8–9 from 9:00 a.m.–6:00 p.m. and on December 10 from 9:00 a.m.–1:00 p.m. are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the **Federal Register** of February 13, 1980, these sessions will be closed to the public pursuant to subsection (c) (4), (6) and (9)(B) of section 552b of Title 5, United States Code.

If you need special accommodations due to a disability, please contact the Office of Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW., Washington, DC 20506, 202/682–5532, TTY 202/682–5496 at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Advisory Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call 202/682–5433.

November 10, 1988.
Yvonne M. Sabine,
Director Council and Panel Operation National Endowment for the Arts.
[FR Doc. 88–26502 Filed 11–15–88; 8:45 am]
BILLING CODE 7537–01–M

Media Arts Advisory Panel; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), a amended, notice is hereby given that a meeting of the Media Arts Advisory Panel (Challenge II Section) to the National Council on the Arts will be held on December 6, 1988, from 9:00 a.m.–5:30 p.m. in Room 716 of the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the Agency by grant applicants. In accordance with the determination of the Chairman published in the **Federal Register** of February 13, 1980, these sessions will be closed to the public pursuant to subsections (c) (4), (6) and (9)(B) of section 552b of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Advisory Committee Management Officer, National Endowment for the Arts, Washignton, DC 20506, or call (202) 682–5433.

November 9, 1988.
Yvonne M. Sabine,
Director, Council and Panel Operations, National Endowment for the Arts.
[FR Doc. 88–26503 Filed 11–15–88; 8:45 am]
BILLING CODE 7537–01–M

Museum Advisory Panel; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that a meeting of the Museum Advisory Panel (Museum Purchase Plan Section) to the National Council on the

Arts will be held on December 6, 1988, from 9:00 a.m.–5:30 p.m. in Room 730 of the Nancy Hanks Center, 1100 Pennsylvania Avenue NW., Washington, DC 20506.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation on applicants for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the Agency by grant applicants. In accordance with the determination of the Chairman published in the **Federal Register** of February 13, 1980, these sessions will be closed to the public pursuant to subsections (c)(4), (6) and (9)(B) of section 552b of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Advisory Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call (202) 682–5433.

November 9, 1988.

Yvonne M. Sabine,

Director, Council and Panel Operations, National Endowment for the Arts.

[FR Doc. 88–26504 Filed 11–15–88; 8:45 am]

BILLING CODE 7537-01-M

Music Advisory Panel; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that a meeting of the Music Advisory Panel (Opera-Musical Theater Overview Section) to the National Council on the Arts will be held on December 5–6, 1988, from 9:00 a.m.–5:30 p.m. in Room M14 of the Nancy Hanks Center, 1100 Pennsylvania Avenue NW., Washington, DC 20506.

This meeting will be open to the public on a space available basis. The topic for discussion will include guidelines.

If you need special accommodations due to a disability, please contact the Office of Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue NW., Washington, DC 20506, 202/682–5532, TTY 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Advisory Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call (202) 682–5433.

November 8, 1988.

Yvonne M. Sabine,

Director, Council and Panel Operations, National Endowment for the Arts.

[FR Doc. 88–26505 Filed 11–15–88; 8:45 am]

BILLING CODE 7537-01-M

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements; Office of Management and Budget Review

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of the Office of Management and Budget review of information collection.

SUMMARY: The NRC has recently submitted to the Office of Management and Budget (OMB) for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

1. *Type of submission, new revision or extension:* New.
2. *Title of the information collection:* Pilot Program on Quality Assurance on Medical Use of Byproduct Material.
3. *The form number if applicable:* Not applicable.
4. *How often the collection is required:* One time.
5. *Who will be required or asked to report:* NRC medical licensees.
6. *An estimate of the number of responses:* 50 licenses.
7. *An estimate of the total number of hours needed to complete the requirements or request:* 3,500 hours.
8. *The average burden per response is:* 70 hours.
9. *An indication of whether section 3504(h), Pub. L. 96–511 applies:* Not applicable.
10. *Abstract:* The NRC is proposing to amend its regulations that would require its medical licensees to implement quality assurance (QA) procedures in order to avoid, detect, and correct simple human errors involving medical use of byproduct material. The pilot program is designed to test the proposed QA procedures clinically in order to minimize any potential interference with the proper delivery of medical care.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 2120 L Street NW., Washington, DC.

Comments and questions should be directed to the OMB reviewer, Nicholas B. Garcia, (202) 395–3084.

NRC Clearance Officer is Brenda J. Shelton, (301) 492–8132.

Dated at Bethesda, Maryland, this 5th day of November, 1988.

For the Nuclear Regulatory Commission.

William G. McDonald,

Director, Office of Administration and Resources Mangement.

[FR Doc. 88–26438 Filed 11–15–88; 8:45 am]

BILLING CODE 7590-01-M

[Dockets Nos. 50–315 and 50–316]

Indiana Michigan Power Co.; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of amendments to Facility Operating Licenses Nos. DPR–58 and DPR–74, issued to the Indiana Michigan Power Company (the licensee) for operation of Donald C. Cook Nuclear Plant, Units Nos. 1 and 2, located in Berrien County, Michigan.

Environmental Assessment

Identification of Proposed Action

The proposed amendments would revise provisions in the D.C. Cook Technical Specifications (TSs) relating to milk sampling for radiological analysis.

The Need for the Proposed Action

The current TSs concerning milk sampling, Item 4.a of Table 3–12.1, require milk samples to be collected for radiological analysis from the following specific areas:

A. Stevensville, Michigan.
B. Bridgman, Michigan.
C. Galien, Michigan.
D. Dowagiac, Michigan.
E. South Bend, Indiana.

However, no milk samples are collected in Stevensville or South Bend or sectors in which these cities are located because there are no willing farmers who wish to participate in the milk sampling program. Literal TS noncompliance was caused by listing the specific towns where samples were to be taken.

The proposed changes to the TSs are more consistent with the NRC guidelines. Specifically, the proposed changes require sampling at each indicator farm and each background farm. Indicator farm and background farm are defined as follows:

Indicator Farm Nearest milk producer in each of the land sectors within 8 miles of the plant site who is willing to participate in the radiological environmental monitoring program.

Background Farm A milk producer in one of the less prevalent wind directions

at a distance greater than 15 miles but less than 25 miles who is willing to participate in the radiological environmental monitoring program.

The number of locations sampled may vary due to the number of sectors which contain farms willing to participate in the milk sampling program. The possibility exists that no willing participants may be found within 8 miles of the plant site. In order to address this possibility, the proposed TSs require broad leaf vegetation sampling. Specifically, if fewer than three willing indicator farms are found, borad leaf vegetation samples will be collected and analyzed when available.

Environmental Impacts of the Proposed Action

The Commission has completed its evaluation of the proposed changes to the TSs. The proposed changes would correct the licensee's current TSs. They would make the TSs more restrictive and more in line with NRC guidelines concerning milk sampling for radiological analysis. The proposed changes do not increase the probability or consequences of accidents, no changes are being made in the types of any effluents that may be released offsite, and there is no significant increase in the allowable individual or cumulative occupational radiation exposure. Accordingly, the Commission concludes that this proposed action would result in no significant radiological impact.

With regard to potential nonradiological impacts, the proposed amendments do not involve systems located within the restricted area as defined in 10 CFR Part 20. The proposed amendments only change the TXs in relation to obtaining milk samples for analysis and correct editorial errors. They do not affect nonradiological plant effluents and have no other environmental impact. Therefore, the Commission concludes that there are no significant nonradiological environmental impacts associated with the proposed amendments.

The Notice of Consideration of Issuance of Amendments and Opportunity for Hearing in connection with this action was published in the **Federal Register** on July 14, 1988 (53 FR 26695). No request for hearing or petition for leave to intervene was filed following this notice.

Alternatives to the Proposed Action

Because the Commission has concluded that there is no significant environmental impact associated with the proposed amendments, any alternative would have either no or greater environmental impact. The principal alternative would be to deny the requested amendments. This would result in the licensee being in noncompliance with the TSs concerning milk sampling.

Alternative Use of Resources

This action involves no use of resources not previously considered in connection with the "Final Environmental Statement Related to Operation of the Donald C. Cook Nuclear Plant, Units 1 and 2, dated August 1973.

Agencies and Persons Consulted

The Commission's staff reviewed the licensee's request and did not consult other agencies or persons.

Finding of No Significant Impact

The Commission has determined not to prepare an environmental impact statement for the proposed amendments.

Based upon the foregoing environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment.

For further details with respect to this action, see the application for amendment dated February 1, 1988, which is available for public inspection at the Commission's Public Document Room, Gelman Building, 2120 L Street, NW., Washington, DC, and at the Maude Preston Palenski Memorial Library, 500 Market Street, St. Joseph, Michigan 49085.

Dated at Rockville, Maryland, this 4th day of November 1988.

For the Nuclear Regulatory Commission.

Theodore Quay,

Acting Director, Project Directorate III-1, Division of Reactor Projects—III, IV, V and Special Projects.

[FR Doc. 88-26439 Filed 11-15-88; 8:45 am]

BILLING CODE 7590-01-M

[Dockets Nos. 50-315 and 50-316]

Indiana Michigan Power Co., Donald C. Cook Nuclear Plant, Units Nos. 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 Licenses Nos. DPR-58 and DPR-74 issued to Indiana Michigan Power Company (the licensee) for operation of the Donald C. Cook Nuclear Plant, Units Nos. 1 and 2, located at the licensee's site in Berrien County, Michigan.

Environmental Assessment

Identification of Proposed Action

The proposed amendment would revise the provisions in the Technical Specifications (TSs) and License Conditions relating to fuel enrichment.

The proposed action is in accordance with the licensee's application dated August 19, 1988.

The Need for the Proposed Action

The proposed amendment is needed so that the licensee can use higher enrichment fuel and provides the flexibility of extending the fuel irradiation and permitting operation of longer fuel cycles.

Environmental Impacts of the Proposed Action

The Commission has completed its evaluation of the proposed amendment. The proposed revisions would permit use of fuel enriched with Uranium 235 in excess of 4 weight percent and up to 4.23 weight percent, and license would expect the fuel to be irradiated to levels above 33 gigwatt days per metric ton (GWD/MT) but not to exceed 50 GWD/MT. The safety considerations associated with reactor operation with higher enrichment and extended irradiation have been evaluated by the Commission's staff. The staff has concluded that such changes would not adversely affect plant safety. The proposed changes have no adverse effect on the probability of any accident. The increase burnup may slightly change the mix of fission products that might be released in the event of a serious accident but such small changes would not significantly affect the consequences of serious accidents. No changes are being made in the types or amounts of any radiological effluents that may be released offsite. There is no significant increase in the allowable individual or cumulative occupational radiation exposure.

With regard to potential nonradiological impacts of reactor operation with higher enrichment and extended irradiation, the proposed changes involve systems located within the restricted area, as defined 10 CFR Part 20. They do not affect nonradiological plant effluents and have no other environmental impact.

The environmental impacts of transportation resulting from the use of higher enrichment fuel and extended irradiation are discussed in the Commission's assessment entitled, "NRC Assessment of the Environmental Effects of Transportation Resulting from Extended Fuel Enrichment and

Irradiation," dated July 7, 1988 (53 FR 30355). As indicated therein, the environmental cost contribution of the proposed increase in the fuel enrichment and irradiation limits are either unchanged or may in fact be reduced from those summarized in Table S-4 as set forth in 10 CFR 51.52(c).

The Notice of Consideration of Issuance of Amendment and Opportunity for Hearing in connection with this action was published in the Federal Register on October 11, 1988 (53 FR 39679). No request for hearing or petition for leave to intervene was filed following this notice.

Therefore, the Commission concludes that there are no significant radiological or nonradiological environmental impacts associated with the proposed amendments.

Alternative to the Proposed Action

Since the Commission concluded that there are no significant environmental effects that would result from the proposed action, any alternative with equal or greater environmental impacts need not be evaluated.

The principal alternative would be to deny the requested amendments. This would not reduce environmental impacts of plant operation and would result in reduced operational flexibility.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the Final Environmental Statement related to the operation of the Donald C. Cook Nuclear Plant, Units 1 and 2, dated August 1973.

Agencies and Person Consulted

The Commission's staff reviewed the licensee's request and did not consult other agencies or persons.

Findings of No Significant Impact

The Commission has determined not to prepare an environmental impact statement for the proposed license amendments.

Based upon the foregoing environmental assessment, we conclude that the proposed action will not have a significant effect on the quality of the human environment.

For further details with respect to this action, see the application for amendments dated August 19, 1988, which is available for public inspection at the Commission's Public Document Room, 2120 L Street, NW., Washington, DC, and at the Maude Preston Palenski Memorial Library, 500 Market Street, St. Joseph, Michigan 49085.

Dated at Rockville, Maryland this 8th day of November 1988.

For the Nuclear Regulatory Commission.

Theodore R. Quay,

Acting Director, Project Directorate III-1, Division of Reactor Projects—III, IV, V & Special Projects.

[FR Doc. 88-26446 Filed 11-15-88; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 70-3054]

Finding of No Significant Impact; Amendment of Materials License No. SNM-1977; Philadelphia Electric Co., Montgomery County, PA

The U.S. Nuclear Regulatory Commission (the Commission) is considering the revision of Special Nuclear Material License No. SNM-1977 to Philadelphia Electric Company (the applicant) for the Limerick Generating Station Unit 2, located in Montgomery County, Pennsylvania.

Environmental Assessment

Identification of Proposed Action

The proposed action would authorize applicant to receive, possess, inspect, and store special nuclear material in the form of unirradiated fuel assemblies. The discussion below will be limited to assessing the potential for environmental impacts resulting from the handling and the storage of new fuel at Limerick, Unit 2.

The Need for the Proposed Action

The proposed action will allow the applicant to receive and store fresh fuel prior to issuance of the Part 50 operating license in order to inspect the fuel and finalize fuel preparation needed to load the fuel into the reactor vessel. Actual core loading, however, will not be authorized by the proposed license amendment.

Environmental Impacts of the Proposed Action

Once at Limerick, Unit 2, the new fuel will be stored outdoors in the new fuel storage area. The fuel will be stored in the outer wooden shipping containers in piles stacked four high. Each pile of fuel will be covered by a five-sided box manufactured out of corrugated steel. This temporary storage of assemblies in their shipping containers will present no significant environmental impact or significant radiation exposure to plant workers.

Assemblies are then moved to the refueling floor and stored in a predesignated storage area. Assemblies are removed from their shipping containers, inspected, and the fuel is then transferred to their designated storage location in the spent fuel storage pool. Criticality safety in the storage location is maintained by limiting interaction between adjacent fuel assemblies. The staff has evaluated the spent fuel pool and found it to be critically safe for all conditions of water moderation and/or reflection. The design of this storage location, combined with plant procedures, will ensure acceptable protection of the general public and plant personnel under either normal or abnormal conditions.

Since the fresh fuel assemblies are sealed sources, the principal exposure pathway to an individual is via external radiation. For low-enriched uranium fuel (<4 percent U-235 enrichment), the exposure rate at 1 foot from the surface is norally less than 1 mR/hr; therefore, it is estimated that the exposure level to workers handling the fuel would be less than 25 percent of the maximum permissible exposure specified in 10 CFR Part 20. Because of the low radiation levels associated with the requested materials and activities and the applicant's radiation protection procedures, the staff concludes that fuel handling and storage activities can be carried out without any significant occupation dose to workers or radiological impact to the environment.

Only a small amount, if any, of radioactive waste (e.g., smear papers and/or contaminated packaged material) is expected to be generated as a result of fuel handling and storage operations. Any waste that is produced will be properly stored onsite until it can be shipped to a licensed disposal facility.

In the event the assemblies must be returned to the fuel fabricator, all packaging and transport of fuel will be in accordance with 10 CFR Part 71. No significant external radiation hazards are associated with the unirradiated fuel, because the radiation level from the clad fuel pellets is low and the shipping packages must meet the external radiation standards in 10 CFR Part 71. Therefore any shipment of unirradiated fuel is expected to have an insignificant environmental impact.

In the unlikely event that an assembly (either within or outside its shipping container) is dropped during transfer, fuel cladding is not expected to rupture. Even if the fuel rod cladding were breached and the pellets were released, an insignificant environmental impact would result. The fuel pellets are composed of a ceramic UO_2 that has been pelletized and sintered to a very high density. In this form, release of UO_2 aerosol is unlikely except under conditions of deliberate grinding.

Additionally, UO_2 is soluble only in acid solution so dissolution and release to the environment are extremely unlikely.

Conclusion

The environmental impacts associated with the handling and storage of new fuel at Limerick, Unit 2, are expected to be insignificant. Essentially no effluents, liquid or airborne, will be released, and acceptable controls will be implemented to prevent a radiological accident. Therefore, the staff concludes that there will be no significant impacts associated with the proposed action.

Alternative to the Proposed Action

The principal alternative would be to deny the requested license amendment. Assuming the operating license will eventually be issued, denial of the storage only license would merely postpone new fuel receipt at Limerick, Unit 2. Although denial of the special nuclear material license for Limerick, Unit 2, is an alternative available to the Commission, it would be considered only if significant issues of public health and safety could not be resolved.

Alternative Use of Resources

This action does not involve the use of resources not previously considered in connection with the Commission's Final Environmental Statement (NUREG-0974) related to this facility.

Agencies and Persons Contacted

The Commission's staff reviewed the applicant's request of May 6, 1988 and supplement dated October 28, 1988, and did not consult other agencies or persons.

Finding of No Significant Impact

The Commission has prepared an Environmental Assessment related to the revision of Special Nuclear Material License No. SNM-1977. On the basis of this assessment, the Commission has concluded that environmental impacts created by the proposed licensing action would not be significant and do not warrant the preparation of an Environmental Impact Statement. Accordingly, it has been determined that a Finding of No Significant Impact is appropriate.

The Environmental Assessment and the May 6, 1988, application related to this proposed action are available for public inspection and copying at the Commission's Public Document Room, 2120 L Street, NW., Washington, DC. Copies of the Environmental Assessment may be obtained by calling (301) 492-3358 or by writing to the Fuel Cycle Safety Branch, Division of Industrial and Medical Nuclear Safety, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Dated at Rockville, Maryland, this 7th day of November, 1988.

For the Nuclear Regulatory Commission.

Leland C. Rouse,

Chief, Fuel Cycle Safety Branch, Division of Industrial and Medical Nuclear Safety, NMSS.

[FR Doc. 88-26440 Filed 11-15-88; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-333]

Power Authority of the State of New York; Environmental Assessment And Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC/the Commission) is considering issuance of an exemption from the requirements of Appendix J of 10 CFR Part 50 to the Power Authority of the State of New York (PASNY/the licensee), for the James A. FitzPatrick Nuclear Power Plant located in Oswego County, New York.

Environmental Assessment

Identification of Proposed Action

The licensee would be exempted from the requirements of Section III.A.6(b) of Appendix J to 10 CFR Part 50 to the extent that a Type A Primary Containment Integrated Leak Rate Test (PCILRT) would not have to be performed during the Reload 8/Cycle 9 refueling outage (which commenced in August 1988) and that the normal PCILRT retest schedule specified in Section III.D(a) of Appendix J would be restored.

In addition, the licensee would be exempted from the requirements of Section IV.A of Appendix J to the extent that a Type C test would not be performed during the Reload 8/Cycle 9 refueling outage on the welds of a containment isolation valve located on the High Pressure Coolant Injection (HPCI) turbine exhaust line. This valve is to be replaced during the outage.

The Need for the Proposed Action

The PCILRTs performed during the 1982, 1985, and 1987 refueling outages were deemed failures in the "as-found" condition. Section III.A6(b) of Appendix J states that, should two consecutive PCILRTs fail to meet the applicable acceptance criteria, a retest must be performed during each subsequent refueling outage until two consecutive tests are deemed acceptable, after which time the retest schedule specified in Section III.D(a) may be resumed. Accordingly, the licensee would be required to perform a PCILRT during the August 1988 refueling outage. As an alternative to performing this test, the licensee has submitted a Corrective Action Plan which entails the replacement of 33 containment isolation valves which previously were identified as having excessive leakage. Replacement of 21 of these valves would take place during the Reload 8/Cycle 9 outage. Implementation of the Corrective Action Plan will ensure that the intent of Section III.A.6(b) is met, in that unacceptable containment leakage is identified and corrected.

In accordance with Section IV.A of Appendix J, a Type A, B or C test (as applicable) is required to be performed following any major modification or replacement of a component which is part of the primary reactor containment boundary. The licensee has determined that the welds of one of the valves to be replaced, located on the HPCI turbine exhaust line, cannot be pressure tested. Also, since the replaced manual valve is not used for containment isolation, it is not subject to PCILRT requirements. Accordingly, the licensee has requested an exemption from Section IV.A. In lieu of a Type A, B or C tests, the licensee has proposed 100 percent radiography of the affected weld as well as dye penetrant or magnetic particle tests. This will ensure that the intent of Section IV.A, (the identification of leakage resulting from replacement of a component which is part of the primary containment boundary) is met.

Environmental Impact of the Proposed Action

The proposed action would ensure that excessive leakage from containment isolation valves is identified and corrected and would provide a level of safety at least equivalent to that attained by compliance with Sections III.A.6(b) and IV.A of Appendix J to 10 CFR Part 50. On this basis, the Commission concludes that there are no significant radiological environmental impacts associated with this proposed exemption.

With regard to potential nonradiological impacts, the proposed exemption involves features located entirely within the restricted areas as defined in 10 CFR Part 20. It does not affect nonradiological plant effluents and has no other environmental impact Therefore, the Commission concludes that there are no significant nonradiological environmental impacts associated with the proposed exemption.

Alternative Use of Resources

This action involves no use of resources not previously considered in the Final Environmental Statement (construction permit and operating license) for the James A. FitzPatrick Nuclear Power Plant.

Agencies and Persons Consulted

The NRC staff reviewed the licensee's request and did not consult other agencies or persons.

Finding of No Significant Impact

The Commission has determined not to prepare an environmental impact statement for the proposed exemption.

Based on the foregoing environmental assessment, we conclude that the proposed action will not have a significant effect on the quality of the human environment.

For further details with respect to this action, see the request for exemption dated April 8, 1988 and the supplements dated June 17, 1988, July 14, 1988 and October 28, 1988, which are available for public inspection at the Commission's Public Document Room, Gelman Building, 2120 L Street, NW., Washington, DC, and at the Penfield Library, State University College of Oswego, Oswego, New York.

Dated at Rockville, Maryland, this 10th of November 1988.

For the Nuclear Regulatory Commission.

Robert A. Capra,

Director, Project Directorate I-1, Division of Reactor Projects, I/II.

[FR Doc. 88-26441 Filed 11-15-88; 8:45 am]

BILLING CODE 7590-01-M

Biweekly Notice Applications and Amendments to Operating Licenses Involving No Significant Hazards Considerations

I. Background

Pursuant to Public Law (P.L.) 97-415, the Nuclear Regulatory Commission (the Commission) is publishing this regular biweekly notice. P.L. 97-415 revised section 189 of the Atomic Energy Act of 1954, as amended (the Act), to require the Commission to publish notice of any amendments issued, or proposed to be issued, under a new provision of section 189 of the Act. This provision grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from October 26, 1988 through November 4, 1988. The last biweekly notice was published on November 2, 1988 (53 FR 44247).

NOTICE OF CONSIDERATION OF ISSUANCE OF AMENDMENT TO FACILITY OPERATING LICENSE AND PROPOSED NO SIGNIFICANT HAZARDS CONSIDERATION DETERMINATION AND OPPORTUNITY FOR HEARING

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendments would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Written comments may be submitted by mail to the Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration and Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room P-216, Phillips Building, 7920 Norfolk Avenue, Bethesda, Maryland from 7:30 a.m. to 4:15 p.m. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC The filing of requests for hearing and petitions for leave to intervene is discussed below.

By December 16, 1988 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 petition for leave to intervene. Requests for a hearing and petitions 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. 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 fifteen (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 fifteen (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, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under consideration. 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.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received before action is taken. Should the Commission take this action, it will publish a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

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 Service 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 ten (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) 325-6000 (in Missouri 1-(800) 342-6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to (*Project Director*): 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 the 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 factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment 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 for the particular facility involved.

Arkansas Power & Light Company, Docket Nos. 50-313 and 50-368, Arkansas Nuclear One, Units 1 and 2, Pope County, Arkansas

Date of amendment requests: May 27, 1988

Description of amendment requests: The amendments would modify the Technical Specifications (TSs) for each unit by adding operability and surveillance requirements for the core-exit thermocouples (CETs). The CET system is one of the inadequate core cooling (ICC) monitoring systems. These systems and the associated TSs are required by NUREG-0737, Section II.F.2, as specified by Generic Letter 83-37.

Basis for proposed no significant hazards consideration determination: The Commission has provided guidance for the application of criteria for no significant hazards consideration determination by providing examples of amendments that are considered not likely to involve significant hazards considerations (51 FR 7751). These examples include: Example (ii), A change that constitutes an additional limitation, restriction, or control not presently included in the Technical Specifications: e.g., "a more stringent surveillance requirement."

The new operability and surveillance requirements for the CET system of each unit constitute additional limitations, restrictions, and controls not presently included in the Technical Specifications. Therefore, the proposed amendments are within the scope of the example.

Since the applications for amendment involve proposed changes that are encompassed by an example for which no significant hazards consideration exists, the staff has made a proposed determination that the applications involve no significant hazards consideration.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801

Attorney for licensee: Nicholas S. Reynolds, Esq., Bishop, Cook, Purcell and Reynolds, 1400 L Street, NW., Washington, DC 20005-3502

NRC Project Director: Jose A. Calvo

Carolina Power & Light Company et al., Docket No. 50-325, Brunswick Steam Electric Plant, Unit No. 1, Brunswick County, North Carolina

Date of application for amendment: May 27, 1988

Description of amendment request: The proposed amendment would change the reactor water level setpoint for the isolation of the Group 1 primary containment isolation valves from low level 2 to low level 3. The proposed amendment also reflects plant modifications that are necessary. New slave units will be added for the low level 3 instrumentation and their tag numbers will be identified in the Technical Specifications. Master trip units will be upgraded and the Technical Specifications will reflect the new tag numbers for low level 2.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a no significant hazards consideration exists as stated in 10 CFR 50.92(c). A proposed amendment to an operating license involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee evaluated the proposed changes in accordance with the standards in 10 CFR 50.92(c) and provided the following analysis:

1. The setpoint change has been evaluated with respect to several operating parameters, including the minimum critical power ratio (MCPR), peak vessel pressure, radiation release, and shutdown capability during abnormal operating transients. Fuel cladding integrity during a loss-of-coolant accident (LOCA) and the reactor response during an anticipated transient without scram (ATWS) event were also evaluated. Results of this evaluation are provided in the GE Topical Report NEDC-30601-P, "Safety Review of Water Level Setpoint Change for Brunswick Steam Electric Plant, Units 1 and 2." As

stated in Section 4.2.3 and 4.2.4 of that report, the change will not cause a reduction in MCPR, an increase in the peak pressure, an increase in radiation release, a cause of equipment damage, a reduction in plant shutdown capability, or a decrease in core cooling capability. The main steam isolation valve (MSIV) water level setpoint change has no impact on LOCA events previously evaluated, nor does it cause consequences of accidents previously evaluated to be increased.

2. Several operating parameters have been evaluated to support the setpoint change, including MCPR, peak vessel pressure, radiation release, and shutdown capability during abnormal operating transients. Fuel cladding integrity during a LOCA and reactor response during an ATWS event were also evaluated. Results of this evaluation are provided in the GE Topical Report NEDC-30601-P, "Safety Review of Water Level Setpoint Change for Brunswick Steam Electric Plant, Units 1 and 2." None of these evaluations indicated that any new or different type of accident would be created by the change. In addition, the present function and structure of the Group 1 isolation valves remains unchanged, thereby eliminating possible operator confusion and training problems that could lead to a new or different type of accident. Therefore, the proposed change does not create the possibility of a new or different kind of accident.

3. The effects of the setpoint change for LOCA events has been reviewed, and it has been determined that the change has no impact. As stated in NEDC-30601-P, large and intermediate LOCA events will not be affected because the rapid depressurization and rapid inventory loss will cause the MSIV to close almost immediately after the accident, before any fuel failure could occur. Thus, the lower MSIV trip will not increase inventory loss from the reactor core or radiation release to the environment. For a small break LOCA, the highest peak cladding temperature for the worst case single failure (i.e., failure of the high pressure coolant injection (HPCI) system) is considerably less than the 2200° F peak clad temperature limit. Therefore, the setpoint change will have no effect on the limiting maximum average planar linear heat generation rate (MAPLHGR).

For a loss of feedwater flow event under the proposed amendment, the reactor would not be isolated while HPCI and reactor core isolation [cooling] (RCIC) are operating. Reactor core isolation cooling system flow would compensate for steam flow through the turbine control valves to the main condenser, thereby maintaining water level above low level 3, keeping the MSIVs open, and preventing the S/RVs from opening. Thus, the MSIV setpoint change will not compromise core cooling capability for the loss of feedwater flow event. Furthermore, it reduces suppression pool heatup for this event because the main condenser is available for a longer time.

The low level 3 reactor water level setpoint for the Group 1 primary containment isolation system valves still "ensures the effectiveness of the instrumentation used to mitigate the consequences of accidents" as demonstrated by the evaluation in Sections 4 and 5 of NEDC-30601-P. Thus, for the reasons described above, the margin of safety is not reduced and may actually be increased.

Based on the above, the licensee has determined that the proposed amendment does not involve a significant hazards consideration. The NRC staff has reviewed the licensee's no significant hazards consideration determination and agrees with the licensee's analysis. Accordingly, the Commission proposes to determine that the requested amendment does not involve a significant hazards consideration.

Local Public Document Room location: University of North Carolina at Wilmington, William Madison Randall Library, 601 S. College Road, Wilmington, North Carolina 28403-3297.

Attorney for licensee: R. E. Jones, General Counsel, Carolina Power & Light Company, P. O. Box 1551, Raleigh, North Carolina 27602

NRC Project Director: Elinor G. Adensam

Carolina Power & Light Company et al., Docket No. 50-325, Brunswick Steam Electric Plant, Unit No. 1, Brunswick County, North Carolina

Date of application for amendment: June 9, 1988

Description of amendment request: The proposed change to Brunswick Steam Electric Plant, Unit No. 1, (BSEP) Technical Specification Tables 3.3.5.2-1 and 4.3.5.2-1 is requested to address alternate shutdown capability requirements associated with 10 CFR Part 50, Appendix R.

Reactor vessel water level transmitter B21-LT-N026A currently provides indication on the remote shutdown panel (B21-LI-R604AX), as well as on the control panel in the control room (via B21-LT-604A), and level transmitter B21-LT-N026B provides indication only on the control panel (via B21-LI-R604B). The remote shutdown panel is located in the reactor building. The proposed modification would have level transmitter B21-LT-N026A providing indication to only the control panel in the control room (on B21-LI-R604A) and level transmitter B21-LT-N026B will provide indication on the remote shutdown panel (B21-LI-R604BX) and, via the remote shutdown panel, on the control panel (B21-LI-R604B).

The licensee states that these modifications are being made to address alternate shutdown capability requirements associated with 10 CFR Part 50, Appendix R, Section III.G. The above described level transmitters and indicators are identified in the Technical Specifications and, subsequently, need to be changed to support the modification.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a no significant hazards consideration exists as stated in 10 CFR 50.92(c). A proposed amendment to an operating license involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

Carolina Power & Light Company (the Company) has reviewed this proposed license amendment request and determined that its adoption would involve no significant hazards consideration for the following reasons:

1. The instrumentation being rewired provides reactor water level indication as part of the plant monitoring instrumentation required for 10 CFR Part 50, Appendix, R, Section III.G. It provides no direct protection against any of the accidents identified in Chapter 15 of the Updated Final Safety Analysis (UFSAR). By rewiring these instruments, the Train A instrumentation will feed the control room and the Train B instrumentation will feed the remote shutdown panel thereby satisfying the requirements of 10 CFR Part 50, Appendix R, Section III.G. The purpose and function of the instrumentation will not change; only the indication point will be exchanged between instrument trains. Therefore, the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Rewiring of level transmitter loops B21-LT-N026A and B21-LT-N026B will allow the Company to safely shutdown the unit using the Alternate Safe Shutdown Procedures. The possibility of a new or different kind of accident from any accident previously evaluated will not be created because this instrumentation will not be performing any different function from its current function. This modification is being made to address the commitments associated with 10 CFR Part 50, Appendix R, Section III.G which require the Train A instrumentation to feed the control room and the Train B instrumentation to feed the remote shutdown panel. The new configuration will ensure consistent indication, i.e., Train A or Train B, in both the control room and at the remote shutdown panel. The necessary indication will be available to the operator at the proper location under fire scenarios which would take out either the Train A or Train B instrumentation.

3. The proposed modification will ensure proper indication in the appropriate area in

the event of a fire that takes out either the Train A or Train B instrumentation. Currently, transmitter B21-LT-N026A feeds the remote shutdown panel, and transmitter B21-LT-N026B feeds the control room. Commitments associated with compliance with 10 CFR Part 50, Appendix R, Section III.G requires that Train A feed the control room and Train B feed the remote shutdown panel. This is to ensure that in the event of a fire that takes out Train A, there will be indication to the remote shutdown panel from Train B, and in a fire that takes out Train B, there will be indication to the control room from Train A. Thus, the proposed amendment does not involve a significant reduction in the margin of safety.

Based on the above reasoning, the licensee has determined that the proposed changes involve no significant hazards consideration. The NRC staff has reviewed the licensee's no significant hazards consideration determination and agrees with the licensee's analysis. Accordingly, the Commission proposes to determine that the requested amendment does not involve a significant hazards consideration.

Local Public Document Room location: University of North Carolina at Wilmington, William Madison Randall Library, 601 S. College Road, Wilmington, North Carolina 28403-3297.

Attorney for licensee: R. E. Jones, General Counsel, Carolina Power & Light Company, P. O. Box 1551, Raleigh, North Carolina 27602

NRC Project Director: Elinor G. Adensam

Carolina Power & Light Company et al., Docket No. 50-325, Brunswick Steam Electric Plant, Unit No. 1, Brunswick County, North Carolina

Date of application for amendment: June 27, 1988

Description of amendment request: The proposed amendment would change Technical Specification (TS) Tables 3.3.5.6-1, 3.3.5.6-2 and 4.3.5.6-1 to replace instrument tag number TS-CR-863 with TS-CIT-863-3. This change is needed as a result of planned upgrading of instrumentation during the Brunswick Steam Electric Plant, Unit 1, refueling outage of November 1988. Item 2 in each of the above tables lists chloride leak detection instrumentation in the condensate pump discharge. This instrumentation provides indication of chloride intrusion in the feedwater and condensate systems. Chlorides pose a long-term threat to the integrity of stainless steel piping systems. The change is necessary due to a plant modification that will replace the instrument represented by TS-CR-863-3 with an upgraded conductivity cell and analyzer represented by tag number TS-CIT-863-3. The upgraded components are capable of detecting and compensating for temperature transients that may occur in the sample being analyzed. The new conductivity analyzer will provide a direct and continuous reading without relying on a recorder, and will also provide an output to a recorder for trending purposes.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a no significant hazards consideration exists as stated in 10 CFR 50.92(c). A proposed amendment to an operating license involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee has determined that:

1. The accidents analyzed in Chapter 15 of the Updated FSAR are not affected by the chloride leak detection instrumentation change because the function of the instrument is not altered and the chloride limits established in TS 3/4.4.4 are not being changed. In addition, the new instruments being installed are capable of detecting and compensating for temperature transients which may occur in the sample being analyzed. The current system requires additional data processing to achieve the same results. Based on this reasoning, CP&L has determined that the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. As stated above, the chloride leak detection instrumentation provides protection from long-term piping degradation in the feedwater and condensate systems caused by chloride intrusion. No possibility of a new or different kind of accident is created because the new instruments perform the same basic function as the ones they are replacing. Also, the reactor coolant system chloride limits established in TS 3/4.4.4 are not being changed. The new instrument has enhanced capabilities; it processes the data into a more useful form prior to readout. Based on the above reasoning, CP&L has determined that the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The margin of safety is not reduced because, as stated above, the new instruments perform the same basic function as the ones they are replacing and the chloride limits established in TS 3/4.4.4 are not being changed. In fact, the new instruments have enhanced capabilities which may provide the user with better data, thereby providing earlier indication of chloride intrusion, and perhaps avoiding long-term problems with pipe degradation due to chloride intrusion. Based on this reasoning, CP&L has determined that the proposed amendment does not involve a significant reduction in the margin of safety.

Based on the above reasoning, the licensee has determined that the proposed changes involve no significant hazards consideration. The NRC staff has reviewed the licensee's no significant hazards consideration determination and agrees with the licensee's analysis. Accordingly, the Commission proposes to determine that the requested amendment does not involve a significant hazards consideration.

Local Public Document Room location: University of North Carolina at Wilmington, William Madison Randall Library, 601 S. College Road, Wilmington, North Carolina 28403-3297.

Attorney for licensee: R. E. Jones, General Counsel, Carolina Power & Light Company, P. O. Box 1551, Raleigh, North Carolina 27602

NRC Project Director: Elinor G. Adensam

Commonwealth Edison Company, Docket Nos. 50-456 and 50-457, Braidwood Station, Unit Nos. 1 and 2, Will County, Illinois

Date of application for amendments: November 26, 1986 and January 14, 1988

Description of amendments request: In accordance with the requirements of 10 CFR 73.55, the licensee submitted an amendment to the Braidwood Nuclear Power Station Security Plan to reflect recent changes to that regulation. The proposed amendment would modify paragraph 2.F of Facility Operating License Nos. NPF-72 and NPF-77 to require compliance with the revised plan.

Basis for proposed no significant hazards consideration determination: On August 4, 1986 (51 FR 27817 and 27822), the Nuclear Regulatory Commission amended Part 73 of its regulations, "Physical Protection and Plants and Materials," to clarify plant security requirements to afford and increased assurance of plant safety. The amended regulations required that each nuclear power reactor licensee submit proposed amendments to its security plan to implement the revised provisions of 10 CFR 73.55. The licensee submitted its revised plan on November 26, 1986 and January 14, 1988, to satisfy the requirements of the amended regulations. The Commission proposes to amend the license to reference the revised plan.

In the Supplementary Materials accompanying the amended regulations, the Commission indicated that it was amending its regulations "to provide a more safety conscious safeguards system while maintaining the current levels of protection" and that the "Commission believes that the clarification and refinement of requirements as reflected in these amendments are appropriate because they afford an increased assurance of plant safety."

The Commission has provided guidance concerning the application of the criteria for determining whether a significant hazards consideration exists by providing certain examples of actions involving no significant hazards considerations and examples of actions involving significant hazards consideration (51 FR 7750). One of these examples of actions involving no significant hazards considerations is example (vii) "a change to conform a license to changes in the regulations, where the license change results in very minor changes to facility operations clearly in keeping with the regulations." The changes in this case fall within the scope of the example. For the foregoing reasons, the Commission proposes to determine that the proposed amendment involves no significant hazards consideration.

Local Public Document Room location: Wilmington Township Public Library, 201 S. Kankakee Street, Wilmington, Illinois 60481.

Attorney to licensee: Michael Miller, Esquire; Sidley and Austin, One First National Plaza, Chicago, Illinois 60603.

NRC Project Director: Daniel R. Muller

Commonwealth Edison Company, Docket No. 50-374, LaSalle County Station, Unit 2, LaSalle County, Illinois

Date of application for amendment: September 14, 1988

Brief description of amendment: The proposed amendment to Operating License No. NPF-18 would revise the LaSalle Unit 2 Technical Specifications in support of the second reload for LaSalle Unit 2. Startup for Cycle 3 is currently scheduled for January 1989. The proposed reload fuel and analyses including the previously approved SAFER/GESTR-LOCA Loss-of-Coolant Accident (LOCA) Analysis are changes resulting from analyses performed to expand the operating region and allow equipment out-of-service and changes that are administrative or provide clarification. The proposed changes for LaSalle Unit 2 are identical to those previously submitted and approved for use at LaSalle Unit 1, except for minor calculation differences in the results for transient analyses and include:

1. Provision for operation in the expanded operating domain including revised APRM and RBM setpoint changes incorporated using standard and previously approved methodology.
2. Use of extended burnup fuel (GE 8x8EB) with increased LHGR limit of 14.4 Kw/ft.
3. Use of improved transient and LOCA analysis methods which allow use of a lower tau-B value in determining the MCPR operating limit as a function of scram time, and deletion of the single loop MAPLHGR limit multiplier of 0.85.
4. Provision for operation with certain equipment inoperable or out of service. Specifically, one of the following systems or components may be out of service when the appropriate Technical Specification Actions are satisfied:
   a. Turbine Bypass System
   b. End-of-Cycle Recirculation Pump Trip (EOC-RPT)
   c. One Safety Relief Valve (SRV)
   d. Feedwater Heaters
5. Several changes for clarification or administrative purposes were proposed including:
   a. Deletion of GEXL correlation and GETAB statistical model in the bases of the safety limit section.
   b. Revision to the Control Rod Program Controls Technical Specification to require the RWM to be demonstrated operable in Operational Condition 1, prior to reaching 20% power, when reducing thermal power.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether no significant hazards consideration exists as stated in 10 CFR 50.92(c). A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from an accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee has determined, and the NRC staff agrees, that the proposed amendment will not:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated because the use of the proposed operating limits is specifically analyzed to ensure that the input assumptions of all existing transient and accident analyses remain valid. These analyses are performed using a methodology which has received review and approval for other similar plants including LaSalle Unit 1. The Technical Specification Actions included in the proposed revisions do not significantly affect the probability of an accident previously analyzed because the required time intervals for corrective action are consistent with the existing specifications.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated because the proposed MCPR, MAPLHGR, and LHGR limits represent limitations on reactor operating state which do not directly affect the operation, or function of any system or component. As a result, there is no impact on or addition of any systems or equipment whose failure could initiate an accident. The proposed operating domain is evaluated to retain the originally required design margins to system integrity during normal operation, transients and accidents and therefore, do not cause significant new loads or stresses on mechanical systems or boundaries. The proposed allowances for operating with prescribed equipment inoperable or out-of-service do not cause physical changes to any systems and therefore do not induce new failure modes.

3. Involve a significant reduction in the margin of safety because no changes to safety limits protective system logic or design are involved. The analyses used to evaluate reactor and system performance are performed using standard methods and the calculated operating limits maintain conservative margin to safety limits to accommodate the anticipated performance during transients and accidents. Changes which are administrative in nature do not affect the operating limits of the plant or the consequences of analyzed transients.

Local Public Document Room location: Public Library of Illinois, Valley Community College, Rural Route No. 1, Oglesby, Illinois 61348.

Attorney to licensee: Michael Miller, Esq., Sidley and Austin, One First National Plaza, Chicago, Illinois 60603

NRC Project Director: Daniel R. Muller

Commonwealth Edison Company (CECo), Docket No. 50-265, Quad Cities Nuclear Power Station, Unit 2, Rock Island County, Illinois

Date of application for amendments: July 7, 1988

Description of amendments request: There are two changes associated with the proposed license amendment. The first change results from the completion

of a Unit 2 Detailed Control Room Design Review (DCRDR) Human Factors modification which resulted in the relocation of the drywell temperature indicator from the 902-21 (back) panel to the 902-3 (front) panel. Such a change would be incorporated into Technical Specifications (TS) Table 3.2-4 and 4.2-2 of DPR-30. The remaining proposed changes would correct typographical errors associated with the same TS tables.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists. As stated in 10 CFR 50.92(c), a proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not; (1) involve a significant increase in the probability or consequences of an accident previously evaluated, (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety. Pursuant to 10 CFR 50.91(a) the licensee has provided the following evaluation of their amendment application addressing these three standards.

CECo has evaluated the proposed Technical Specifications changes and determined that they do not present a significant hazards consideration. Based on the criteria for defining a significant hazards consideration established in 10 CFR 50.92(c), operation of QCNPS in accordance with the proposed changes:

(1) Will not involve a significant increase in the probability or consequences of an accident previously evaluated because only the location of the drywell temperature indication has been changed (from the back to the front panel) in the Control Room. This is an enhancement over the previous location to make it more observable for operators. Functions and range of the drywell instrument remain the same. This modification was considered to be a change in the conservative direction.

(2) Will not create the possibility of a new or different kind of accident from any accident previously evaluated because there were no hardware changes (addition or deletion of equipment) per-se, nor are there any new modes of operation associated with this amendment. The changes to Tables 3.2-4 and 4.2-4 reflect changes to equipment (instrumentation) location only.

(3) Will not involve a significant reduction in the margin of safety because revising an instrument location readout in the control room does not adversely affect the operation of any plant systems. Therefore, the margin of safety has not been unchanged as a result of this change.

The NRC staff has reviewed the licensee's evaluation related to the proposed changes and concurs with their conclusions.

In addition, administrative and editorial TS changes are considered representative of example (i) in the Commission's guidance (51 FR 7751) for examples of no significant hazards, which is defined as "a purely administrative change to TS; for example a change to achieve consistency throughout the Technical Specification, correction of an error, or change in nomenclature."

Therefore the NRC staff proposes to determine that this amendment request does not involve significant hazards considerations based upon a preliminary review of the application, the licensee's evaluation of no significant hazards, and NRC guidance.

Local Public Document Room location: Dixon Public Library, 221 Hennepin Avenue, Dixon, Illinois 61021.

Attorney for licensee: Michael I. Miller, Esquire; Sidley and Austin, One First National Plaza, Chicago, Illinois 60603.

NRC Project Director: Daniel R. Muller

Commonwealth Edison Company, Docket Nos. 50-254 and 50-265, Quad Cities Nuclear Power Station, Units 1 and 2, Rock Island County, Illinois

Date of application for amendments: October 5, 1988

Description of amendments request: This amendment would delete Figure 6.1-1, 'Corporate Organization," and Figure 6.1-2, "Station Organization," from the Technical Specifications (TS) and would revise Section 6 to require inclusion of these organization charts in the QA Topical Report. However, the NRC will continue to be notified of licensee organization changes through other regulatory controls. In accordance with 10 CFR 50.34(b)(6)(i), the applicant's organizational structure is required to be included in the Final Safety Analysis Report (FSAR). Chapter 13 of the FSAR provides a description of the station organization and a detailed organization chart. Updates to the FSAR are required by 10 CFR 50.71(e) to be submitted annually to the NRC. Even though Figures 6.1-1 and 6.1-2 would be deleted from TS, Section 6 of the TS would be revised to require inclusion of these organization charts in the CECo QA Topical. Whereupon, Appendix B to 10 CFR Part 50, and 10 CFR 50.4(b)(7), will govern any changes made to the organization as it is described in the Quality Assurance (QA) Program. Finally, it is CECo's normal practice to inform the NRC of organizational changes affecting their nuclear facilities prior to implementation.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards in 10 CFR 50.92(c) for determining whether a significant hazards consideration exists. A proposed amendment to an Operating License for a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated, (2) involve a significant increase in the probability of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety. CECo evaluated the proposed TS changes and determined, and the NRC staff agrees that:

(1) The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated because deletion of the organization charts from the TS does not affect plant operation, nor does it involve any physical modification of the plant. Furthermore, the aforementioned administrative and regulatory controls remain in force to ensure that organizational changes are reviewed by the NRC.

(2) The proposed amendment does not create the possibility of a new or different kind of accident than previously evaluated because the proposed change is administrative in nature; and does not physically alter any systems or components, or the way they are operated.

(3) The proposed amendment does not involve a significant reduction in a margin of safety because CECo through its Quality Assurance programs, and its commitment to maintain only qualified personnel in positions of responsibility, and other required controls, assures that safety-related operations will be performed at a high level of competence. Futhermore, this amendment does not change any setpoints or operating parameters. Consequently, removal of organization charts from the Technical Specifications will not affect the margin of safety. The NRC staff has reviewed the licensee's evaluation related to the proposed changes and concurs with their conclusions.

In addition, the associated editorial TS changes proposed by CECo are considered representative of example (i) in the Commission's guidance (51 FR 7751) for examples of no significant hazards, which is defined as "a purely administrative change to TS; for example a change to achieve consistency throughout the Technical Specifications, correction of an error, or change in nomenclature."

Therefore the NRC staff proposes to determine that this amendment request does not involve significant hazards considerations based upon a preliminary review of the application, the licensee's evaluation of no significant hazards, and NRC guidance.

Local Public Document Room location: Dixon Public Library, 221 Hennepin Avenue, Dixon, Illinois 61021.

Attorney for licensee: Michael I. Miller, Esquire; Sidley and Austin, One First National Plaza, Chicago, Illinois 60603.

NRC Project Director: Daniel R. Muller

Duke Power Company, et al., Docket Nos. 50-413 and 50-414, Catawba Nuclear Station, Units 1 and 2, York County, South Carolina

Date of amendment request: July 26, 1988

Description of amendment request: The proposed amendment would revise Technical Specification (TS) 3/4.7.6 to clarify the emergency power requirements for the Control Room Area Ventilation System. The word "train" is substituted for the word "system" where reference is made to one of the two independent trains which comprise the ventilation system for the control room area shared by the two Catawba units. Also, TS 3/4.7.6 and its Bases are revised to eliminate the possibility of misinterpreting the existing TS requirements for diesel generator (D/G) operability when one or both Catawba units are shutdown.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee, in its submittal of July 26, 1988, provided the following discussion and analysis with regard to the three 10 CFR 50.92 standards:

The Control Room Area Ventilation (VC) and Chilled Water (YC) Systems combine to form one system which is designed to maintain a suitable environment in the following plant areas at all times: Control Room, Cable Room, Battery Room, Switchgear Rooms, Motor Control Center Rooms, and the Electrical Penetration Rooms at elevation 594+0. The VC/YC System is shared between both Units. There are two 100% redundant trains of VC/YC equipment. Each is capable of being powered by Unit 1 or Unit 2 Essential Auxiliary Power, but under normal conditions both trains are aligned to Unit 1. Two diesel generators (D/Gs) are provided per Unit to energize the Essential Auxiliary Power buses during emergency conditions.

Technical Specification 3.7.6 specifies that two independent trains of VC/YC shall be Operable during all operational modes. If one train becomes Inoperable while either Unit is in Mode 4, Hot Shutdown, or above, the Inoperable train must be restored to Operable status within seven days, or the operating Units must be shutdown. If both Units are below Mode 4 and one train is Inoperable, the train must be restored to Operable status within seven days or the Operable train must be operated in the filter mode. If both trains are Inoperable, or with the Operable train not capable of being powered by an Operable emergency power source, all core alterations and positive reactivity changes must be suspended on both Units. The requirement for an Operable emergency power source is only specifically stated for Units operating below Mode 4. However, the bases for Technical Specification 3.7.6 states that the operability of VC/YC ensures that ambient air temperature does not exceed allowable limits for equipment and instrumentation, and the Control Room will remain habitable, during and following all credible accident conditions. This implies that an Operable emergency power supply should be a prerequisite to VC/YC operability in all modes.

Technical Specification 3.8.1.1 specifies for each individual Unit that two separate and independent D/Gs are required to be Operable per Unit, if the Unit is in Mode 4, or above. Below Mode 4, Technical Specification 3.8.1.2 applies and only one D/G is required Operable per Unit. Action Statement c. for Technical Specification 3.8.1.1 specifies that when one D/G becomes Inoperable, all required systems (or trains) that depend on the remaining Operable D/G as a source of emergency power, must be verified Operable within two hours, or the Unit must be shutdown. This is intended to provide assurance that a loss of offsite power event, while one D/G is Inoperable, will not result in a complete loss of safety function of critical systems. it is also the reason Technical Specification 3.7.6 does not specifically require that VC/YC have an Operable emergency power source in Mode 4, or above. This action statement is deficient with respect to VC/YC because VC/YC is a Unit shared system, and Technical Specification 3.8.1.1 applies only to individual Units. In order for VC/YC operability to be protected by this Action Statement, the D/G must become Inoperable while the Unit is in Mode 4, or above. There is no such Action Statement in Technical Specification 3.8.1.2 since only one D/G is required Operable, and the Unit is already shut down.

This amendment request would remove the ambiguity as to the emergency power source requirements for the VC System by stating the requirements in the VC System Technical Specification.

To clarify the requirements the Specification is to be split into two separate Specifications. The first Specification (Technical Specification 3.7.6.1) would state the requirements for the VC System when either unit is in Modes 1, 2, 3 or 4. This Specification will now specifically require that each train of the VC System be capable of being powered by an Operable emergency power source whenever either unit is in Mode 1, 2, 3 or 4. This will alleviate the confusion which is currently contained in the Specification as to the emergency power source requirements when one unit is in Modes 1, 2, 3 or 4 and the other unit is in Modes 5 or 6.

Technical Specification 3.7.6.2 is being proposed to clearly state the VC System requirements when both units are in Modes 5 or 6.

The proposed changes to the VC System Specification will also specify that the requirements are to be performed on a per train basis. The VC System is comprised of two independent and redundant trains. The current wording is that which appears in the Standard Technical Specification and should be changed to more clearly reflect what is in place at Catawba.

These proposed changes will add clarification to the requirements of the VC System Specification. The changes will not delete any current requirements or operating restrictions contained in the Specifications and will not allow the plant to be operated in any different mode or configuration. As such, these changes are considered to be administrative in nature and do not involve any Significant Hazards Considerations.

The proposed amendment does not involve an increase in the probability or consequences of any previously evaluated accident. The operating parameters and the design of the VC System are unchanged and no new modes of operation will be introduced by this amendment request. All previous accident analyses are still applicable and remain unchanged by this proposal.

The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated. The proposed changes will not change the design or allowed modes of operation of the VC System. As such, no new failure modes are introduced and no new types of accidents are possible.

The proposed amendment does not involve a significant reduction in a margin of safety. These changes will add clarification to the

existing Specification without changing any of the current requirements.

For the above reasons, Duke Power concludes that this proposed amendment does not involve any Significant Hazards Considerations.

The staff has reviewed the proposed changes to TS 3/4.7.6, and agrees with the licensee's evaluation of each of these changes with respect to the three standards of 10 CFR 50.92.

On this basis, the Commission has concluded that the requested changes meet the three standards and, therefore, has made a proposed determination that the amendment application does not involve a significant hazards consideration.

Local Public Document Room location: York County Library, 138 East Black Street, Rock Hill, South Carolina 29730

Attorney for licensee: Mr. Albert Carr, Duke Power Company, 422 South Church Street, Charlotte, North Carolina 28242

NRC Project Director: David B. Matthews

Duke Power Company, et al., Docket Nos. 50-413 and 50-414, Catawba Nuclear Station, Units 1 and 2, York County, South Carolina

Date of amendment request: October 6, 1988

Description of amendment request: The proposed amendments would revise Technical Specification (TS) Table 3.3-3, Item 14.g., to reflect a proposed modification to the pumphouse pit level instrumentation of the Nuclear Service Water (RN) System. The system is designed to supply cooling water to various heat loads in both the safety and non-safety portions of each unit. This modification would change the swapover logic of the RN system.

There are currently four level transmitters per pit at the RN pumphouse. Two are safety-related and two are not safety-related. The modification will upgrade 1 out of the 2 non-safety level transmitters per pit to safety grade. This would accommodate a 2 out of 3 logic instead of the present 1 out of 2 logic. Past experience has shown that a single spurious failure to the "low" position of one level transmitter can initiate a swapover when there is an adequate water level in the RN pits. Inadvertently challenging the system with numerous valves changing position and starting all RN pumps is unnecessary and reduces the reliability of the system.

The failure mode of all the safety grade level transmitters is the same. They fail low on loss of power. This is desirable in order to realign suction from Lake Wylie to the Standby Nuclear Service Water Pond (SNSWP) which is the ultimate heat sink.

The proposed amendments would also temporarily waive the requirements of the Action Statement for Item 14.g. in Table 3.3-3, for 48 hours per pit, on a one time basis in order to allow orderly implementation of this modification. During this time at least one RN pit will be available. The 48 hours is needed for implementation of the modification on each pit separately. During this period, the pit will be inoperable only from the standpoint of automatic realignment to the SNSWP from its normal supply if low level is sensed in the affected pit. All necessary automatic functions would still occur in the opposite pit. The only automatic valve actuation which is activated by train specific pit level instrumentation is the loop cross-over isolation valves. Closure of these valves is only required in the event of design basis accident accompanied by a failure of a pit supply valve to open when an emergency diesel generator or nuclear service water pump is out-of-service for extended maintenance. All four diesel generators and nuclear service water pumps will be maintained in an operable status for the duration of the requested 48 hour period. Therefore, the RN system would be capable of performing its design function during any design basis event, including any concurrent postulated single failure, throughout the requested 48 hour period.

In a letter to Duke Power Company dated September 30, 1987, the NRC staff noted that this proposed modification would improve the overall reliability of the RN System.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR Part 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards considerations if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possiblity of new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The proposed amendments do not involve a significant increase in the probability or consequences of an accident previously evaluated because the proposed modification would increase the reliability of the RN system by eliminating unnecessary actuations of the swapover instrumentation and components, and during implementation of the modification the system would be capable of performing its intended function during any design basis event.

The proposed amendments do not create the possibility of a new or different kind of accident from any accident previously evaluated because the RN system design basis would not be changed as a result of this modification, and the proposed modification would improve the reliability of the system.

The proposed amendments do not involve a significant reduction in a margin of safety because the modification would enhance the reliability of the RN system by decreasing the likelihood of inadvertent actuations, and during implementation of the modification the RN system would be capable of performing its intended function during any design basis event.

Accordingly, the Commission has concluded that the requested changes meet the three standards and, therefore, has made a proposed determination that the requested license amendments do not involve a significant hazards consideration.

Local Public Document Room location: York County Library, 138 East Black Street, Rock Hill, South Carolina 29730

Attorney for licensee: Mr. Albert Carr, Duke Power Company, 422 South Church Street, Charlotte, North Carolina 28242

NRC Project Director: David B. Matthews

Duke Power Company, et al., Docket Nos. 50-413 and 50-414, Catawba Nuclear Station, Units 1 and 2, York County, South Carolina

Date of amendment request: October 7, 1988

Description of amendment request: The proposed amendment would revise Section 6.2 "Organization" of the Technical Specifications (TS) to delete the offsite and onsite organization charts, Figures 6.2-1 and 6.2-2. In place of the charts, the revision would add general requirements which capture the essential features of the organizational structure that are defined by the existing organization charts.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility

in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee, in its submittal of October 7, 1988, provided the following discussion and analysis with regard to the three 10 CFR 50.92 standards:

This proposed amendment would incorporate the guidance contained in the NRC's Generic Letter 88-06, dated March 22, 1988. The Generic Letter provided for deletion of the organization charts contained within Section 6 of the Technical Specifications provided certain statements be added to cover particular administrative control requirements.

This proposed amendment has been developed based on the Generic Letter guidance.

The NRC Staff concluded and Duke Power concurs that the removal of organization charts from the Technical Specifications will provide greater flexibility to implement changes in organization structure but will not reduce plant safety.

The proposed amendment does not involve an increase in the probability or consequences of any previously evaluated accident. This amendment is administrative in nature and does not change the design or operation of the facility. The accident analyses are therefore unaffected by this proposal.

The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated. The design and operation of the facility will not be changed by this amendment and no new modes of operation will be introduced.

The proposed amendment does not involve a significant reduction in a margin of safety. This change is administrative in nature and therefore has no effect on any margin of safety.

The NRC's discussion in their Generic Letter 88-06 concluded that any facility incorporating the changes outlined in the Generic Letter will have greater flexibility to implement changes to their organizational structures and will not reduce plant safety.

For the above reasons, Duke Power concludes that this proposed amendment does not involve any Significant Hazards Considerations.

The NRC staff has reviewed the licensee's submittal against the guidance provided in Generic Letter (GL) 88-06, "Removal of Organization Charts from Technical Specification Administrative Control Requirements." The proposed TS revisions, deleting the organization charts and adding more flexible provisions regarding organizational structure, are in accord with this guidance. As also recommended in GL 88-06, the Final Safety Analysis Report (FSAR) contains the offsite and onsite organization charts (Figures 13.1.1-1 and 13.1.2-1) and the qualifications for those positions designated by the charts as requiring a Senior Reactor Operator or Reactor Operator license (FSAR, Section 13.1.3.1). The staff therefore finds that the proposed revisions do not adversely affect the organizational characteristics which are important to the safe operation of the facility. The staff also agrees with the licensee's evaluation of the proposed revisions with respect to the three standards of 10 CFR 50.92.

On this basis, the Commission has concluded that the requested amendment meets the three standards and, therefore, has made a proposed determination that the amendment application does not involve a significant hazards consideration.

Local Public Document Room location: York County Library, 138 East Black Street, Rock Hill, South Carolina 29730

Attorney for licensee: Mr. Albert Carr, Duke Power Company, 422 South Church Street, Charlotte, North Carolina 28242

NRC Project Director: David B. Matthews

Duquesne Light Company, Docket No. 50-412, Beaver Valley Power Station, Unit No. 2, Shippingport, Pennsylvania

Date of amendment request: October 24, 1988

Description of amendment request: The proposed amendment would extend the interval for several 18-month surveillances: reactor trip system response time, reactor trip bypass breakers automatic undervoltage trip check, engineered safety feature (ESF) logic response time, manual actuation switches for several ESF systems, reactor trip P-4 interlock, seismic monitoring instruments, containment isolation check valve lift tests, containment isolation phase B isolation valve actuations, containment recirculation spray valve actuations, diesel generator maintenance inspection, and battery discharge test. To perform these surveillances, the licensee would have to shutdown the unit. Therefore, the licensee requested that the surveillances specified above be permitted to be done at the first refueling outage, but no later than April 1, 1989. If approved, the amendment would permit extension of the 18-month intervals by several days to about three months. The amendment would thus avert a reactor shutdown only to perform surveillances. The licensee agreed to perform these surveillances if there is an unscheduled shutdown of sufficient duration before the refueling outage.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The proposed schedular extensions are not made as a result of, nor would they lead to any design changes. When approved by the staff, only certain surveillance intervals would be extended. The affected systems will continue to perform as stated in the licensee's Final Safety Analysis Report (FSAR); other requirements regarding these components/systems are not changed. From experience in the past, surveillances were performed usually to confirm that components were operable as designed. The probability of finding inoperable components was not high, and consequently, the probability of occurrence of an accident can only be increased by an insignificant amount if the surveillance interval is extended by a small amount. Therefore, the answers to questions (1) and (2) would be negative. The safety limits assumed in FSAR analyses are not affected by the proposed amendment since all assumptions are expected to remain unchanged. Hence the answer to question (3) is also negative.

On such basis, the staff proposes to determine that the requested amendment involves no significant hazards consideration.

Local Public Document Room location: B. F. Jones Memorial Library, 663 Franklin Avenue, Aliquippa, Pennsylvania 15001.

Attorney for licensee: Gerald Charnoff, Esquire, Jay E. Silberg, Esquire, Shaw, Pittman, Potts & Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Project Director: John F. Stolz

Florida Power and Light Company, et al., Docket No. 50-389, St. Lucie Plant, Unit No. 2, St. Lucie County, Florida

Date of amendment request: October 20, 1988

Description of amendment request: The amendment would change the maximum allowable control element assembly (CEA) drop time from 2.7 seconds to 3.1 seconds. The application is the result of the licensee's review of NRC Information Notice No. 88-47 entitled, "Slower-than-Expected Rod-Drop Time Testing."

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards considerations if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee addressed the above three standards in the amendment application and made a no significant hazards consideration determination. In regard to the first standard, the licensee provided the following analysis:

Operation of the facility in accordance with the proposed amendment would not involve a significant increase in the probability or consequences of an accident previously evaluated.

The change does not affect any active hardware involving plant operation; rather it affects an acceptance criterion for confirming the required performance of the existing control element assembly (CEA) hardware. Therefore, the proposed change does not increase the probability of an accident previously analyzed.

The impact of changing the CEA drop time from 2.7 to 3.1 seconds on all safety analysis related Design Basis Events (DBE's), for which a scram of the CEA's is predicted, was assessed by specifically re-analyzing only the most limiting events with respect to the various safety analysis fuel and system criteria. In particular, the following events were re-analyzed:

Loss of Condenser Vacuum (LOCV)
Loss of Forced Reactor Coolant Flow
Pre-Trip Steam Line Break (SLB)
Hot Full Power CEA Ejection (CEA Ejection)

It has been demonstrated that the events are either totally unrelated to CEA drop time considerations or are not significantly impacted. Additionally, it was demonstrated for each potentially impacted analysis that the consequences of the analysis remain unchanged or are bounded by the existing analysis. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

With respect to the second standard, the licensee stated:

Use of the modified specification would not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed change in the Technical Specifications does not affect any active hardware involving plant operation; rather it affects only an acceptance criterion for confirming the required performance of the existing CEA hardware. Therefore, the proposed change would not create the possibility of a new or different kind of accident from any previously evaluated.

With regard to the third standard, the licensee provided the following rationale:

Use of the modified specification would not involve a significant reduction in a margin of safety.

The increased CEA drop time has been evaluated for its impact on the current licensed safety analysis. The results of the re-analysis for those transients which are potentially impacted by the proposed change show that the reference analyses are valid or that the new analysis results still show acceptable results with respect to the acceptance criteria. Therefore, there is no significant reduction in the margin of safety.

The staff has reviewed the analysis provided by the licensee in support of a no significant hazards consideration determination. The staff believes that the licensee has met the standards for such a determination. Therefore, the staff proposes to determine that the proposed change does not involve a significant hazards consideration.

Local Public Document Room location: Indian River Junior College Library, 3209 Virginia Avenue, Fort Pierce, Florida 33450

Attorney for licensee: Harold F. Reis, Esquire, Newman and Holtzinger, 1615 L Street, NW., Washington, DC 20036

NRC Project Director: Herbert N. Berkow

Florida Power and Light Company, et al., Docket No. 50-389, St. Lucie Plant, Unit No. 2, St. Lucie County, Florida

Date of amendment request: October 24, 1988

Description of amendment request: The amendment would expand the Departure from Nucleate Boiling and Linear Heat Rate-related Axial Shape Index limits contained in Figures 3.2-4 and 3.2-2, respectively. In addition, a similar expansion of limits is proposed for the Linear Heat Rate-related Limited Safety System Setpoints as contained in Figure 2.2-2. The licensee is requesting these changes to give the plant greater flexibility at low and intermediate power levels.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards considerations if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee addressed the above three standards in the amendment application and provided a no significant hazards consideration determination. In regard to the first standard, the licensee provided the following analysis:

Operation of the facility in accordance with the proposed amendment would not involve a significant increase in the probability or consequences of an accident previously evaluated.

The Axial Shape Index (ASI) limits are used as initial assumptions for all Design Basis Events (DBEs) evaluated in the safety analysis. The expansion of these ASI limits for lower powers is applicable only to those DBEs that are evaluated between hot full and hot zero power. Events are not typically analyzed at intermediate power levels. Events initiated from intermediate power levels (100% greater than initial power greater than 0%) are unaffected since these are bounded by the results of events initiated from either the full power or zero power events.

The existing safety analyses for these events use input parameters that are axial shape dependent, such as scram reactivity insertion curves, which are more adverse (conservative) than the Technical Specification Limiting Condition for Operation (LCO) and Limiting Safety System Setpoint (LSSS) axial shape limits at all power levels in order to bound future cycles' operation. It was verified, using current methodology and the proposed ASI limits, that the current safety analysis remains valid.

The current ASI limits allowed by the Departure from Nucleate Boiling (DNB) and Linear Heat Rate (LHR) LCOs and LSSSs are expanded for greater operational flexibility at lower powers. [These] proposed change[s] will not increase the probability or consequences of an accident previously evaluated because the proposed limits are still conservative with respect to the actual calculated limiting values.

With regard to the second standard, the licensee stated:

Use of the modified specification would not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes in the Technical Specifications do not affect any active hardware involving plant operation, nor do they alter the assumptions or methodology of the safety analyses. Therefore, they will not create the possibility of a new or different

kind of accident from any previously evaluated.

With regard to the third standard, the licensee provided the following rationale:

Use of the modified specification would not involve a significant reduction in a margin of safety.

The wider ASI bands allowed at lower powers have been reviewed for their impact upon the current licensed safety analysis. The licensed safety analysis of record remains unchanged due to the expanded ASI range for low powers. Therefore, there is no significant reduction in a margin of safety.

The staff has reviewed the licensee's no significant hazards consideration determination analysis. Based upon the review, the staff believes that the licensee has met the three standards. Based upon the above discussion, the staff proposes to determine that the proposed changes do not involve a significant hazards consideration.

Local Public Document Room location: Indian River Junior College Library, 3209 Virginia Avenue, Fort Pierce, Florida 33450

Attorney for licensee: Harold F. Reis, Esquire, Newman and Holtzinger, 1615 L Street, NW., Washington, DC 20036

NRC Project Director: Herbert N. Berkow

Florida Power and Light Company, et al., Docket No. 50-389, St. Lucie Plant, Unit No. 2, St. Lucie County, Florida

Date of amendment request: October 24, 1988

Description of amendment request: The proposed amendment would relax the maximum allowable primary loop resistance temperature detector (RTD) delay time from 8 seconds to 16 seconds. This delay time is a factor that must be considered in the thermal margin/low pressure reactor trip. According to the licensee, this change would provide increased operational flexibility without decreasing the margin of safety.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards considerations if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee addressed the above three standards in the amendment application and provided a no significant hazards consideration determination. In regard to the first standard, the licensee provided the following analysis:

Operation of the facility in accordance with the proposed amendment would not involve a significant increase in the probability or consequences of an accident previously evaluated.

The Resistance Temperature Detector (RTD) response time affects only measurement hardware which passively ascertains the coolant temperature condition, not active hardware impacting the plant's physical thermal-hydraulic operations. Therefore, the proposed change does not increase the probability of occurrence of any accident. As described before, the safety analyses demonstrate that the same degree of protection is available at the longer RTD response times since the ex-core power detectors (which do not depend on RTD response time) now provide the required protection when more realistic physics inputs are used. With regard to operations, it should be noted that the plant will be operated in the same manner as before. Therefore, the calculated consequences of the accidents will not increase due to this change.

With regard to the second standard, the licensee stated:

Use of the modified specification would not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed change to the Technical Specifications does not affect any active hardware involving plant operation, nor does it alter the basic methodology of the safety analyses. Therefore, it will not create the possibility of a new or different kind of accident from those accidents previously evaluated.

With regard to the third standard, the licensee provided the following rationale:

Use of the modified specification would not involve significant reduction in a margin of safety.

The value of the RTD response time affects the ability of the delta T-power calculator to accurately measure power during a transient. It has been demonstrated that the ex-core power detectors will provide an adequate power measurement input to the Thermal Margin/Low Pressure (TM/LP) trip for the full spectrum of possible power excursions associated with the CEA withdrawal events with a slight increase in margin to the TM/LP trip setpoint. Thus, the margin of safety is not reduced.

The staff has reviewed the licensee's no significant hazards consideration determination analysis. Based upon this review, the staff believes that the licensee has met the three standards. Based upon the above discussion, the staff proposes to determine that the proposed change does not involve a significant hazards consideration.

Local Public Document Room location: Indian River Junior College Library, 3209 Virginia Avenue, Fort Pierce, Florida 33450

Attorney for licensee: Harold F. Reis, Esquire, Newman and Holtzinger, 1615 L Street, NW., Washington, DC 20036

NRC Project Director: Herbert N. Berkow

Illinois Power Company, Soyland Power Cooperative, Inc., Western Illinois Power Cooperative, Inc. (the licensees), Docket No. 50-461, Clinton Power Station, Unit No. 1, DeWitt County, Illinois

Date of amendment request: September 23, 1988

Description of amendment request: This proposed amendment would revise Technical Specification Sections 3.8.1.1 and 3.8.1.2, which are the Limiting Conditions for Operation specified for the AC electrical power sources, to change the number of gallons of fuel oil specified for the Division II diesel generator (1B). These Technical Specifications indicate the minimum amount of diesel fuel that should be available for the diesel generators. The licensees have requested to change the number of gallons of fuel oil specified for the Division II diesel generator (1B) from 41,500 to 45,000.

The licensees have prepared a plant modification to replace the Fuel Pool Cooling and Cleanup (FC) System pump motors (1A and 1B) and remove the associated LOCA shunt trips. This modification is in accordance with their commitment "Until the first refueling, the pump motors will be tripped on a LOCA signal.... By the first refueling, replacement motors qualified to the maximum environment conditions will be installed and the LOCA-trip signal will be removed." Removing the associated LOCA shunt trips and ensuring the FC pump motors are qualified to operate in a post-LOCA environment allows the pump motors to be regarded as safety-related essential loads powered from the Class 1E emergency busses. This effectively increases the maximum expected emergency loading for the associated diesel generators (1A and 1B). The resultant increase in the maximum expected loading thus requires a revision of the minimum fuel oil volume specified in the Technical Specifications to ensure that the diesels are capable of supplying and maintaining emergency power for all essential loads.

Basis for proposed no significant hazards consideration determination: The staff has evaluated this proposed amendment and determined that it involves no significant hazards considerations. According to 10 CFR

50.92(c), a proposed amendment to an operating license involves no significant hazards consideration if operation of the facility in accordance with the amendment would not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or

(3) Involve a significant reduction in a margin of safety.

The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated because the proposed change will ensure that an adequate volume of diesel fuel is available for the diesel generator (1B) to perform its intended function in mitigating the consequences of the design basis accident while carrying the maximum expected load (including the associated FC pump motor). The increased maximum expected loading for the diesel generator(s), resulting from the plant modification, does not exceed the rated capacity of the diesel generators.

The impact of the proposed change is confined to two areas of concern: diesel generator operability and the ability to maintain an adequate supply of high quality cooling water in the spent fuel storage pool(s) under post-accident conditions. The changes associated with the plant modification have been evaluated and found to have no adverse impact on the diesel generators' capability to perform their intended function during or following a design basis accident (DBA-LOCA). With respect to any concerns regarding the spent fuel storage pool, including the FC pump motors as essential loads, will ensure that an FC pump is available for cooling and maintaining the volume and quality of water in the spent fuel storage pools under post-accident conditions. The proposed change therefore does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed change does not involve a significant reduction in a margin of safety because the increased minimum amount of diesel fuel to be stored for diesel generator 1B is well within the storage capacity of the fuel storage tank. In addition, the added electrical load requiring the extra amount of diesel fuel does not cause the maximum expected load for diesel generator 1B to exceed its rated capacity. The electrical loading and fuel storage demand for diesel generator 1B will still be in compliance with the original design requirements.

For the reasons stated above, the staff believes this proposed amendment involves no significant hazards consideration.

Local Public Document Room location: Vespasian Warner Public Library, 120 West Johnson Street, Clinton, Illinois 61727

Attorney for licensees: Sheldon Zabel, Esq., Schiff, Hardin and Waite, 7200 Sears Tower, 233 Wacker Drive, Chicago, Illinois 60606

NRC Project Director: Daniel R. Muller

Long Island Lighting Company, Docket No. 50-322, Shoreham Nuclear Power Station, Suffolk County, New York

Date of amendment request: May 19, 1988

Description of amendment request: This amendment would revise Technical Specifications 3.5.2a.2.b, Emergency Core Cooling Systems - Shutdown, and 3.5.3.1b.3 Suppression Pool Water Level, to read "...equivalent to an indicated level of 11.5 feet" rather than "...equivalent to a level of 9 feet". This change reduces the potential for operator misinterpretation but does not affect the minimum 100,000 gallons of water availability requirement for the condensate storage tank.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR 50.92(c). A proposed amendment to an operating license for a facility involves no significant hazards considerations if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

In accordance with 10 CFR 50.92 the licensee has reviewed the proposed changes and has concluded as follows:

The proposed change does not involve a significant hazards consideration because operation of Shoreham Nuclear Power Station - Unit 1 in accordance with this change would not:

(1) involve a significant increase in the probability or consequences of an accident previously evaluated. This change merely clarifies and identifies the Condensate Storage Tank (CST) level (indicated level) which meets or exceeds the technical specification requirement of maintaining 100,000 gallons of water available for Core Spray system use. The CST low-low level alarm (since May 19, 1982) has always been set at an indicated level of 13 feet as measured from the bottom of the tank. This was always the intended level which was to be used for ECCS reserve.

(2) create the possibility of a new or different kind of accident from any accident previously evaluated. It has been determined that a new or different kind of accident will not be possible due to this change. Design documentation specifically calls out a low-low level alarm and a CST transfer pump trip at an indicated level of 13 feet of tank evaluation. Without the foregoing pumps to drain the tank, the ECCS systems are the only users of the water volume below the 13 foot level. If the suction line elevation (approximately 1.75 ft.) is deducted from the 13 ft., a useable volume of 11.25 ft. is achieved. This is equivalent to an approximate available volume of 133,800 gallons.

(3) involve a significant reduction in a margin of safety. The use of an 11.5 ft. indicated level as proposed in the technical specification change clarifies the 1.5 foot (i.e., 13 ft.-11.5 ft) operational deviation that has always existed. If the CST transfer pumps do not deenergize - due to malfunction - at the 13 ft. level, the operator is permitted the same period of time to deenergize the pumps and not place himself in a technical specification violation.

The staff reviewed the licensee's determination that the proposed license amendment involves no significant hazards consideration and agrees with the licensee's analyses. Accordingly, the staff proposes to determine that the proposed license amendment does not involve a significant hazards consideration.

Local Public Document Room location: Shoreham-Wading River Public Library, Route 25A, Shoreham, New York 11786-9697

Attorney for licensee: W. Taylor Reveley, III, Esq., Hunton and Williams, P. O. Box 1535, Richmond, Virginia 23212

NRC Project Director: Walter R. Butler

Long Island Lighting Company, Docket No. 50-322, Shoreham Nuclear Power Station, Suffolk County, New York

Date of amendment request: June 13, 1988

Description of amendment request: The amendment would delete Figure 6.2.1-1, "Corporate-Nuclear Organization," and Figure 6.2.2-1, "Unit Organization," from the Technical Specifications and revise sections 6.2.1 and 6.2.2 to include appropriate changes to the administrative control requirements.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards in 10 CFR 50.92(c) for determining whether a significant hazards consideration exists. A proposed amendment to an Operating

License for a facility involves no significant hazards considerations if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability of consequences of an accident previously evaluated, (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety. The Long Island Lighting Company (LILCO) reviewed the proposed change and determined, and the NRC staff agrees, that:

(1) The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated because deletion of the organization charts from the Technical Specifications does not affect plant operation. The NRC will continue to be informed of organizational changes through other required controls.

- 10 CFR 50.34(b)(6)(i) requires that the applicant's organizational structure be included in the Final Safety Analysis Report. Chapter 13 of the SNPS Final Safety Analysis Report provides a description of the LILCO/SNPS organization and detailed organization charts.
- As required by 10 CFR 50.71(e), LILCO submits annual updates to the FSAR.
- Appendix B to 10 CFR 50 and 10 CFR 50.54(a)(3) govern changes to organization described in LILCO's Quality Assurance Program.

LILCO is mindful that some organizational changes may require prior NRC approval. Also, it is LILCO's practice to inform the NRC of organizational changes affecting the nuclear facility prior to implementation. LILCO intends to continue this practice for future organizational changes.

(2) The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated because the proposed change is administrative in nature, and no physical alterations of plant configuration or changes to setpoints or operating parameters are proposed.

(3) The proposed amendment does not involve a significant reduction in a margin of safety. Through the Company's strong Nuclear Quality Assurance Program and its commitment to maintain only qualified personnel in positions of responsibility, it is assured that safety functions performed by the nuclear organizations will continue to be performed at a high level of performance.

Accordingly, the Commission proposes to determine that the proposed license amendment does not involve a significant hazards consideration.

Local Public Document Room location: Shoreham-Wading River Public Library, Route 25A, Shoreham, New York 11786

Attorney for licensee: W. Taylor Reveley, III, Esq., Hunton and Williams, P. 0. Box 1535, Richmond, Virginia 23212

NRC Project Director: Walter R. Butler

Louisiana Power and Light Company, Docket No. 50-382, Waterford Steam Electric Station, Unit 3, St. Charles Parish, Louisiana

Date of amendment request: September 21, 1988

Description of amendment request: The proposed amendment would change the Technical Specifications by deleting the Ammonia Detection System. Ammonia detection would be provided by the Broad Range Toxic Gas Detection System which is currently in the Technical Specifications.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR 50.92. A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with a proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety.

The Broad Range Toxic Gas Detection (BRTGD) system provides toxic gas chemical protection for the control room. The BRTGD system detects ammonia and thereby duplicates the function of the ammonia detection system. Deleting the ammonia detection system will not significantly reduce the protection to the control room envelopment from an ammonia toxic chemical release. The BRTGD system will isolate the control room before the Immediately Dangerous to Life and Health (IDLH) concentrations for ammonia is reached. The technical specifications for the BRTGD system is equivalent to those for the Ammonia Detection System and either system provides for control room isolation as the availability of the system declines. Deletion of the ammonia system as a duplicate to the BRTGD system does not involve a significant increase in the probabilities or consequences of any accident previously evaluated.

The function of both the BRTGD and ammonia systems is solely to isolate the control room in the unlikely event of a toxic chemical release in the area. The BRTGD and ammonia system do not provide any other protective function. Since the BRTGD system will provide ammonia detection, the deletion of the ammonia detection system will not create the possibility of a new or different kind of accident from any accident previously evaluated.

The ammonia detection system setpoint is 50 ppm ammonia and will respond in .33 seconds for concentration at and above 50 ppm. The BRTGD system responds at different times for any concentration above environmental background; the higher the concentration, the faster the response time. For concentration of ammonia of concern at the control room, the BRTGD system will have a faster response time than the ammonia system and while the BRTGD will respond below 50 ppm, the ammonia detection system will not. Such a comparison evaluation demonstrates equivalent or better protection by the BRTGD system. Therefore, the deletion of the ammonia detection system will not involve a significant reduction in a margin of safety.

Based on the above, the staff proposes to determine that the amendment does not involve a no significant hazards consideration.

Local Public Document Room Location: University of New Orleans Library, Louisiana Collection, Lakefront, New Orleans, Louisiana 70122

Attorney for licensee: Bruce W. Churchill, Esq., Shaw, Pittman, Potts and Trowbridge, 2300 N St., NW., Washington, DC 20037

NRC Project Director: Jose A. Calvo

Mississippi Power & Light Company, System Energy Resources, Inc., South Mississippi Electric Power Association, Docket No. 50-416, Grand Gulf Nuclear Station, Unit 1, Claiborne County, Mississippi

Dates of amendment request: October 19, 1988, as supplemented October 31, 1988

Description of amendment request: The amendment would authorize the sale and leaseback of an individual interest in the Grand Gulf Nuclear Station, Unit 1 (GGNS Unit 1).

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a no significant hazards consideration exists as stated in 10 CFR 50.92(c). A proposed amendment to an operating license involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee has provided an analysis of no significant hazards considerations in its request for a license amendment. The licensee's analysis of the proposed amendment against the three standards in 10 CFR 50.92 is reproduced below.

a. The proposed change will not increase the probability or consequences of an accident previously evaluated. As a result of the proposed amendment, there will not be physical changes to the facility, and all Operating Procedures, Limiting Conditions for Operation, Limiting Safety System Settings, and Safety Limits specified in the Technical Specifications will remain unchanged. SERI will continue in its present role under the Operating Agreement and Ownership Agreement. There will be no changes to the operating organization or personnel as a result of the transaction(s) described herein.

b. The proposed amendment will not create the possibility of a new or different kind of accident from any accident previously evaluated. The design and design bases of GGNS Unit 1 will remain the same. Therefore, the current plant safety analyses will remain complete and accurate in addressing the licensing basis events and in analyzing plant response and consequences. Further, the Operating Procedures, Limiting Conditions for Operation, Limiting Safety System Settings, and Safety Limits specified in the Technical Specifications are not affected. As such, the plant conditions for which the design basis accident analyses were performed are still valid.

c. The proposed amendment will not involve a reduction in any margin of safety. Plant safety margins are established through Limiting Conditions for Operation, Limiting Safety System Settings, and Safety Limits specified in the Technical Specifications. Because there will be no change to either the physical design of the plant or to any of these settings and limits, there will be no change to any of the margins of safety.

The licensee has concluded that the proposed amendment meets the three standards in 10 CFR 50.92 and, therefore, involves no significant hazards consideration.

The NRC staff has made a preliminary review of the licensee's no significant hazards consideration determination and agrees with the licensee's analysis. Accordingly, the Commission proposes to determine that the requested amendment does not involve a significant hazards consideration.

Local Public Document Room location: Hinds Junior College, McLendon Library, Raymond, Mississippi 39154

Attorney for licensee: Nicholas S. Reynolds, Esquire, Bishop, Liberman, Cook, Purcell and Reynolds, 1200 17th Street, NW., Washington, DC 20036

NRC Project Director: Elinor G. Adensam

Northeast Nuclear Energy Company, et al., Docket No. 50-423, Millstone Nuclear Power Station, Unit No. 3, New London County, Connecticut

Date of amendment request: October 5, 1988

Description of amendment request: The proposed amendment would change Technical Specification (TS) 3/4.1.1.3, "Moderator Temperature Coefficient," to allow a more negative moderator temperature coefficient in the Limiting Condition for Operation, TS 3.1.1.3b, and in the associated Surveillance Requirement, TS 4.1.1.3b.

Basis for proposed no significant hazards consideration determination: The Moderator Temperature Coefficient (MTC) represents the relationship between the reactor coolant system (RCS) temperature and core reactivity. Near the end of the operating cycle the MTC is strongly negative, that is, decreasing RCS temperature causes a substantial increase in core reactivity. Thus, for accidents that involve a significant decrease in RCS temperature, such as a steam line break accident, the MTC strongly influences the severity of the accident. The purpose of TS 3/4.1.1.3b is to assure that the facility will not operate with an MTC more negative than the value incorporated in the safety analyses. The following MTC values are presently in the TS:

- TS 3.1.1.3b - The Limiting Condition for Operation (LCO) for the end-of-life MTC is -4.0×10^{-4} delta K/K/° F. Should the MTC be more negative than the LCO MTC, the reactor would have to be shutdown within 12 hours.
- TS 4.1.1.3b - The Surveillance Requirement (SR) MTC for the end-of-life MTC is -3.1×10^{-4} delta K/K/° F. The SR MTC must be measured within 7 effective full power days (EFPD) after reaching an equilibrium RCS boron concentration of 300 ppm. If the SR MTC is more negative than -3.1×10^{-4} delta K/K/° F, the MTC must be remeasured at least every 14 EFPD during the remainder of the fuel cycle.

Accident analyses do not explicitly input an MTC, but rather a constant moderator density coefficient (MDC). Converting the MDC used in the accident analyses to an MTC is a simple calculation which accounts for the rate of change of moderator density with temperature at the conditions of interest; namely, hot full power. In addition, the MTC that is measured must be corrected to reflect the assumptions used in the safety analysis which includes control rod positions. In this regard, the MDC used in the Millstone Unit 3 accident analysis would be equivalent to an MTC of -5.5×10^{-4} delta K/K/° F.

Westinghouse has recently developed a refined methodology for comparing the measured MTC with the accident analysis MDC. The method developed by Westinghouse is documented in WCAP-11951, "Safety Evaluation Supporting a More Negative EOL Moderator Temperature Coefficient Technical Specification for the Millstone Nuclear Power Station Unit 3," September 1988. By using the methodology of WCAP-11951 for Millstone Unit 3, the following changes are proposed by the licensee for TS 3/4.1.1.3b:

- TS 3.1.1.3b - The LCO MTC would be changed from -4.0 to -4.75×10^{-4} delta K/K/° F.
- TS 4.1.1.3b - The SR MTC would be changed from -3.1 to -4.0×10^{-4} delta K/K/° F.

No change in the safety analysis is involved and the safety analysis MTC value of -5.5×10^{-4} delta K/K/° F is still considered bounding.

Title 10 CFR Part 50, Section 50.92 contains standards for determining whether a proposed license amendment involves significant hazards considerations. In this regard, the proposed changes to the TS does not involve a significant increase in the probability or consequences of an accident previously evaluated. The proposed change to the LCO and SR MTCs provide adequate assurance that Millstone Unit 3 will not be operated with an MTC more negative than the equivalent MDC assumed in the safety analysis. The proposed license amendment does not create the possibility of a new or different kind of accident since no changes to plant equipment or operating modes are involved. Finally, no safety margins are reduced since there are no changes in the safety analyses.

Accordingly, the staff has made a proposed determination that the application for amendment involves no significant hazards consideration.

Local Public Document Room location: Waterford Public Library, 49 Rope Ferry Road, Waterford, Connecticut 06385.

Attorney for licensee: Gerald Garfield, Esquire, Day, Berry & Howard, One Constitution Plaza, Hartford, Connecticut 06103-3499.

NRC Project Director: John F. Stolz

Omaha Public Power District, Docket No. 50-285, Fort Calhoun Station, Unit 1, Washington County, Nebraska

Date of amendment request: December 2, 1986 as supplemented January 9, 1988 and September 30, 1988.

Brief description of amendment: In accordance with the requirements of 10 CFR 73.55, the licensee submitted an

amendment to the Physical Security Plan for the Fort Calhoun Station, Unit 1, to reflect recent changes to that regulation. The proposed amendment would modify paragraph 3.C of Facility Operating License No. DPR-40 to require compliance with the revised plan.

Basis for proposed no significant hazards consideration determination: On August 4, 1986 (51 FR 27817 and 27822), the Nuclear Regulatory Commission amended Part 73 of its regulations, "Physical Protection of Plants and Materials," to clarify plant security requirements to afford an increased assurance of plant safety. The amended regulations required that each nuclear power reactor licensee submit proposed amendments to its security plan to implement the revised provisions of 10 CFR 73.55. The licensee submitted its revised plan on December 2, 1986, with additional information on January 9, 1988 and September 30, 1988, to satisfy the requirements of the amended regulations. The Commission proposes to amend the license to reference the revised plan.

In the Supplementary Materials accompanying the amended regulations, the Commission indicated that it was amending its regulations "to provide a more safety conscious safeguards system while maintaining the current levels of protection" and that the "Commission believes that the clarification and refinement of requirements as reflected in these amendments is appropriate because they afford an increased assurance of plant safety."

The Commission has provided guidance concerning the application of the criteria for determining whether a significant hazards consideration exists by providing certain examples of actions involving no significant hazards considerations and examples of actions involving significant hazards considerations (51 FR 7750). One of these examples of actions involving no significant hazards considerations is example (vii) "a change to conform a license to changes in the regulations, where the license change results in very minor changes to facility operations clearly in keeping with the regulations." For the foregoing reasons, the Commission proposes to determine that the proposed amendment involves no significant hazards consideration.

Local Public Document Room location: W. Dale Clark Library, 215 South 15th Street, Omaha, Nebraska 68102

Attorney for licensee: LeBoeuf, Lamb, Leiby, and MacRae, 1333 New Hampshire Avenue, NW., Washington, DC 20036

NRC Project Director: Jose A. Calvo

Philadelphia Electric Company, Docket No. 50-352, Limerick Generating Station, Unit 1, Montgomery County, Pennsylvania

Date of amendment request: September 29, 1988

Description of amendment request: The proposed amendment would change the Technical Specifications (TSs) to: (1) delete the primary containment isolation valves and instrumentation associated with the permanent removal of the RHR head spray piping and (2) modify the reportability requirements for seismic monitor XR-VA-151 whenever the reactor head has been removed.

Basis for proposed no significant hazards consideration determination: Limerick Units 1 and 2 are BWR-4 reactors. All BWR-4s were designed with three penetrations at the top of the reactor vessel head, one four-inch and two six-inch penetrations. One of the six-inch penetrations was intended to provide a water spray to the space at the top of the reactor vessel. Located above the reactor core are the steam separators and dryers. It was postulated that during cooldown of the reactor system, a spray of water would be required to cool the large mass of metal in the separators and dryers. The source of water was primary coolant from the residual heat removal (RHR) system. Over 15 years ago, it was found that this RHR head spray was not needed and is no longer used during system cooldown. Keeping the system in place poses a number of potential safety and economic disadvantages. Each time the reactor vessel head is removed (e.g., during refueling), the array of piping and valves has to be disassembled and removed and then reinstalled after the head is replaced. Since the piping contains "stagnant" primary coolant at system temperature and pressure, there exists the potential for intergranular stress corrosion cracking of the many welds in the system, increasing the potential for leakage. Consequently, these welds are subject to the augmented inspection requirements of NUREG-0313. The piping constitutes one more potential source for a high energy line break and for pipe whip. Since all of the BWR-4s have demonstrated that there is no need for the RHR head spray and since removing the piping inside containment enhances plant safety, the NRC has approved removal of this system in most BWR-4s. Limerick Unit 1 is one of the minority that has so far retained the RHR head spray system.

The proposed application requests NRC approval for removal of the RHR head spray piping and associated valves, and for blanking off the associated primary containment penetration and the existing reactor head spray piping stubout used for the head spray. At present, there is a seismic monitor (XR-VA-151) located on the head spray piping. The licensee proposes to relocate this monitor to place it directly on the reactor head at the nozzle presently used for the head spray piping penetration. This seismic monitor has to be removed (and subsequently replaced) each time the vessel head is removed. The present TSs require that whenever the seismic monitor is inoperable - and disconnecting the monitor renders it inoperable - a special report has to be submitted to the Commission.

The proposed changes to the TSs would eliminate all references to the RHR head spray piping and isolation valves, instruments and controls. The changes would also eliminate the requirement for a special report to the Commission when the seismic monitor XR-VA-151 is inoperable because it had to be disconnected to remove the reactor vessel head.

The Commission has provided standards for determining whether a significant hazards determination exists as stated in 10 CFR 50.92(c). A proposed amendment to an operating license involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee's analysis contained in their September 29, 1988 letter states the following in response to the three NRC criteria referenced above with respect to the changes to the TSs to delete the isolation valves and instrumentation associated with permanent removal of the RHR head spray piping:

(1) Operation of the plant under the proposed Technical Specifications after removal of the RHR Head Spray piping and associated valves along with blanking the associated primary containment penetration, would not involve a significant increase in the probability or consequences of an accident previously evaluated.

Three areas were previously evaluated in the FSAR regarding the reactor head spray piping:

- Primary Containment Isolation - FSAR Section 6.2
- Seismic Analysis - FSAR Section 3.7.4
- Pipe Whip Analysis - FSAR Section 3.6

The Reactor Head Spray piping removal modification was reviewed and found to be acceptable in the above referenced FSAR areas.

• The primary containment isolation will be maintained after removal of the Reactor Head Spray piping by welding a closure on the outboard containment side of penetration 17. The penetration is included in the Inservice Inspection (ISI) program and the integrity of the welded closure will be verified by periodic testing.

• Seismic Category I piping, hangers and snubbers on the RHR Head Spray would be removed by the proposed modification. Stress calculations have been reviewed and appropriately revised to assure that any remaining components are not impacted.

• Any potential pipe whip problems would be eliminated by removal of the pipe and pipe supports, as proposed. Further, Licensee has reviewed the potential effects of the proposed removal in previous evaluations in the areas of Fire Protection, Electrical Separation, Environmental Qualification, Inservice Inspection, and Piping Stresses. Evaluations in these areas did not uncover any areas of safety significance.

Based on these reviews, the Licensee concludes that the RHR Head Spray modifications do not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) Operation of the plant under the proposed Technical Specifications after removal of the Reactor Head Spray System along with blanking the primary containment penetration would not create the possibility of a new or different kind of accident from any accident previously evaluated.

Removal of the RHR Head Spray piping and blanking the primary containment penetration eliminates the piping from being a potential pipe whip problem and removes the containment penetration as a potential leakage source. No credit has been taken for the RHR Head Spray in the mitigation or prevention of an accident, therefore, the modification does not create the possibility of new or different kind of accident from any accident previously evaluated.

(3) Operation of the plant under the proposed Technical Specifications after removal of the RHR Head Spray and associated valves along with blanking the primary containment penetration, would not involve a significant reduction in a margin of safety.

The integrity of the reactor pressure boundary after removal of the RHR Head Spray would be maintained by a blank flange installed over the Reactor Head Spray nozzle. The reactor pressure boundary would then become part of the Inservice Inspection (ISI) program and would be hydrostatically tested each time the reactor head is reinstalled on the reactor vessel. The primary containment penetration will be welded closed on the outboard side of the containment penetration and will be periodically tested for integrity during scheduled integrated leak rate testing. The seismic category I piping, hangers and snubbers and containment isolation valves on the Head Spray piping would be removed by the proposed modification.

Therefore, the RHR Head Spray modification would not involve a reduction in a margin of safety. Based on the three standards discussed above, operation of the facility subsequent to removal of the RHR Head Spray along with the associated primary containment isolation valves, involves No Significant Hazard Considerations.

The licensee separately evaluated the deletion from the TSs of the special report when seismic monitor XR-VA-151 is inoperable solely because it has to be disconnected to remove the reactor vessel head. With respect to the three NRC criteria in 10 CFR 50.92, the licensee stated:

(1) Operation of the plant under the proposed Technical Specifications in regard to changing the operability reporting requirements for seismic monitor XR-VA-151 whenever the reactor head has been removed, would not involve a significant increase in the probability or consequences of an accident previously evaluated.

The Seismic monitor would continue to function under the proposed amendment whenever the reactor head is installed on the reactor vessel. When the reactor head has been removed from the reactor vessel, the seismic monitor will become inoperable by necessity and presently is reportable after 30 days under the existing Technical Specifications.

The purpose of the existing requirement is to report unexpected seismic monitor malfunctions during periods when monitors are required to be operable. Eliminating the requirement for submission of a special report when only one seismic monitor becomes inoperable for more than 30 days, during the course of normal activities taking place with the reactor head removal, will not affect the reporting requirements for the monitor under any other operating conditions. Following the reinstallation of the reactor head, the seismic monitor will be reconnected and its operability re-established. The reporting requirements for other seismic monitors would not be affected by this proposed change.

The intent of the specification for reporting seismic monitor malfunction would continue under the proposed amendment. Lack of a report whenever the reactor head is removed, does not affect the intent of the specification which is to accrue data on unexpected seismic monitor malfunctions and on the reliability of the monitors, rather than on intentional disconnections of a monitor.

Therefore, deletion of the reportability requirement under these expected conditions would not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) Operation of the plant under the proposed Technical Specifications in regard to changing the operability reporting requirements for Seismic Monitor XR-VA-151 whenever the reactor head has been removed would not create the possibility of a new or different kind of an accident from any accident previously evaluated.

After completion of the proposed Head Spray removal modification, a blanking flange on the reactor nozzle would maintain the reactor pressure boundary. Seismic monitor XR-VA-151 would be remounted at the time to the new blanking flange on top of the reactor vessel head. No other changes are being proposed for seismic monitor XR-VA-151. Also, the reportability requirements would not be changed for any other monitor except XR-VA-151 under the proposed amendment. Changing the reportability requirements for seismic monitor XR-VA-151 when the reactor head has been removed does not affect any plant safe shutdown capabilities.

Therefore, elimination of the reportability requirements without making changes to the location or to the normal operability status of the seismic monitor would not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) Operation of the plant under the proposed Technical Specification in regard to changing the operability reporting requirements for Seismic Monitor XR-VA-151 whenever the reactor head has been removed would not involve a significant reduction in a margin of safety.

The Seismic Monitoring System provides information to the operators after a seismic event and does not perform any direct plant shutdown function or affect plant operation. When monitor XR-VA-151 becomes inoperable during times the RPV head is removed, it does not provide any information following a seismic event occurring during that period. Other monitors in the plant remain operable and would provide this information. The lack of post-seismic data from seismic monitor XR-VA-151 would remain the same whether or not a special report was submitted to the Commission. Elimination of the Special Report when seismic monitor XR-VA-151 is inoperable during times when the RPV head is removed, does not involve a significant reduction in a margin of safety. The lack of seismic information from seismic monitor XR-VA-151 after any seismic event when the reactor head is removed, would not affect the safety of the plant. Seismic monitors provide information to reinforce and verify previous seismic calculations. Other monitors in the plant would provide this information when XR-VA-151 is not operable.

Based on the three standards discussed above, operation of the facility after changing the seismic monitor reportability requirements in the Technical Specifications, involves No Significant Hazards Considerations.

The staff has reviewed the licensee's analyses and agrees with it. Therefore, we conclude that the amendment satisfies the three criteria listed in 10 CFR 50.92(c). Based on that conclusion, the staff proposes to determine that the proposed license amendment does not involve a significant hazards consideration.

Local Public Document Room location: Pottstown Public Library, 500 High Street, Pottstown, Pennsylvania 19464.

Attorney for licensee: Conner and Wetterhahn, 1747 Pennsylvania Avenue, NW.,Washington, DC 20006

NRC Project Director: Walter R. Butler

Power Authority of the State of New York, Docket No. 50-333, James A. FitzPatrick Nuclear Power Plant, Oswego, New York

Date of amendment request: April 14, 1988

Description of amendment request: The proposed amendment would revise the Technical Specification (TS) Section 4.6.G.1 to resolve a conflict with the corresponding Bases section. Section 4.6.G.1 specifies surveillance requirements to verify jet pump performance. The revision would reduce the maximum permissible recirculation loop flow imbalance between recirculation loops from 15 percent to 10 percent when the recirculation pumps are operated at the same speed, which would then agree with the limits stated in the TS Bases section. The 10 percent value is consistent with the TS Bases, NRC staff and industry guidance.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR 50.92. A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with a proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) Create the possibility of a new or different kind of accident from any previously evaluated; or (3) Involve a significant reduction in a margin of safety.

The licensee has determined, that the proposed TS change will not involve a significant hazards consideration. The proposed change will not involve a significant increase in the probability or consequences of an accident previously evaluated in that the effect is to bring the TS section into agreement with the actual practice and the TS Bases section. The proposed change is administrative in nature and as such does not involve hardware or procedural changes to the facility. The proposed change will not create the possibility of a new or different kind of accident since it does not involve an actual change to present operating criteria and as stated previously does not involve any facility hardware or procedural changes. The proposed change does not involve a reduction in the margin of safety because the change is administrative in nature. In fact, the proposed change increases the probability that a jet pump failure will be promptly identified by the operators since the effect is to reduce the jet pump performance surveillance acceptance limit. The 10 percent figure complies with the General Electric Company's Service Information Letter No. 330, which verifies that the 10 percent value is the proper limit.

The staff has reviewed the licensee's no significant hazards consideration determination. Based on the review and the above discussions, the staff proposes to determine that the proposed changes do not involve a significant hazards consideration.

Local Public Document Room location: State University of New York, Penfield Library, Reference and Documents Department, Oswego, New York 13126.

Attorney for licensee: Mr. Charles M. Pratt, 10 Columbus Circle, New York, New York 10019.

NRC Project Director: Robert A. Capra, Director

Power Authority of the State of New York, Docket No. 50-333, James A. FitzPatrick Nuclear Power Plant, Oswego, New York

Date of amendment request: September 13, 1988

Description of amendment request: The licensee provided, in part, the following description: The application for amendment proposes changes to page 4, Table 3.1-1 and Table 3.2-1 of the Technical Specifications (TS). The change to page 4 would delete the reactor protection scram bypass from the definition of Startup/Hot Standby. The change to Table 3.1-1 would delete the requirement for a reactor scram on main steam isolation valve (MSIV) closure in the refuel and the startup modes. Also note 3 to this Table, which established 1005 psig as the reactor pressure below which the scram is bypassed, will be deleted. The change to Table 3.2-1 involves adding a reference to note 7 for the low condenser vacuum trip of the MSIVs to indicate that the trip is functional only in the run mode. Note 8 to Table 3.2-1, which already refers to the low condenser vaccum trip of the MSIVs, would be changed to read, "Bypassed when mode switch is not in run mode and turbine stop valves are closed." This would remove the requirement that reactor pressure be less than 1005 psig before the bypass occurs.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR 50.92. A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with a proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) Involve a significant reduction in a margin of safety.

The licensee has evaluated the proposed amendment against the standards in 10 CFR 50.92 and the licensees' findings are summarized below:

1. The proposed change does not increase the probability or consequences of an accident previously evaluated. Pressure switches set at 1005 psig were installed a few years ago after instability was observed in an early European Boiling Water Reactor during its startup. However, a series of recent reactivity and pressue perturbation tests conducted as part of the startup test program at Browns Ferry (a typical BWR 4 design of the FitzPatrick type) showed that following the initial disturbance, all parameters returned to steady state values and the reactor stabilized.

In addition, since the switches are set to bypass up to the normal reactor operating pressure of 1005 psig, the pressures which would allow the scram on MSIV closure and main steam line isolation on low condenser vacuum when the turbine stop valves are closed are outside the range of pressures for the refuel and startup modes. Thus, scram and isolation functions are bypassed and the pressure switches are not necessary. The consequences of inadvertent MSIV closure in the refuel or startup modes at or below 1005 psig will remain unchanged with the removal of the switches. In the startup mode, the reactor power is between approximately 0-15% of full power and the peak reactor pressure and the critical power ratio responses are significantly below the limits established for transients during full power operation.

In startup mode, the Intermediate Range Monitor (IRM) subsystem and the Average Power Range Monitor (APRM) subsystem provide signals to the Reactor Protection System (RPS) to shutdown the reactor. If MSIV closure occurs while the reactor is in the startup mode, the reactor will scram on high neutron flux or high reactor pressure. The overpressure protection analysis, for the limiting event of MSIV closure at

100% power terminated by the high neutron flux scram, provides the bounding analysis for the pressure transient. If a loss of condenser vacuum event occurs during refuel or startup modes, the turbine bypass valves would close to isolate the condenser, and operator action can be taken to manually close the MSIVs if necessary. Therefore, removal of pressure switches and deletion of scram and isolation functions does not increase the probability or the consequences of an accident.

2. The proposed change will not create the possibility of a new or different kind of accident from any previously evaluated. The purpose for which the pressure switches were installed does not exist (as discussed above). With the switches set for bypass at 1005 psig (which is above the full range of reactor pressures for refuel and startup modes), scram on MSIV closure and isolation on low condenser vacuum during refuel and startup modes of operation are bypassed. Therefore, the pressure switches are not used for any safety function and no new or different kind of accident can be created by the removal of these switches and deletion of the scram and isolation functions.

3. The proposed amendment will not involve a significant reduction in the margin of safety. The current setpoint for the pressure switches bypass the scram and isolation functions for the full range of reactor pressures in the refuel and startup modes. Furthermore, the operating limits of the plant are not determined by the setpoint of these switches. The limiting plant transients are still those initiated from full power operation and not from operation in the refuel or startup modes with the scram and isolation bypass. Therefore, the operating limits and the limiting safety system settings remain unchanged and the margin of safety is not reduced.

The staff has reviewed the licensee's no significant hazards consideration determination. Based on the review and the above discussions, the staff proposes to determine that the proposed changes do not involve a significant hazards consideration.

Local Public Document Room location: State University of New York, Penfield Library, Reference and Documents Department, Oswego, New York 13126.

Attorney for licensee: Mr. Charles M. Pratt, 10 Columbus Circle, New York, New York 10019.

NRC Project Director: Robert A. Capra, Director

Power Authority of The State of New York, Docket No. 50-286, Indian Point Nuclear Generating Unit No. 3, Westchester County, New York

Date of amendment request: August 16, 1988

Description of amendment request: The proposed amendment would revise the Technical Specifications to streamline the Monthly Operating Report to conform to that of the Standard Technical Specifications. Redundancy within the current Monthly Operating Report will be eliminated, and the reporting of safety and relief valve challenges will be provided on a more frequent basis by including this information within the monthly rather than the annual report. The Monthly Operating Report will continue to provide the information outlined in Regulatory Guide 1.16.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR 50.92. A proposed amendment to an operating license for a facility in accordance with a proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) Create the possibility of a new or different kind of an accident from any accident previously evaluated; or (3) Involve a significant reduction in a margin of safety.

The licensee made the following analysis of these changes:

(1) Does the proposed license amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response

The proposed changes described and evaluated above do not involve a significant increase in the probability or consequences of an accident previously evaluated. Revising the wording of the section on Monthly Operating Reports does not alter any system or subsystem and will not change the conclusions of either the FSAR or SER accident analysis.

(2) Does the proposed license amendment create the possibility of a new or different kind of accident from any previously evaluated?

Response

These changes do not create the possibility of a new or different kind of accident from any accident previously evaluated. The proposed changes do not involve any changes to the hardware, operability, surveillance, or record-keeping requirements of the facility. In addition, safety and relief valve challenges will subsequently be reported on a more frequent basis.

(3) Does the proposed amendment involve a significant reduction in a margin of safety?

Response.

The proposed changes do not involve a reduction in a margin of safety since they do not in any way affect the availability, operability, or surveillance requirements of any equipment within the facility. The changes revise the wording of the IP3 Technical Specifications section concerning monthly reporting requirements to conform to that of the Standard Technical Specifications.

Based on the above, the staff proposes to determine that the proposed changes do not involve a significant hazards consideration.

Local Public Document Room location: White Plains Public Library, 100 Martine Avenue, White Plains, New York 10601.

Attorney for licensee: Mr. Charles M. Pratt, 10 Columbus Circle, New York, New York 10019.

NRC Project Director: Robert A. Capra, Director

Power Authority of The State of New York, Docket No. 50-286, Indian Point Nuclear Generating Unit No. 3, Westchester County, New York

Date of amendment request: August 23, 1988

Description of amendment request: By NRC Generic Letter 84-13 dated May 3, 1984, "Technical Specifications for Snubbers," an option was provided to delete snubber listings from a plant's Technical Specifications. The proposed amendment will revise the Technical Specifications by deleting the snubber listing (Table 3.13-1) while maintaining operability, surveillance, and record-keeping requirements.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR 50.92. A proposed amendment to an operating license for a facility in accordance with a proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) Involve a significant reduction in a margin of safety.

The licensee made the following analysis of these changes:

1. Does the proposed license amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response

The proposed changes described and evaluated above do not involve a significant increase in the probability or consequences of an accident previously evaluated. The proposed changes do not alter any system or subsystem and will not change the

conclusions of either the FSAR or the SER accident analysis.

2. Does the proposed license amendment create the possibility of a different kind of accident from any accident previously evaluated?

Response

These changes do not create the possibility of a new or different kind of accident from any accident previously evaluated. The changes do not involve hardware or procedural changes to the facility. Deletion of the snubber listing from the Technical Specifications does not affect safety-related snubber operability, surveillance or record-keeping requirements, and thus cannot create the possibility of a new or different kind of accident. A listing of all the safety-related snubbers is maintained as part of the surveillance performance test procedures, which is a controlled document.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response

The proposed changes do not involve a reduction in a margin of safety since they do not in any way reduce the availability of the snubbers that are provided to ensure that the structural integrity of the reactor coolant and all other safety-related systems are maintained during and following a seismic or other event that induces dynamic loads.

Based on the above discussion, the staff proposes to determine that the proposed amendment involves no significant hazards consideration.

Local Public Document Room location: White Plains Public Library, 100 Martine Avenue, White Plains, New York 10601.

Attorney for licensee: Mr. Charles M. Pratt, 10 Columbus Circle, New York, New York 10019.

NRC Project Director: Robert A. Capra, Director

Public Service Company of Colorado, Docket No. 50-267, Fort St. Vrain Nuclear Generating Station, Weld County, Colorado

Date of amendment request: September 23, 1988

Description of amendment request: This amendment request results from the licensee's need to have a 500 curie source of cesium-137 on site to perform calibration of a high range detection instrumentation. Amendment 41 to the Fort St. Vrain Technical Specifications directed Public Service Company of Colorado to, at a future time, replace the listing of specific isotopes with a statement similar to that now requested in 2.c.(4). The current Radiological Control Program maintains adequate control of the use and storage of calibration sources. This will serve to place the Fort St. Vrain License in a format more similar to the recently issued Licenses.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR 50.92(c). A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The licensee provided an analysis that addressed the above three standards in the amendment application as follows:

The proposed change does not involve a significant hazards consideration because operation of FSV in accordance with this change would not:

(1) involve a significant increase in the probability or consequences of an accident previously evaluated. The use of sources for calibration purposes does not effect the design or function of any plant system/component. The updating of this license condition to not specify individual isotopes will allow more flexibility, and is being done based on an NRC recommendation.

(2) create the possibility of a new or different kind of accident from any accident previously evaluated. The calibration of detection instrumentation does not create the possibility of any accident different from those already analyzed. Non-specific designation of the calibration sources will not create any new failure modes.

(3) involve a significant reduction in a margin of safety. There is no margin of safety associated with calibration source strength.

Further, reformatting the license does not alter the requirements expressed in the License.

The staff has reviewed the licensee's no significant hazards consideration determination. Based on the review and the above discussions, the staff proposes to determine that the proposed changes do not involve significant hazards considerations.

Local Public Document Room location: Greeley Public Library, City Complex Building, Greeley, Colorado

Attorney for licensee: James K. Tarpey, Public Service Company Building, Room 900, 550 15th Street, Denver, Colorado 80202

NRC Project Director: Jose A. Calvo

Public Service Company of Colorado, Docket No. 50-267, Fort St. Vrain Nuclear Generating Station, Weld County, Colorado

Date of amendment request: October 13, 1988

Description of amendment request: The proposed Amendment would modify Technical Specification Section LCO 4.4.1, which provides a listing of the Plant Protective System (PPS) instrumentation parameters and the associated bases. The PPS is the reactor protective circuitry and the circuitry oriented towards protecting various plant components from major damage.

The Technical Specification LCO 4.4.1 has been modified to clarify the time permitted to reset trip setpoints per the detector decalibration curve, Figure 3.3-1, for the linear channel - high neutron flux channels following a power reduction.

If the linear channel - high neutron flux channels are outside their Allowable Values, they must be considered inoperable and the appropriate actions apply. The linear channel - high neutron flux RWP and scram will be available but may not be set properly. The Technical Specifications currently requires a plant shutdown within 12 hours. There are various plant situations where power level is automatically reduced and the applicable Trip Setpoints for the linear channel - high neutron flux channels change.

To avoid unnecessary shutdown requirements after control rod runback or power reduction events, the licensee proposes that an action be added to the Technical Specifications that allows 12 hours after a power reduction to regain compliance with Figure 3.3-1 for linear channel - high neutron flux. This added action provides a reasonable period of time to regain compliance, either by adjusting the Trip Setpoints or by changing power level. During this time, the linear channel - high neutron flux RWP and scram, (which may improperly set), and the reheat steam temperature-high scram provide protection against an unexpected increase in power level. The likelihood of a rod withdrawal accident (for which these scram parameters provide protection) is small. The 24 hour orderly shutdown requirement reduces rapid transients on plant components and is consistent with actions included in the Technical Specification Upgrade Program.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR 50.92(c). A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of

a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The licensee provided an analysis that addressed the above three standards in the amendment application as follows:

The proposed amendment does not involve a significant hazards consideration because operation of the Fort St. Vrain Nuclear Generating Station in accordance with this change would not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated.

The linear channel - high neutron flux parameters are part of the Plant Protective System (PPS). The primary function of the linear channel - high neutron flux parameters is to provide a scram prior to reactor power exceeding 140% of rated power. Additional protection is provided by a rod withdrawal prohibit prior to reactor power exceeding 120% of rated power. These high neutron flux scram and RWP actions are backed up by the PPS reheat steam temperature - high scram. Section 14.2.2 of the FSAR analyzes accident scenarios that would produce reactor power levels of 140% of rated power. The condition that is most likely to cause an increase in power level of this nature is a rod withdrawal accident. Section 14.2.2.6 analyzes maximum worth control rod pair withdrawal at full power. Included are scenarios where the reactor is scrammed 88 seconds and 105 seconds after accident initiation by the reheat steam temperature - high scram. These accident analyses are not modified by this amendment.

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated.

FSAR Section 14.2.2 contains the analysis of core reactivity accidents. Permitting a reasonable amount of time to regain compliance with Figure 3.3-1 for the linear channel - high neutron flux channels and a reasonable amount of time to shut down the reactor in an orderly manner does not change that analysis.

(3) Involve a significant reduction in a margin of safety.

The margin of safety against an increase in reactivity accident is provided by five protective actions identified in FSAR Section 14.2.2.1. This amendment clarifies the time that is available to regain compliance with Figure 3.3-1 for two of these protective actions following a power reduction that changes the applicable trip setpionts for the linear channels. Any reduction of safety during this time is not significant in that all five protective actions are available. (The RWP and scram for the linear channels may be improperly set on an interim bases.) The effectiveness of the other three protective actions is analyzed in FSAR Section 14.2.2.6. The other protective actions include reheat steam temperature - high scram, manual scram, and manual actuation of the reserve shutdown system.

In this requested revision to LCO 4.4.1 for the power reduction situation, 12 hours would be permitted to ensure proper trip setpoints for the linear channel - high neutron flux channels. This could include either adjusting the trip setpoints for the lower power level, or increasing reactor power, if appropriate. Also, 24 hours would be permitted to effect an orderly shutdown of the reactor in the unlikely event that compliance with Figure 3.3-1 could not be regained. Interim Technical Specification LCO 3.1.5 permits 4 hours to restore the control rods to an acceptable configuration following a control rod runback. The resetting of the trip setpoints must be done after the control rods are restored to an acceptable configuration. The twelve hours includes time to position the control rods to conform to the requirements of interim Technical Specification LCO 3.1.5.

PSC considers this change to LCO 4.4.1 justified because adequate protective actions remain in place and a rod withdrawal accident is a low probability event. During the interval in which the high neutron flux scram trip setpoint may not be in compliance with Figure 3.3-1, the reheat steam temperature - high scram would be available to protect against an unexpected increase in reactor power. The RWP and scram due to high neutron flux would be available but mat not actuate by the 120% or 140% analyzed values. The manual scram is also available in addition to the automatic scram and RWP actions.

The staff has reviewed the licensee's no significant hazards considerations determination. Based on the review and the above discussions, the staff proposes to determine that the proposed changes do not involve a significant hazards determination.

Local Public Document Room location: Greeley Public Library, City Complex Building, Greeley, Colorado.

Attorney for licensee: J. K. Tarpey, Public Service Company Building, Room 900, 550 15th Street, Denver, Colorado 80202

NRC Project Director: Jose A. Calvo

Public Service Company of Colorado, Docket No. 50-267, Fort St. Vrain Nuclear Generating Station, Weld County, Colorado

Date of amendment request: October 14, 1988

Description of amendment request: The amendment would make certain changes to Section 7 of the Technical Specifications, concerning Administrative Controls. The changes include deletion of the organizational charts from the Technical Specifications as per Generic Letter 88-06 dated March 22, 1988. AC 7.1.1 is reformatted to better conform with the Standard Technical Specifications (based on Westinghouse plants). AC 7.1.1, 7.1.2, 7.1.3, and 7.2 have changes made to position titles reflecting a recent reorganization at Fort St. Vrain.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR 50.92(c). A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The licensee provided an analysis that addressed the above three standards in the amendment application as follows:

A. Specification AC 7.1.1 is revised as follows:

Section 1, "RESPONSIBILITY," was added delegating control room command responsibility and corporate responsibility for overall nuclear plant safety. This section directly correlates to Section 6.1 of the Westinghouse Standard Technical Specifications (STS), NUREG-0452.

Section 2.a, "Onsite and Offsite Organization," was added to provide a directive for the establishment and definition of lines of authority, responsibility, and communication for onsite and offsite organizations. This section directly correlates to Section 6.2.1 of the STS, as amended by Generic Letter 88-06 for deletion of the organization charts from the Technical Specifications (Tech. Specs.).

Section 2.b(1) designates on-duty shift minimum shift crew composition per Table 7.1-1. This section follows the guidelines of Generic Letter 88-06, and incorporates the requirements of Generic Letter 88-06, and incorporates the requirements of current Section 2.a.

Section 2.b(2,3,4) discuss licensed operator on-shift requirements. These sections are added to conform to the formatting effort of this amendment; and include part of the current clarification text following Table 7.1-1 and the requirements of current Section 2.b.

Sections 2.b(5,6,7,8,9) are reformatting and editorial corrections, which incorporate the requirements of current Sections 2.c, 2.d, 2.e, 2.i, and the position titles of the Fort St. Vrain (FSV) reorganization.

Section 2.b(10) was added to delineate those requiring a Senior Reactor Operator's (SRO) license and those requiring a Reactor Operator's (RO) license; and follows the guidelines of Generic Letter 88-06.

Section 2.b(11) discusses shift crew composition and incorporates the requirements of the current final clarification paragraph following Table 7.1-1, which were not included in proposed Sections 2.b(2,3,4).

Section 2.b(12) was added to delineate control room command responsibility in the absence of the Shift Supervisor, and further expounds on proposed Section 1.b.

Table 7.1-1 was relocated within Specification AC 7.1.1. The table retains the same requirements as the current Table 7.1-1.

However, the page is reformatted to include the applicable notes.

Section 3, "TECHNICAL ADVISORS," is a reformatting addition. This section incorporates the requirements of current Section 1.c and 2.f, with position titles per the FSV reorganization.

Section 4, "UNIT STAFF QUALIFICATIONS," is a reformatting addition and incorporates the requirements of current Sections 2.g and 2.h. "upon commencement of commercial operation" is deleted since this stipulation is not necessary.

Section 5, "TRAINING," reformats and incorporates the requirements of current Section 3. "Compliance with Section 5.5 of ANSI 18.1-1971 shall be achieved no later than 6 months following commencement of commercial operation" is deleted since this stipulation is not necessary.

B. Specification AC 7.1.2 is revised as follows:

Section 1, Plant Operations Review Committee (PORC) Membership, is revised to incorporate position titles of the FSV reorganization. No expertise is deleted from the PORC, and the positions meet the description of ANSI N18.1.

Sections 5.a, 5.3, 6.d and 7 contain a position title change only. Responsibility and expertise remain the same.

Sections 3, 4, 9, and 10 contain position title change only. Responsibility and expertise remain the same.

Section 5.k, relative to PORC review of every unplanned onsite release of radioactive material to the environs, is deleted. This requirement is considered to be adequately covered in Sections 5.a through 5.g. Also, several recent plant Technical Specifications have been found not to include this requirement: River Bend 1, Grand Gulf 1, Nine Mile Point 2, and Palo Verde 1. Deletion of Section 5.k is also consistent with the Tech. Spec. Upgrade Program draft.

C. Specification AC 7.1.3 is revised as follows:

Section 1 contains only formatting changes.

Section 2 contains revisions to the Nuclear Facility Safety Committee (NFSC) Membership relative to position titles per the FSV reorganization. The actual membership and areas of responsibility/ expertise remain the same.

Sections 3, 4, and 9 contain a position title change only. Responsibility and expertise remain the same.

Section 10.a is revised to delete the requirement that each NFSC meeting's minutes be approved within 30 days following each meeting. Section 10.b was added to direct the preliminary approval of the NFSC meeting minutes by the Senior Vice President, Nuclear Operations. It also directs the distribution of the minutes to the NFSC members, and approval of the minutes at the next NFSC meeting. These revisions will ensure that the entire NFSC membership will be given the opportunity to vote on the approval of the minutes of the last NFSC meeting.

D. Pages 7.1-20, 7.1-21, 7.1-22, and 7.1-23 are deleted:

Pages 7.1-20 and 7.1-21 contain Table 7.1-1 and its associated notes and clarification information. All this information is included elsewhere in the proposed amendment.

Pages 7.1-22 and 7.1-23 contain the organization charts (Figures 7.1-1 and 7.1-2). These charts are deleted from the Tech. Specs., based on the recommendation of Generic Letter 88-06.

E. Specification AC 7.2 is revised as follows:

Sections b. and d. contain a position title change only. Responsibility and expertise remain the same.

Except as otherwise noted above, this proposed amendment reformats current Administrative Controls Specification 7.1.1 requirements to better conform to STS formatting; deletes organization charts per the guidelines of Generic Letter 88-06; and retitles certain positions in AC 7.1.1, 7.1.2, 7.1.3, and 7.2 to conform to the FSV reorganization begun May 12, 1988.

Based on the above, this proposed change does not involve a significant hazards consideration because operation of FSV in accordance with this change would not: involve a significant increase in the probability or consequences of an accident previously evaluated; create the possibility of a new or different kind of accident from any accident previously evaluated; involve a significant reduction in a margin of safety.

The staff has reviewed the licensee's no significant hazards consideration determination. Based on the review and the above discussions, the staff proposes to determine that the proposed changes do not involve a significant hazards consideration.

Local Public Document Room location: Greeley Public Library, City Complex Building, Greeley, Colorado

Attorney for licensee: J. K. Tarpey, Public Service Company Building, Room 900, 550 15th Street, Denver, Colorado 80202

NRC Project Director: Jose A. Calvo

Public Service Company of Colorado, Docket No. 50-267, Fort St. Vrain Nuclear Generating Station, Weld County, Colorado

Date of amendment request: October 14, 1988

Description of amendment request: The proposed changes would modify SR 5.0 to add a new inservice inspection criterion. SR 5.2.1, Prestressed Concrete Reactor Vessel (PCRV) and PCRV Penetration Overpressure Surveillance and its basis would be modified. The modifications would require testing of the overpressure protection assembly in accordance with Subsection IGV or IWV of Section XI of the ASME Code.

Basis for proposed no significant hazards consideration determination: The Commission has provided guidance for the application of criteria for no significant hazards consideration determination by providing examples of amendments that are considered not likely to involve a significant hazards consideration (51 FR 7751). These examples include "(ii) A change that constitutes an additional limitation, restriction, or control not presently included in the technical specifications, e.g., a more stringent surveillance requirement."

The proposed change would require the licensee to test the PCRV overpressure assembly in accordance with the widely accepted ASME code. This constitutes an additional and more stringent restriction that is not currently included in the Technical Specifications and is therefore within the scope of the example cited above.

Since the application for amendment involves proposed changes that are encompassed by an example for which no significant hazards consideration exists, the staff has made a proposed determination that the application involves no significant hazards consideration.

Local Public Document Room location: Greeley Public Library, City Complex Building, Greeley, Colorado

Attorney for licensee: J. K. Tarpey, Public Service Company Building, Room 900, 550 15th Street, Denver, Colorado 80202

NRC Project Director: Jose A. Calvo

Public Service Electric & Gas Company, Docket No. 50-354, Hope Creek Generating Station, Salem County, New Jersey

Date of amendment request: September 28, 1988

Description of amendment request: This amendment would revise Technical Specification Tables 2.2.1-1, 3.3.2-1, and 3.3.2-2 to replace the footnote created with the issuance of Amendment 8 (restrictions associated with the hydrogen injection test) with the necessary requirements associated with the installation of a permanent Hydrogen Water Chemistry (HWC) System. These changes would permit the operation of an HWC system by creating two separate main steam line background radiation levels and associated trip setpoints while restricting operation to power levels greater than 20% of Rated Thermal Power.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed

amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. In accordance with 10 CFR 50.92 the licensee has reviewed the proposed changes and has concluded as follows that they do not involve a significant hazards consideration:

Significant Hazards Analysis Consideration

The proposed changes to the Technical Specifications:

1. Do not involve a significant increase in the probability or consequences of an accident previously evaluated.

The only accident scenario which takes credit for the MSL high radiation scram and isolation setpoint is the Control Rod Drop Accident (CRDA) as described in the Updated Final Safety Analysis Report (UFSAR) Section 15.4.9. Specifically, the Main Steam Isolation Valves (MSIVs) are assumed to receive an automatic closure signal at 0.5 seconds after detection of high radiation in the main steam lines and to be fully closed at 5 seconds from the receipt of the closure signal. The MSL radiation monitors are provided to detect a gross failure of the fuel cladding. When high radiation is detected, a trip is initiated to reduce the continued failure of fuel cladding. At the same time, the MSIVs are closed to limit the release of fission products. The trip setting is high enough above background radiation levels to prevent spurious trips yet low enough to promptly detect gross failures in the fuel cladding.

NEDO-10527, Supplement 1, "General Electric Rod Drop Accident Analysis for Large Boiling Water Reactors" dated July 1972 concluded that the consequences of the CRDA are most severe under Hot Standby conditions. Furthermore, the consequences of the CRDA are increasingly less severe above 10 percent power due to a faster Doppler response and a lower rodworth. Finally and most importantly, this report concluded that above 20 percent power the consequences of the CRDA are minimal. Therefore, the Guidelines (Section 8.2.1 and Table 2-1) indicate that the hydrogen injection system should not be operated below the limiting low power setpoint for the CRDA as discussed in the UFSAR. HCGS UFSAR Section 15.4.9 does not actually specify this low power limit; however, Sections 7.7.1.1.5.4 and 7.7.1.1.5.4.1 do-20% of Rated Thermal Power. This limit is known as the Low Power Setpoint (LPSP) and is contained in Technical Specifications 3/4.1.4.1 (Rod Worth Minimizer) and 3/4.1.4.2.(Rod Sequence Control System).

As a result, the MSL radiation monitor setpoint will only be adjusted upward when the hydrogen water chemistry system is operated. HWC system operation is restricted to power levels greater than 20 percent of Rated Thermal Power. This power level differs from the 22 percent of Rated Thermal Power level contained in Amendment 8 for the hydrogen injection test for two main reasons. First, the hydrogen injection test was only a test, the permanent system is a complete, long-term system with the necessary instrumentation, controls and trips to more accurately control hydrogen injection. Since the HWC system is designed in accordance with the Guidelines and utilizes the experience gained during the hydrogen injection test and from systems installed at other utilities, system operation is closely and accurately controlled and monitored. Second, the Guidelines specify that injection should occur at the LPSP and does not require an additional margin. The hydrogen injection test added an additional 2% power margin simply to assure that the system was not operated below the LPSP. The permanent HWC system will contain sufficient controls to assure operation above the LPSP. Therefore, operating the HWC system at HCGS with such a setpoint (i.e. 20% of Rated Thermal Power) provides adequate assurance that the consequences of a CRDA are negligible when the system is in operation.

Furthermore, in order to assure that the setpoint adjustment process itself does not have any impact on the plant, if a power reduction event occurs so that the reactor power is below 20% of Rated Thermal Power without the required setpoint change, control rod motion will be suspended (except for scrams or other emergency conditions) until the necessary setpoints adjustment is adjusted. This restriction further assures that the possibility of a CRDA occurring while the setpoints are being adjusted is precluded.

Therefore, it can be concluded that the proposed changes to the Technical Specifications do not increase the probability or consequences of an accident previously evaluated.

2. Do not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes do not affect the design of any safety related systems and as such do not affect the performance of any safety related functions. The proposed changes do permit the operation of the station with a new system, namely a hydrogen water chemistry system. However, this system has been extensively analyzed by EPRI, approved for use by the NRC (reference the Guidelines and the associated NRC SER on them cited in Item III above), and is in operation at a variety of utilities including the Dresden-2, FitzPatrick and Duane Arnold stations. Attachment 4 [of the licensee's submittal] contains a graphical comparison of the operation of HWC systems at these and other utilities which have utilized the services of General Electric in the design and operation of the hydrogen injection test and hydrogen water chemistry system.

The decision to seek a permanent change to the HCGS Technical Specifications is plant specific since a change is necessary only if the increase in the MSL radiation levels does not provide an acceptable margin to the MSL radiation monitor setpoint established without operation of a HWC system. Although the operation of a HWC system introduces hydrogen in the recirculation system, this condition has already been analyzed in UFSAR Sections 6.2.5 (Combustible Gas Control System), 10.4.2 (Main Condenser Evacuation System), and 11.3.2.1 (Offgas System). In addition, the level of hydrogen in the offgas system is controlled and monitored in accordance with Technical Specifications 3/4.3.7.11 and 3/4.11.2.6, respectively.

PSE&G is evaluating the impact of slightly increased radiation levels in the plant against the equipment qualification criteria for systems and components located in the affected areas. Any changes in qualified life or service will be accounted for in the design/installation of the HWC system and reflected in [on] the plant prior to HWC system operation.

With regard to the presence of hydrogen and oxygen in the yard, the two mediums meet the requirements of NPFA 50 and 50A for separation from the facility as discussed in Item III.3 above [of the licensee's submittal]. UFSAR Section 9.5.1.1.11 has analyzed the presence and storage of combustible materials in the yard and the HWC hydrogen and oxygen storage facilities do not affect the conclusions reached (other than the incorporation of the storage information in Table 9.5-3). Finally, in following the EPRI Guidelines and addressing the NRC staff requirements in Item III above, PSE&G concludes that the probability for an explosion, flammable vapor cloud or fire is minimized. Even if such an accident were to occur, there would be no impact of the station due to the separation distance to the storage vessels from safety related structures. Thus the information contained in UFSAR Section 2.2.3.1 is not affected due to the presence of a HWC system.

Finally, extensive safety features for the HWC system have been established which provide assurance that the operation of the system at HCGS will not create an unacceptable situation nor adversely impact the operation of any other system. Therefore, since the changes to the Technical Specifications themselves do not affect existing system function nor create a situation which has not been previously analyzed and appropriately designed for, the changes do not create any new or different kinds of accidents than previously evaluated.

3. Do not involve a significant reduction in a margin of safety.

The proposed changes to the Technical Specifications contain specific requirements regarding their applicability:

- Operation of the HWC system is only permitted above 20 percent of Rated Thermal Power.
- When the HWC system is in operation the MSL radiation monitor setpoints can be adjusted upward, to levels previously determined during the hydrogen injection test, to account for the increase in the background MSL radiation levels.
- Prior to decreasing reactor power to below 20% of Rated Thermal Power, the setpoints must be readjusted to their pre-HWC system operation levels.
- If the power level falls below 20% without the setpoint change, control rod motion is suspended (except for scrams or other

emergency situations) until the setpoint adjustment is made.

These requirements will assure that the HWC system is operated safely and with sufficient margin such that spurious MSL isolations are precluded while still assuring that any gross failures in the fuel cladding remain detectable.

As discussed in Item IV.1 above [of the licensee's submittal], the CRDA is the only accident which takes credit for the MSL isolation trip function; however, above 20 percent power, the consequences of the CRDA are so minimal that they may be considered negligible (reference the above cited NEDO report.) Therefore, the change in the Technical Specification setpoint has no significant effect on the margins of safety for this accident scenerio and the restriction regarding suspending control rod motion further assures that during setpoint adjustments, a CRDA is minimized.

Finally as discussed in Item III.8 above [of the licensee's submittal], the increase in background radiation levels has been analyzed and PSE&G has concluded that neither plant personnel nor the health and safety of the public are at risk when operating with the HWC system. Therefore, it can be concluded that the proposed changes do not involve a significant reduction in a margin of safety.

The staff reviewed the licensee's determination that the proposed license amendment involves no significant hazards consideration and agrees with the licensee's analyses. Accordingly, the staff proposes to determine that the proposed license amendment does not involve a significant hazards consideration.

Local Public Document Room location: Pennsville Public library, 190 S. Broadway, Pennsville, New Jersey 08070

Attorney for licensee: Troy B. Conner, Jr., Esquire, Conner and Wetterhahn, 1747 Pennsylvania Avenue, NW., Washington, DC 20006

NRC Project Director: Walter R. Butler

Public Service Electric & Gas Company, Docket No. 50-354, Hope Creek Generating Station, Salem County, New Jersey

Date of amendment request: September 28, 1988

Description of amendment request: This amendment would revise Technical Specification Table 3.3.7.5-1 to permit actions consistent with Technical Specification 3.6.3 regarding allowable out-of-service times for inoperable primary containment isolation valves and their associated position indication instrumentation. The change would avert the currently required plant shutdown in the event that position indication instrumentation for a primary containment isolation valve in an otherwise isolated penetration is declared inoperable.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR 50.92(c). A proposed amendment to an operating license for a facility involves no significant hazards considerations if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

In accordance with 10 CFR 50.92 the licensee has reviewed the proposed changes and has concluded as follows that they do not involve a significant hazards consideration.

The proposed change to the HCGS Technical Specifications:

(1) Does not involve a significant increase in the probability or consequences of an accident previously evaluated.

As required by Action (a) of Technical Specification 3.6.3, should a primary containment isolation valve be declared inoperable the affected penetration must be isolated. This isolation can be accomplished by either deactivating at least one automatic valve, closing at least one manual valve or installing a blind flange in the affected penetration. Furthermore, the system for which the inoperable valve provides containment isolation must also be declared inoperable and the appropriate Action statements for that system performed. Assuming that the plant can continue to operate under these conditions, the concern which must be addressed as a result of this proposed change is whether or not the probability or consequences of an accident previously evaluated are significantly increased when the position indication instrumentation for an otherwise inoperable containment isolation valve is permitted to remain inoperable longer than the currently imposed 30 or 7 days, per Action 82(a) and 82(b) of Technical Specification Table 3.3.7.5-1, respectively.

The requirement to isolate the affected penetration due to an inoperable valve establishes containment isolation for that penetration. This action establishes a safe configuration for continued operation assuming of course that the affected system is not required to remain Operable. For those systems which can be isolated without jeopardizing continued safe operation, the need for monitoring containment isolation is no longer necessary as isolation has already been achieved.

Therefore, it can be concluded that if the provisions of Technical Specification 3.6.3, Action a.2 or a.3 are in effect:

(i) the penetration is in a safe configuration with regards to the provisions for containment isolation - closed,

(ii) spurious movement of the valve is precluded by either the lack of power, the need for local manual operation, or the presence of an installed blind flange, and

(iii) administrative controls and surveillance requirements exist to assure continued containment isolation.

The current requirements of ACTION 82 of Technical Specification Table 3.3.7.5-1 regarding AOT for primary containment isolation valve position indication instrumentation serve no purpose with regard to assurance of containment integrity if and only if the associated penetration is isolated pursuant to Technical Specification 3.6.3, Action a.2 or a.3. This function is adequately controlled under the auspices of Technical Specifications 4.6.1.1 and the administrative controls already in place. Consequently, extending the AOT for inoperable position indication in penetrations isolated as described above does not represent an increase in the probability or consequences of a previously evaluated accident since containment isolation (the accident function of concern) is already achieved and assured.

(2) Does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed change does not negate the requirement for containment integrity or isolation but simply makes use of the existing Technical Specifications which require such. By (sic) extending the provisions for isolated penetrations to the required actions for associated inoperable position indication simply takes advantage of the physical constraints and administrative controls already imposed.

Furthermore, the proposed change does not require any plant modification nor (sic) design change but merely permits a specific case of inoperability to exist while plant operation continues. This condition is well bounded in terms of the extent to which inoperability is permitted. Additionally, the flexibility provided by this proposed change will not result in a change to the operational characteristic of any system or process. The inoperability of primary containment isolation valve position indication instrumentation is already permitted for the currently identified AOT. This change simply extends the AOT as long as other compensating measures are in effect.

Therefore, it can be concluded that the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) Does not involve a significant reduction in a margin of safety.

The increase in AOT for an inoperable primary containment isolation valve position indication instrument from either 7 or 30 days to an unlimited time does not decrease the margin of safety since a more restrictive compensating measure is in effect, namely the subject penetration is in the safe configuration with regard to containment isolation provisions - closed. Therefore, the margin of safety remains the same as that permitted by Technical Specification 3.6.3, Action a.2 or a.3. With the penetration in an isolated position and the assurances available that such a position will be maintained, the maximum margin of safety

has been achieved, i.e. the penetration has been placed in the post accident configuration.

The length of time that either or both position indication instrumentation channels for either or both containment isolation valves remain inoperable has no bearing on the position of the valves in the subject penetration. Realizing that the information provided by the position indication instrumentation is simply indication only, i.e. no automatic isolation or actuation function results from loss of or change in position indication, further substantiates the proposed change. Therefore, it can be concluded that the proposed change does not involve a significant reduction in a margin of safety.

The staff reviewed the licensee's determination that the proposed license amendment involves no significant hazards consideration and agrees with the licensee's analyses. Accordingly, the staff proposes to determine that the proposed license amendment does not involve a significant hazards consideration.

Local Public Document Room location: Pennsville Public library, 190 S. Broadway, Pennsville, New Jersey 08070

Attorney for licensee: Troy B. Conner, Jr., Esquire, Conner and Wetterhahn, 1747 Pennsylvania Avenue, NW., Washington, DC 20006

NRC Project Director: Walter R. Butler

Sacramento Municipal Utility District, Docket No. 50-312, Rancho Seco Nuclear Generating Station, Sacramento County, California

Date of amendment request: September 19, 1988 as supplemented November 4, 1988.

Description of amendment request: The proposed changes would delete the requirement to perform local leak rate tests (LLRT) on containment penetration pipes associated with two systems, high pressure injection and decay heat removal systems. The licensee contends that the penetrations being removed from the LLRT requirements would be filled with water and pressurized to a pressure greater than the maximum containment pressure associated with accident conditions. As a result, these penetrations would not provide a pathway for radioactive contaminants in the containment atmosphere to escape to the environment.

The proposed change would also increase the interval between LLRT's from 18 months to a maximum of 24 months.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR 50.92. A proposed amendment to an operating license for a facility involves no significant hazards considerations if operation of the facility in accordance with a proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; (2) Create the possibility of new or different kind of accident from any accident previously evaluated; or (3) Involve a significant reduction in a margin of safety.

The proposed amendment does not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated because based on the licensee's evaluation, the containment penetrations being deleted from the LLRT program are not potential release pathways for airborne activity during accident conditions and therefore will not change accident consequences; increasing the LLRT interval from 18 months to 24 months is in accordance with regulatory guidance and is not a significant change in terms of accident consequences; (2) create the possibility of a new or different kind of accident from any accident previously evaluated because containment penetrations and LLRT's are an integral part of accident evaluations, and the proposed changes do not create new or different accident concerns; (3) involve a significant reduction in a margin of safety. The proposed changes are relatively minor changes to the LLRT program. The penetrations being deleted from the LLRT requirements are a small fraction of all containment penetrations and even under worst conditions, radioactive releases through these penetrations would constitute a small fraction of releases from all pathways.

Based on the above discussion, the staff proposes to determine that the proposed amendment does not involve a significant hazards consideration.

Local Public Document Room location: Martin Luther King Regional Library, 7340 24th Street Bypass, Sacramento, California 95822.

Attorney for licensee: David S. Kaplan, Sacramento Municipal Utility District, 6201 S Street, P. O. Box 15830, Sacramento, California 95813.

NRC Project Director: George W. Knighton

Virginia Electric and Power Company, Docket No. 50-338, North Anna Power Station, Unit No. 1, Louisa County, Virginia

Date of amendment request: October 19, 1988

Description of amendment request: The proposed change involves an amendment, in the form of a license condition, to Operating License No. NPF-4 for NA-1. Specifically, the proposed license condition allows a one-time extension of the surveillance test intervals for certain surveillance tests as specified in the NA-1 Technical Specifications (TS) for the seventh cycle of operation. NA-1 completed applicable Mode 4, 5 and 6 surveillance tests during the sixth refueling outage which ended on June 29, 1987. It was not considered reasonable to repeat these surveillance tests during the time frame that Unit 1 was shutdown for steam generator repairs which occurred from July 15, 1987 to October 13, 1987. However, this unplanned outage did serve to impact the surveillance test intervals between the sixth and the forthcoming seventh refueling outages. This delay, together with additional time allowed for an optimum fuel burn-up before the next refueling, has resulted in a deferral of the next refueling outage for NA-1 until April 1989.

Currently, NA-1 TS require the performance of certain surveillance tests at 18, 36, and 60 month intervals to coincide with normal 18-month refueling cycles.

The proposed change would extend these surveillance test intervals for the NA-1 seventh cycle by 6 months to compensate for several unanticipated outages including the steam generator tube rupture event and to permit optimum fuel burn-up prior to refueling. Use of the allowable extension of the surveillance intervals in accordance with Specification 4.0.2 of the TS would require an extension corresponding to the 3-month unplanned outage. Rather than use the extension allowed by Specification 4.0.2 and request an additional extension, a 6-month extension for the affected surveillance test intervals is requested for the seventh cycle only to preserve the extension allowed by Specification 4.0.2 for future refueling cycles.

One-time changes to the surveillance test intervals associated with a plant shutdown or refueling outage as specified in the TS for License Number NPF-4 are requested as follows:

(1) The 18-month surveillance test cycle requirement as specified in the following TS sections would be changed to 24 months for the seventh cycle of unit operation only:

4.1.2.2.c	4.3.2.1.2	4.3.3.9.c	4.4.3.2.1.b
4.9.3.1.b	4.4.10.1.1	4.5.1.d	4.5.2.e
4.6.1.3.c	4.6.2.1.c	4.6.2.2.1.c	4.6.2.3.c
4.6.3.1.2	4.7.1.2.b	4.7.4.1.c	4.7.7.1.d
4.7.8.1.d	4.7.9.1.b	4.7.10.c	4.7.10.f
4.8.1.1.1.b	4.8.1.1.2.d	4.8.1.1.3.e	4.8.2.3.2.d
4.8.2.3.2.f			

(2) The 18/36-month surveillance test cycle requirement as specified in the following TS sections would be changed to 24/42 months for the seventh cycle of unit operation only:

4.3.1.1.3 4.3.2.1.3

(3) The 60-month surveillance test interval requirement as specified in the following TS section would be changed to 66 months for the seventh cycle of unit operation only:

4.8.1.1.3.d

(4) Table 1.2 of Section 1.0, Definitions, which defines "R" as "At least once per 18 months" as it applies to the following TS sections and related tables, and the 18-month requirement in the note in the tables indicated below, would be changed to 24 months for the seventh cycle of unit operation only:

Section	Table	Note
4.3.1.1.1	4.3-1	(4)
4.3.2.1.1	4.3-2	(1)
4.3.3.1	4.3-3	—
4.3.3.3.1	4.3-4	—
4.3.3.5	4.3-6	—
4.3.3.6	4.3-7	—

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards considerations if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee has evaluated the change request against the standards provided above and has determined that this change will not:

Involve a significant increase in the probability or consequences of an accident previously evaluated. Current monitoring instrumentation and ongoing [TS] surveillance tests ensure the equipment and systems involved in the extended surveillance interval will remain in an operable condition until their inspection at the next refueling outage.

Create the possibility of a new or different kind of accident from any accident previously evaluated. Extending the interval for the performance of specific surveillance tests does not create the possibility of a new or different kind of accident. Periodic surveillance tests have been performed since the sixth outage to monitor system and component performance and to detect degradation. Surveillance tests will continue to be performed during the extension interval.

Involve a significant reduction in the margin of safety. Extending the interval for these specific surveillance tests for the [seventh] cycle of [NA-1] does not significantly degrade the margin of safety. Surveillance tests will continue to be performed during the extension interval. Current monitoring instrumentation and ongoing [TS] surveillance tests ensure the affected equipment and systems remain in an operable condition.

The NRC staff has made a preliminary review of the licensee's analyses of the proposed change and agrees with the licensee's conclusion that the three standards in 10 CFR 50.92(c) are met. Therefore, the staff proposes to determine that the proposed amendment does not involve a significant hazards consideration.

Local Public Document Room location: The Alderman Library, Manuscripts Department, University of Virginia, Charlottesville, Virginia 22901.

Attorney for licensee: Michael W. Maupin, Esq., Hunton and Williams, P.O. Box 1535, Richmond, Virginia 23212.

NRC Project Director: Herbert N. Berkow

Virginia Electric and Power Company, Docket Nos. 50-338 and 50-339, North Anna Power Station, Units No. 1 and No. 2, Louisa County, Virginia

Date of amendment request: July 20, 1988

Description of amendment request: The proposed change would clarify the current NA-1&2 Technical Specifications (TS) regarding reactor coolant system leakage detection systems. Specifically, the change would clarify the NA-1&2 TS 3.4.6.1 regarding reactor coolant system leakage detection systems and bring the present TS into closer agreement with Regulatory Guide 1.45 and Revision 4 of the Westinghouse Standard TS which are appropriate to NA-1&2.

The current TS Limiting Condition of Operation (LCO) is difficult to understand and can be interpreted to require two leakage detection systems to be operable, whereas the associated action statement can be interpreted to require three separate and independent methods to be operable. Regulatory Guide 1.45 requires three separate detection methods of which two of the methods should be: (1) the containment particulate radioactivity monitoring system and (2) the containment sump level and discharge flow measurement system. Regulatory Guide 1.45 also requires a third method which is satisfied by the containment gaseous radioactivity monitoring system.

The proposed change would clarify the TS such that the containment particulate and gaseous monitoring system are considered as two separate detection methods but are not considered as two independent systems. Specifically, the monitors share a common piping system, power supply and piping arrangement that do not make them truly independent. Therefore, the action statement would be modified to achieve consistency with the LCO. Specifically, if either of the two required leakage monitoring systems are inoperable, a compensatory leakage measurement using the RCS water inventory balance method would be specified instead of obtaining grab samples. The current TS does not require a compensatory leakage measurement if the containment sump discharge measurement system is inoperable whereas the revised TS does. This compensatory leakage measurement along with a fully operable leakage detection system is the basis for extending the action statement from 6 hours to 30 days when one leakage detection system is inoperable. The surveillance requirements have also been rewritten to require a periodic calibration of the containment sump level monitor.

The proposed TS changes are consistent with the regulatory position of Regulatory Guide 1.45, "Reactor Coolant Pressure Boundary Leakage Detection Systems" and NUREG-0452, "Westinghouse Standard Technical Specifications." Specifically, three separate detection methods are

provided but they are grouped as two separate and redundant detection systems. The loss of a single system would not result in the loss of detection capability. Therefore, regulatory position 9 of Regulatory Guide 1.45 is fully met.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards considerations if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee has evaluated the change request against the standards provided above and has determined that the proposed changes would not:

(a) result in a significant increase in the probability or consequence of an accident previously evaluated, i.e., a loss of coolant accident, because the specification continues to require two redundant and diverse means of continuously monitoring for reactor coolant system leakage. In addition, an operability requirement for the containment sump level monitor has been added to the LCO, and a requirement to implement a compensatory leakage measurement (i.e., inventory mass balance) if either or both of the sump leakage monitors are inoperable has been added to the Action Statement. Finally, the requirement to obtain and analyze appropriate containment grab samples if one of the radioactivity monitors is inoperable has been replaced with a requirement to perform a compensatory leakage measurement using the mass balance method. This method is considered equivalent to the grab sample method in terms of leakage detection sensitivity and therefore will provide the same level of protection as previously provided.

(b) create the possibility of a new or different kind of accident. The additional required reactor coolant system leakage monitor (i.e., sump level) is already required by the related [TS] 3/4.4.6.2 regarding reactor coolant system leakage limits (see [TS] 4.4.6.2.1b) and therefore does not introduce any new or unique accident precursors. Similarly, the additional required compensatory leakage measurement (i.e., inventory mass balance) is a test that is routinely performed in accordance with [TS] 4.4.6.2.1d and existing station period test procedures, and therefore does not create any new or unique accident precursors.

(c) result in a significant reduction in the margins of safety as defined in the bases for any [TS] because the proposed [TS] continue to require two redundant and diverse means of leakage monitoring as well as a compensatory leakage measurement every 24 hours if either of the two required leakage monitoring systems is inoperable, and therefore the [TS] Bases and the recommendations of Regulatory Guide 1.45 (regulatory position 9 regarding [TS]) continue to be satisfied.

The NRC staff has made a preliminary review of the licensee's analyses of the proposed change and agrees with the licensee's conclusion that the three standards in 10 CFR 50.92(c) are met. Therefore, the staff proposes to determine that the proposed amendments do not involve a significant hazards consideration.

Local Public Document Room location: The Alderman Library, Manuscripts Department, University of Virginia, Charlottesville, Virginia 22901.

Attorney for licensee: Michael W. Maupin, Esq., Hunton and Williams, P.O. Box 1535, Richmond, Virginia 23212.

NRC Project Director: Herbert N. Berkow

Virginia Electric and Power Company, Docket Nos. 50-338 and 50-339, North Anna Power Station, Units No. 1 and No. 2, Louisa County, Virginia

Date of amendment request: September 30, 1988

Description of amendment request: The proposed change would support full power operation for NA-1&2 at steam generator (SG) tube plugging levels of up to 18%. The results of the analysis supporting the increase in SG tube plugging limits also support a new maximum core peaking factor (FQ) of 2.19. To support the proposed change a reanalysis of the Emergency Core Cooling System (ECCS) performance for the postulated large-break loss-of-coolant accident (LOCA) has been performed in compliance with Appendix K to 10 CFR Part 50. The results of the reanalysis are presented in compliance with 10 CFR 50.46, "Acceptance Criteria for Emergency Core Cooling Systems for Light Water Reactors." The analysis was performed with the NRC-approved 1981 model with BART version of the Westinghouse LOCA-ECCS evaluation model. The analysis includes the evaluation model revisions described in WCAP-9561-P, Addendum 3, Revision 1, "Addendum to BART-A1: A Computer Code for the Best Estimate Analysis of Reload Transients," dated July 1986 and approved by NRC letter dated August 25, 1986. The analytical techniques used are in full compliance with 10 CFR Part 50 Appendix K.

As required by Appendix K of 10 CFR Part 50, certain conservative assumptions were made for the LOCA-ECCS analysis. The assumptions pertain to the conditions of the NA-1&2 reactors and associated safety system equipment at the time that the LOCA is assumed to occur. These assumptions include such items as the core peaking factors, the containment pressure, and the performance of the ECCS. All assumptions and initial operating conditions used in this reanalysis were the same as those used in previous LOCA-ECCS analyses, with two exceptions. The steam generator plugging level was increased to 18% (from 7% and 15%) and the maximum core peaking factor, FQ, was increased from 2.15 to 2.19. With these changes incorporated into the analysis, it was found that the LOCA analysis results continue to meet the 10 CFR 50.46 acceptance criteria.

The large-break LOCA transient is divided, for analytical purposes, into three phases: blowdown, refill, and reflood. There are three distinct transients analyzed in each phase, including the thermal-hydraulic transient in the reactor coolant system, the pressure and temperature transient within the containment and the fuel clad temperature transient of the hottest fuel rod in the core. Based on these considerations, a system of interrelated computer codes were used for the analysis.

The description of the various aspects of the LOCA analysis methodology is provided in WCAP-8339, "Westinghouse ECCS Evaluation Model-Summary," dated July 1974. This document describes the major phenomena modeled, the interfaces among the computer codes, and the features of codes that ensure compliance with 10 CFR Part 50, Appendix K. The SATAN-VI, COCO, WREFLOOD, BART, and LOCTA-IV codes, which are used in the LOCA analysis, are described in detail in WCAP-8306, WCAP-8326, WCAP-8171, WCAP-9695, WCAP-10062 and WCAP-8305, respectively. These codes assess whether sufficient heat transfer geometry and core amenability to cooling are preserved during the time spans applicable to the blowdown, refill, and reflood phases of the LOCA. The SATAN-VI computer code analyzes the thermal-hydraulic transient in the reactor coolant system (RCS) during blowdown, and the COCO computer code calculates the containment pressure transient during all three phases of the LOCA analysis. The thermal-hydraulic response of the RCS during refill and reflood is calculated by the WREFLOOD computer code. A mechanistic estimate of the heat transfer coefficient in the core during reflood is provided by the BART computer code. For the three phases of the LOCA, the

LOCTA-IV computer code is used to compute the thermal transient of the hottest fuel rod.

SATAN-VI is used to determine the RCS pressure, enthalpy, and density, as well as the mass and energy flow rates in the RCS and steam-generator secondary side, as a function of time during the blowdown phase of the LOCA. SATAN-VI also calculates the accumulator mass and pressure and the pipe break mass and energy flow rates that are assumed to be vented to the containment during blowdown. At the end of the blowdown, the mass and energy release rates during blowdown are transferred to the COCO code for use in the determination of the containment pressure response during the first phase of the LOCA. Additional SATAN-VI output data from the end of the blowdown, including the core inlet flowrate and enthalpy, the core pressure, and the core power decay transient, are input to the LOCTA-IV code.

With input from the SATAN-VI code, WREFLOOD uses a system thermal-hydraulic model to determine the core flooding rate (i.e., the rate at which coolant enters the bottom of the core), the coolant pressure and temperature, and the quench front height during the refill and reflood phases of the LOCA. WREFLOOD also calculates the mass and energy flow rates that are assumed to be vented to the containment. Since the mass flowrate to the containment depends upon the core pressure, which is a function of the containment backpressure, the WREFLOOD and COCO codes are interactively linked. With the input and boundary conditions from WREFLOOD, the mechanistic core heat transfer model in BART calculates the fluid and heat transfer conditions in the core during reflood.

LOCTA-IV is used throughout the analysis of the LOCA transient to calculate the fuel and clad temperatures of the hottest rod in the core. The input to LOCTA-IV consists of appropriate thermal-hydraulic outputs from SATAN-VI, WREFLOOD and BART, and conservatively selected initial RCS operating conditions.

The COCO code, which is also used throughout the LOCA analysis, calculates the containment pressure. Input to COCO is obtained from the mass and energy flowrates assumed to be vented to the containment, as calculated by the SATAN-VI and WREFLOOD codes. In addition, conservatively chosen initial containment conditions and an assumed mode of operation for the containment cooling system are input to COCO.

The NA-1&2 LOCA-ECCS reanalysis has evaluated plant operation at SG tube plugging levels of up to 18% based on the acceptance criteria delineated in 10 CFR 50.46. The evaluation concluded that reanalysis of non-LOCA accidents is not required to support this increased tube plugging level provided the measured RCS flow rate remains above the thermal design flow rate assumed for the safety analyses. SG tube plugging in sufficient quantity can potentially affect non-LOCA safety analysis due to reduced primary system flow, more severe pump coastdown characteristics, and the reduction of the reactor primary coolant system volume. Primary flowrate becomes a key parameter in the Departure from Nucleate Boiling Ratio (DNBR) limited events (e.g., uncontrolled RCCA bank withdrawal at power) when it falls below the thermal design flowrate. Pump coastdown characteristics impact analysis results when they become more severe than the conservative values used in the loss-of-flow related analyses. The reduced primary coolant system volume affects dilution times in uncontrolled boron dilution events.

A conservative estimate of the NA-1&2 RCS flow versus tube plugging is based on past flow measurements taken at NA-1&2 for several levels of steam generator tube plugging. More recent NA-1 measurements at greater tube plugging levels validate the conservatism of RCS flow versus tube plugging curve. A re-evaluation of the projection indicates that the conservatively estimated flow rate at the proposed 18% plugging level is approximately equal to the North Anna thermal design flow. Therefore, while measured flow exceeds the thermal design flow, the current docketed licensing analyses remain valid for those events in which flow rate is an important concern.

The impact of 18% tube plugging on dilution times in the uncontrolled boron dilution events was also evaluated. Relative to the boron dilution events, the evaluation indicated: (1) for uncontrolled dilution during startup, time to criticality is 37 minutes. This is more than adequate time for the operator to recognize the high count rate signal and terminate the dilution flow, and (2) for uncontrolled dilution at power, the operator has ample time (greater than 15 minutes) after the over-temperature delta T alarm or trip to determine the cause of dilution, isolate the water source, and initiate reboration before total shutdown margin is lost due to dilution.

Tube plugging levels exhibit no influence on dilution times for the refueling mode of operation, since the SG volumes are not a part of the active system. The evaluation shows that for SG tube plugging levels of up to 18 percent, no reanalysis of the DNBR related non-LOCA safety events is necessary and that the currently licensed analyses remain valid. In the case of the uncontrolled boron dilution events, the available operator response times for the startup and at power evaluations are reduced but remain well above the minimum acceptance values.

Based on the large break LOCA analysis, a double-ended cold-leg guillotine break with a discharge coefficient (C_D) of 0.4 was found to be the limiting break size and location. The analysis resulted in a limiting peak clad temperature of 2165.2° F for the $C_D = 0.4$ case, a maximum local cladding oxidation level of 5.77%, and a total core metal-water reaction of less than 0.3%.

For breaks up to and including the double-ended rupture of a reactor coolant pipe, the ECCS will meet the acceptance criteria as presented in 10 CFR 50.46, as follows: (1) the calculated peak fuel rod clad temperature is below the requirement of 2200° F, (2) the amount of fuel element cladding that reacts chemically with water or steam does not exceed 1% of the total amount of Zircaloy in the reactor, (3) the clad temperature transient is terminated at a time when the core geometry is still amenable to cooling. The localized cladding oxidation limits of 17% are not exceeded during or after quenching, (4) the core remains amenable to cooling during and after the break, and (5) the core temperature is reduced and the long-term decay heat is removed for an extended period of time.

The effects of increasing the allowable steam generator tube plugging to 18% has been assessed for existing non-LOCA event analyses. This evaluation has concluded: (1) current analyses for which RCS flow is an important concern remain valid as long as measured flow is greater than the thermal design flow assumed in safety analyses, (2) the existing loss-of-flow related analyses assume a conservative reactor coolant pump flow coastdown characteristic which accommodates the effect of increased tube plugging on loop flow resistance, and (3) boron dilution analyses assuming the reduced RCS volume associated with tube plugging result in dilution times which remain adequate for the required operator actions to be performed.

Basis for proposed no significant hazards consideration determination:

The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards considerations if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee has evaluated the change request against the standards provided above and has determined that:

1. Since the proposed changes involve parameters which are not accident initiators, they will not increase the probability of occurrence of any malfunction or accident previously addressed. The reanalyzed large break LOCA analysis verifies that operation under the revised specifications would also not result in any increase in accident consequences over those in previously accepted analyses.

2. No new accident types or equipment malfunction scenarios will be introduced as a result of operating in accordance with the revised specifications. The change which potentially affects physical components in the plant systems (steam generator tube plugging) was explicitly included in the analysis and shown not to produce any new or unique accident precursors.

3. The margin of safety, as defined in the basis for the plant Technical Specifications, is not reduced. The revised ECCS analysis meets the acceptance criteria of 10 CFR 50.46. Additionally, since evaluation of non-LOCA accidents concluded that acceptance criteria are met when considering the proposed changes, the current margin of safety is maintained for LOCA and non-LOCA accidents.

Based on the above evaluation, the licensee has determined that the proposed change involves no significant hazards considerations.

The NRC staff has made a preliminary review of the licensee's analyses of the proposed change and agrees with the licensee's conclusion that the three standards in 10 CFR 50.92(c) are met. Therefore, the staff proposes to determine that the proposed amendments do not involve a significant hazards consideration.

Local Public Document Room location: The Alderman Library, Manuscripts Department, University of Virginia, Charlottesville, Virginia 22901.

Attorney for licensee: Michael W. Maupin, Esq., Hunton and Williams, P.O. Box 1535, Richmond, Virginia 23212.

NRC Project Director: Herbert N. Berkow

Virginia Electric and Power Company, Docket Nos. 50-338 and 50-339, North Anna Power Station, Units No. 1 and No. 2, Louisa County, Virginia

Date of amendment request: September 30, 1988

Description of amendment request: The proposed change would increase the allowable enrichment of fuel assemblies irradiated at NA-1&2 to 4.3 weight percent (w/o) U-235. An increase in the current NA-1&2 Technical Specifications (TS) limit of 4.1 w/o U-235 to 4.3 w/o U-235 would allow an increase in batch average discharge burnup to levels approaching the currently licensed limit of 45,000 Mega-Watt Days per Metric Ton Uranium (MWD/MTU). The enrichments currently used limit the batch average burnup to a value from 38,000 MWD/MTU to 42,000 MWD/MTU depending on the number of fuel assemblies loaded each cycle. An increase in the enrichment limit would result in significant fuel cycle cost savings and enhance fuel management plans to increase batch average discharge burnups.

The safety impact for operation of NA-1&2 with high burnup fuel was previously addressed by the licensee in letters to the NRC dated December 4, 1980, March 6 and 26, 1981 and July 24, 1981. By letter dated April 9, 1984, the NRC approved operation of NA-1&2 to a batch of discharge of 45,000 MWD/MTU. A generic impact of extended burnup on the design and operation of Westinghouse fuel was addressed in WCAP-10125-P-A, "Extended Burnup Evaluation of Westinghouse Fuel," dated December 1985. In addition, the NRC made an independent assessment of the environmental and economic impacts of the use of extended burnup fuel in light water power reactors. This assessment was dated February 1988 and entitled "Assessment of the Use of Extended Burnup Fuel in Light Water Power Reactors," Pacific Northwest Laboratory, NUREG/CR-3009. The overall findings of NUREG/CR-3009 were that no significant adverse effects would be generated by increasing the present batch-average burnup level to values of 50,000 MWD/MTU or above, as long as the maximum rod average burnup of any rod is no greater than 60,000 MWD/MTU. Since the findings of these evaluations provided in NUREG/CR-3009 concerning the impact of extended burnup fuel are valid for an enrichment of 4.3 w/o U-235, and since the NA-1&2 spent fuel storage facility is currently licensed to 4.3 w/o U-235, the license's submittal addresses only the impact of increased enrichment on the requirements for the currently approved new fuel storage racks at NA-1&2.

The specific 10 CFR Part 50 Appendix A General Design Criteria for new fuel storage facilities are listed in Section 9.1.1 of the Standard Review Plan (NUREG-0800). Since no physical modifications are being made to the current NA-1&2 new fuel racks, the licensee's analysis only addresses the impact of the increased enrichment on the requirement of subcriticality under normal and postulated abnormal rack conditions (General Design Criterion 62). The highest K-effective allowable by Section 9.1.1 of NUREG-0800 for all conditions is 0.98.

The computer modeling of the storage racks was performed in three-dimensions (3-D) to minimize unnecessary conservatism and uncertainty. All K-effective calculations were performed with the Monte-Carlo program KENO V.a and contained within the modular code system SCALE. KENO V.a is addressed in ORNL-NUREG-CSD-2-VI-R2 entitled "KENO V.a, An Improved Monte Carlo Criticality Program with Supergrouping," dated December 1984. SCALE is addressed in ORNL-NUREG-CSD-2-VI-R3, "SCALE: A Modular Code System for Performing Standardized Computer Analysis for Licensing Evaluation," dated December 1984. The SCALE package automatically processes cross sections to create a set of resonance self shielded cross sections for use by KENO. Because all calculations for this analysis were made using a discrete pin representation, no spatial self shielding was performed prior to the KENO execution. The cross section set chosen was the 27 group ENDF/B-IV data contained in the SCALE package. Sufficient neutron histories were run for each case to limit the statistical uncertainties in the K-effective to less than 0.4% delta K/K.

The results of the licensee's analysis indicate that for a fuel enrichment of 4.3 w/o U-235, the NA-1&2 fuel storage area meets the criticality limit of K-effective less than 0.98 and is safe under the criticality specifications set forth in the NRC Standard Review Plan (NUREG-0800).

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards considerations if operation of the facility in accordance with the proposed amendment would not: (1) involve a

significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The proposed change does not involve a significant hazards consideration because operation of NA-1&2 in accordance with the proposed change would not:

1. Involve a significant increase in the probability or consequences of accidents previously evaluated. The only accident scenarios for which the probability of occurrence are potentially affected by fuel enrichments involve criticality events during fuel handling and storage. The criticality safety analyses demonstrates that K-effective during fuel handling and storage of new fuel is low enough to ensure subcriticality during postulated accident conditions. The probability of occurrence of criticality during fuel handling or storage is therefore not increased. Since subcriticality is maintained, no releases would result from the fuel handling and storage accident scenarios. In addition, since the burnup limit will not be increased beyond that already approved in NRC letter dated April 9, 1984, the radiological consequences of the accidents discussed in WCAP-10125-P-A and NUREG/CR-3009 will not be increased.

2. The proposed amendments do not create the possibility of a new or different kind of accident from any previously evaluated. The only potential impact of increased enrichment upon fuel storage and handling involves the potential for criticality and the licensee's analyses that has determined that subcriticality will be maintained.

3. The proposed amendments do not involve a significant reduction in the margin of safety. The criticality analysis demonstrates that there is adequate margin to ensure subcriticality of the fuel during storage and handling of new fuel. The NRC safety analysis provided in a letter dated December 21, 1984, provides the same assurance for spent fuel.

Therefore, pursuant to 10 CFR 50.92, based on the above considerations, it has been determined that these changes do not constitute a significant safety hazards consideration.

The NRC staff has made a preliminary review of the proposed change and concludes that the three standards in 10 CFR 50.92(c) are met. Therefore, the staff proposes to determine that the proposed amendments do not involve a significant hazards consideration.

Local Public Document Room location: The Alderman Library, Manuscripts Department, University of Virginia, Charlottesville, Virginia 22901.

Attorney for licensee: Michael W. Maupin, Esq., Hunton and Williams, P.O. Box 1535, Richmond, Virginia 23212.

NRC Project Director: Herbert N. Berkow

Virginia Electric and Power Company, Docket Nos. 50-338 and 50-339, North Anna Power Station, Units No. 1 and No. 2, Louisa County, Virginia

Date of amendment request: September 30, 1988

Description of amendment request: The proposed change would allow the direct reactor trip on turbine trip to be blocked below 30% of the rated thermal power. Currently, Permissive Setpoint P-7 is used to block the reactor trip on turbine trip below 10% of rated thermal power. The proposed modification would rewire the Solid State Protection System so that Permissive Setpoint P-8 is used to block the reactor trip on turbine trip below 30% power. A licensee review of historical trip data shows that the most commonly occurring reactor trip on turbine trip events are well below 30% of rated thermal power. Thus, it was concluded that the use of the existing P-8 bistable to block the direct reactor trip on turbine trip would be an effective means of reducing unneeded trips at low power. Direct reactor trip on turbine trip would be available above 30% power. The plant's designed load rejection capability is 50% of full load.

At present, for all power levels above 10% (the P-7 permissive setpoint) of Rated Thermal Power (RTP), the NA-1&2 nuclear reactors are tripped directly on turbine trip from a signal derived from the turbine autostop oil pressure or turbine stop valve position. A direct reactor/turbine trip at low power is unnecessary and unduly stresses plant systems. Thus, the licensee is proposing a change which would allow for a block of the direct reactor trip on turbine trip below 30% of rated thermal power.

The proposed modification would rewire the Solid State Protection System so that Permissive P-8 is also used to block the reactor trip on turbine trip instead of Permissive P-7. It was concluded that the use of the existing P-8 bistable to block the direct reactor trip on turbine trip would be an effective means of eliminating unneeded low power transient reactor trips. Direct reactor trip on turbine trip would still be available above 30% power.

Three items were considered in the licensee's safety analysis and were addressed in the licensee's submittal.

(1) The results of the worst-case analyses show that a total loss of external electrical load without a direct or immediate reactor trip below 30% of RTP presents no hazards to the integrity of the reactor coolant system or the main steam system. Pressure-relieving devices incorporated in the two systems are adequate to keep the maximum pressure within the design limits. The licensee concluded that the results of this analysis demonstrates that plant parameters are maintained within the design limits previously analyzed for the loss-of-load accident from full power described in Section 15.2.7 of the NA-1&2 Updated Final Safety Analysis Report (UFSAR).

(2) An analysis was also performed for a complete loss of forced reactor coolant flow initiated from the most adverse preconditions of a turbine trip, and demonstrated that the integrity of the core is maintained by operation of the reactor protection system, i.e., the DNBR will be maintained above the design limit value. Thus, there will be no cladding damage and no release of fission products to the reactor coolant system. The licensee concluded that plant parameters are maintained within design limits and that this analysis is bounded by the results of a complete loss of flow from full power as described in Section 15.3.4 of the UFSAR.

(3) Finally, an analysis was conducted to verify that the applicable NUREG-0737 requirements were met. NUREG-0737 required that the frequency of a small break loss-of-coolant-accident (LOCA) caused by a stuck-open pressurizer power operated relief valve (PORV) be reduced and that it be demonstrated not to be a significant contributor to the probability of a small break LOCA. Both the loss-of-load and the loss-of-flow accidents have the potential of causing the PORV to open. The licensee has conducted an analysis which demonstrates that the PORVs are not normally challenged during this event and thus the NUREG-0737 requirements are met.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards considerations if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from

any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee has evaluated the change request against the standards provided above and has determined that:

1. No significant increase in the probability of occurrence or consequences of an accident analyzed in the UFSAR will result from elimination of reactor trip on turbine trip below 30% of Rated Thermal Power (RTP). The analyses results show that the DNBR does not decrease below the design limit at any time. The analysis also shows that, except under [most] conservative assumptions, the pressurizer PORVs are not challenged during the transient. Pressure-relieving devices incorporated in the primary and the secondary systems are adequate to keep the maximum pressure within the design limit. Since the predicted results are within the range of existing safety analysis values, it is concluded that operation with the proposed Technical Specification changes will neither significantly increase the probability of occurrence nor the consequences of initiating events for any known accident.

2. No new or different accident type not previously considered in the UFSAR is created by this proposed change. The complete loss of unit load without a direct reactor trip on turbine trip is a design event and is addressed in Section 15.2.7 of the UFSAR. The results for a loss of flow due to fast bus transfer failure after a turbine trip are bounded by the results for a complete loss of flow from full power, which is discussed in Section 15.3.4 of the UFSAR. Thus, the results of all the relevant accident analyses show that operation with this modification does not create a new or different accident type than any evaluated previously in the UFSAR.

3. The margin of safety is not reduced. The proposed Technical Specification changes have been incorporated in the safety analyses. These analyses have demonstrated that calculated results meet all design acceptance criteria as stated in the UFSAR.

Based on the above evaluation, the licensee has determined that the proposed change involves no significant hazards considerations.

The NRC staff has made a preliminary review of the licensee's analyses of the proposed change and agrees with the licensee's conclusion that the three standards in 10 CFR 50.92(c) are met. Therefore, the staff proposes to determine that the proposed amendments do not involve a significant hazards consideration.

Local Public Document Room location: The Alderman Library, Manuscripts Department, University of Virginia, Charlottesville, Virginia 22901.

Attorney for licensee: Michael W. Maupin, Esq., Hunton and Williams, P.O. Box 1535, Richmond, Virginia 23212.

NRC Project Director: Herbert N. Berkow

Wisconsin Electric Power Company, Docket Nos. 50-266 and 50-301, Point Beach Nuclear Plant, Unit Nos. 1 and 2, Town of Two Creeks, Manitowoc County, Wisconsin

Date of amendments request: January 6, 1987 as supplemented April 14 and May 15, 1987.

Description of amendments request: The licensee proposes to change Technical Specification Table 15.4.1-1, "Minimum Frequencies for Checks, Calibrations and Tests of Instrument Channels," to increase the period of the logic channel test of the reactor trip on low reactor coolant flow in both loops from monthly to each (annual) refueling outage.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a no significant hazards consideration exists as stated in 10 CFR 50.92(c). A proposed amendment to an operating license involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

In 51 FR 7751, the Commission cited examples of amendments that are considered not likely to involve significant hazards considerations. Example (vi) involves a change which may either result in some increase to the probability or consequences of a previously-analyzed accident or may reduce in some way a safety margin, but where the results of the change are clearly within all acceptable criteria with respect to the system or component specified in the Standard Review Plan.

The amendment proposed by the licensee would increase the logic testing period on the two-loop reactor coolant loss of flow reactor trip from monthly to every refueling outage (currently annually). However, the surveillance frequency for the logic channel test of the relays/contacts which initiate the reactor trip on low reactor coolant flow in either loop will remain monthly. Since all bistables and relay coils will still be tested monthly, the net effect of the proposed amendment would be to slightly increase the risk of failing to get a reactor trip upon simultaneous detection of low reactor coolant flow in both loops, due to failure of both of the specific relay contacts which initiate the trip during the increased period between surveillances. Although a numerical quantification of the increase in risk has not been performed, the staff believes that it would be quite small since the event of concern would require two contact failures (one in each loop) between refueling outages and a loss of flow condition occurring while the reactor is between 10% and 50% power.

Section 7.2 of the Standard Review Plan discusses various aspects of the Reactor Trip System. Section 7.2 references Regulatory Guide 1.22, "Periodic Testing of Protection System Actuation Functions." Regulatory Guide 1.22 provides for acceptable methods of testing protection systems during reactor operation. In its May 15, 1987 letter, the licensee states that all actuation devices and all actuated devices which are part of the reactor trip logic for loss of flow in both loops are tested in accordance with the guidance contained in Safety Guide 1.22 (Safety Guide 1.22 and Regulatory Guide 1.22 are identical). Therefore, the proposed change is in conformance with guidance endorsed by the Standard Review Plan.

Local Public Document Room location: Joseph P. Mann Library, 1516 Sixteenth Street, Two Rivers, Wisconsin.

Attorney for licensee: Gerald Charnoff, Esq., Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Project Director: John N. Hannon.

NOTICE OF ISSUANCE OF AMENDMENT TO FACILITY OPERATING LICENSE

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License and Proposed No Significant Hazards Consideration Determination and Opportunity for Hearing in connection with these actions was published in the **Federal Register** as indicated. No request for a hearing or petition for leave to intervene was filed following this notice.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendments, (2) the amendments, and (3) the Commission's related letters, Safety Evaluations and/or Environmental Assessments as indicated. All of these items 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 rooms for the particular facilities involved. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Reactor Projects.

Arizona Public Service Company, et al, Docket Nos. STN 50-528, STN 50-529 and STN 50-530, Palo Verde Nuclear Generating Station, Units 1, 2 and 3, Maricopa County, Arizona

Date of application for amendments: March 16, 1988, as supplemented by letter dated July 6, 1988.

Brief description of amendments: The amendments revise Technical Specification Surviellance Requirement 4.5.2.h which specifies flow requirements that the Low Pressure Safety Injection subsystem must meet during flow balance testing.

Date of issuance: October 17, 1988

Effective date: October 17, 1988

Amendment Nos.: 37, 24, and 13

Facility Operating License Nos. NPF-41, NPF-51 and NPF-74: Amendments changed the Technical Specifications.

Date of initial notice in **Federal Register:** August 10, 1988 (53 FR 30126). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 17, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Phoenix Public Library, Business and Science Division, 12 East McDowell Road, Phoenix, Arizona 85004.

Arizona Public Service Company, et al, Docket Nos. STN 50-528, STN 50-529 and STN 50-530, Palo Verde Nuclear Generating Station, Units 1, 2 and 3, Maricopa County, Arizona

Date of application for amendments: May 27, 1988

Brief description of amendments: The Amendments revise the technical specification to modify the azimuthal power tilts to require the measured power tilt to be equal to or less than the Core Protection Calculation allowance and the limit in Figure 3.2-1A when the Core Operating Limit Supervisory System is in service. The wording of the surveillance requiment was revised for clarity. In addition, the azimuthal power tilt limit is increased for Unit 2.

Date of issuance: October 17, 1988

Effective date: October 17, 1988

Amendment Nos.: 38, 25, and 14

Facility Operating License Nos. NPF-41, NPF-51 and NPF-74: Amendments changed the Technical Specifications.

Date of initial notice in **Federal Register:** July 13, 1988 (53 FR 26518). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 17, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Phoenix Public Library, Business and Science Division, 12 East McDowell Road, Phoenix, Arizona 85004.

Arizona Public Service Company, et al, Docket Nos. STN 50-528, STN 50-529 and STN 50-530, Palo Verde Nuclear Generating Station, Units 1, 2 and 3, Maricopa County, Arizona

Date of application for amendments: September 6, 1988

Brief description of amendments: The amendments revise Technical Specification 6.3.1, "Unit Staff Qualifications," to modify the Senior Reactor Operator license requirements for the Operations Manager.

Date of issuance: October 24, 1988

Effective date: October 24, 1988

Amendment Nos.: 39, 26 and 15

Facility Operating License Nos. NPF-41, NPF-51 and NPF-74: Amendments changed the Technical Specifications.

Date of initial notice in **Federal Register:** September 21, 1988 (53 FR 36668). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 24, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Phoenix Public Library, Business and Science Division, 12 East McDowell Road, Phoenix, Arizona 85004.

Arizona Public Service Company, et al, Docket Nos. STN 50-528, STN 50-529 and STN 50-530, Palo Verde Nuclear Generating Station, Units 1, 2 and 3, Maricopa County, Arizona

Date of application for amendments: August 25, 1988, as supplemented by letter dated October 18, 1988.

Brief description of amendments: The amendments delete the organization charts from the technical specifications in accordance with guidance provided by the NRC in Generic Letter 88-06.

Date of issuance: October 25, 1988

Effective date: October 25, 1988

Amendment Nos.: 40, 27 and 16

Facility Operating License Nos. NPF-41, NPF-51 and NPF-74: Amendments changed the Technical Specifications.

Date of initial notice in **Federal Register:** September 21, 1988 (53 FR 36667). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 25, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Phoenix Public Library, Business and Science Division, 12 East McDowell Road, Phoenix, Arizona 85004.

Carolina Power & Light Company, Docket No. 50-261, H. B. Robinson Steam Electric Plant, Unit No. 2, Darlington County, South Carolina

Date of application for amendment: May 25, 1988

Brief description of amendment: The amendment changes the Technical Specifications to remove the offsite and facility organization charts consistent with the guidance of Generic Letter 88-06, "Removal of Organization Charts from Technical Specifications."

Date of issuance: November 3, 1988

Effective date: November 3, 1988

Amendment No. 120

Facility Operating License No. DPR-23. Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register:** June 29, 1988 (53 FR 24506). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 3, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Hartsville Memorial Library, Home and Fifth Avenues, Hartsville, South Carolina 29535

Commonwealth Edison Company, Docket Nos. 50-237 and 50-249, Dresden Nuclear Power Station, Units No. 2 and 3, Grundy County, Illinois

Date of application for amendments: August 31, 1988

Brief description of amendments: These amendments modify Section 3.5.F of the Technical Specifications to include more prescriptive requirements for Emergency Core Cooling Systems operability during cold shutdown and refueling operational modes.

Date of issuance: October 26, 1988

Effective date: October 26, 1988 and to be implemented within 60 days.

Amendment Nos.: 101, 97

Provisional Operating License Nos. DPR-19 and DPR-25. These amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 21, 1988 (53 FR 36669). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated Ocotber 26, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Morris Public Library, 604 Liberty Street, Morris, Illinois 60450.

Attorney to licensee: Michael Miller, Esq., Sidley and Austin, One First National Plaza, Chicago, Illinois 60603.

NRC Project Director: Daniel R. Muller

Commonwealth Edison Company, Docket Nos. 50-237/249, Dresden Nuclear Power Station, Unit Nos. 2, and 3 Grundy County, Illinois

Date of application for amendments: June 20, 1988

Brief description of amendments: The amendments change Technical Specifications for Dresden Units 2 and 3 to reflect instrumentation enhancements for post-accident monitoring completed per Regulatory Guide 1.97 and NUREG-0737 Supplement 1. In addition several minor corrections and clarifications and have been incorporated.

Date of issuance: November 3, 1988

Effective date: November 3, 1988 and to be implemented within 60 days

Amendment Nos.: 102, 98

Provisional Operating License No. DPR-19 and DPR-25. The amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** August 10, 1988 (53 FR 30128). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 3, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Morris Public Library, 604 Liberty Street, Morris, Illinois 60450.

Connecticut Yankee Atomic Power Company, Docket No. 50-213, Haddam Neck Plant, Middlesex County, Connecticut; Northeast Nuclear Energy Company, et al; Nos. 1, 2, and 3, New London County, Connecticut

Date of application for amendment: April 29, 1988 as supplement by letter dated July 21, 1988.

Brief description of amendment: The changes affect the TSs which specify the qualifications and conduct of the Nuclear Review Board (NRB) for all Units and the Site Nuclear Review Board for Millstone Units 1, 2 and 3.

Date of Issuance: October 26, 1988

Effective date: October 26, 1988

Amendment Nos.: 108, 25, 144, 26

Facility Operating License Nos. DPR-61, DPR-21, DPR-65 and NPF-49. Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** August 24, 1988 (53 FR 32292). The Commission's related evaluation of these amendments is contained in a Safety Evaluation dated October 26, 1988

No significant hazards consideration comments received: No.

Local Public Document Room locations: Russell Library, 123 Broad Street, Middletown, Connecticut 06457 and Waterford Public Library, 49 Rope Ferry Road, Waterford, Connecticut 06385.

GPU Nuclear Corporation, et al., Docket No. 50-219, Oyster Creek Nuclear Generating Station, Ocean County, New Jersey

Date of application for amendment: March 30, 1988 as supplemented April 12, 1988 and September 22, 1988.

Brief description of amendment: The amendment modified Section 3.10 of the Technical Specifications to accommodate the Cycle 12 Core Reload. Specifically, the Minimum Critical Power Ratio (MCPR) and the maximum average planar linear heat generator rated (MAPLHGR) limit was changed. It also permitted the use of GE 8x8EB fuel.

Date of Issuance: October 31, 1988

Effective date: October 31, 1988

Amendment No.: 129

Provisional Operating License No. DPR-16. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** May 4, 1988 (53 FR 15912). The September 22, 1988 submittal provided additional clarifying information and did not change the determination of the initial notice. The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated October 31, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Ocean County Library, Reference Department, 101 Washington Street, Toms River, New Jersey 08753.

Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket No. 50-424, Vogtle Electric Generating Plant, Unit 1, Burke County, Georgia

Date of application for amendment: June 14, 1988, as supplemented September 27, 1988.

Brief description of amendment: The amendment modified the Technical Specifications to make training requirements be in accordance with 10 CFR 55.

Date of issuance: November 1, 1988

Effective date: November 1, 1988

Amendment No.: 12

Facility Operating License No. NPF-68: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** July 13, 1988 (53 FR 26523). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 1, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Burke County Library, 412 Fourth Street, Waynesboro, Georgia 30830

Niagara Mohawk Power Corporation, Docket No. 50-220, Nine Mile Point Nuclear Station, Unit No. 1, Oswego County, New York

Date of application for amendment: March 7, 1988, as supplemented April 13, 1988.

Brief description of amendment: This amendment revises Technical Specification 3.1.2 and 4.1.2 for the liquid poison system to comply with the requirements of 10 CFR 50.62, "Requirements for Reduction of Risk from Anticipated Transients without Scram (ATWS) Events for Light-Water-Cooled Nuclear Power Plants."

Date of issuance: October 31, 1988

Effective date: October 31, 1988

Amendment No.: 101

Facility Operating License No. DPR-63: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** June 1, 1988 (53 FR 20044). The staff has found one of the requested changes, the revision to Figure 3.1.2b, to be unacceptable and has issued a Notice of Denial. The Commission's related evaluation of the amendment is

contained in a Safety Evaluation dated October 31, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Omaha Public Power District, Docket No. 50-285, Fort Calhoun Station, Unit No. 1, Washington County, Nebraska

Date of amendment request: July 19, 1988

Brief description of amendment: The amendment modified the Technical Specifications to provide the addition of a Table of Contents for Tables and Figures and to correct an error to a location reference found in Section 2.19.

Date of issuance: November 3, 1988

Effective date: November 3, 1988

Amendment No.: 116

Facility Operating License No. DPR-40. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** August 24, 1988 (53 FR 32294). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 3, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: W. Dale Clark Library, 215 South 15th Street, Omaha, Nebraska 68102

Pacific Gas and Electric Company, Docket Nos. 50-275 and 50-323, Diablo Canyon Nuclear Power Plant, Units 1 and 2, San Luis Obispo County, California

Date of applications for amendments: November 21, 1986 and November 9, 1987

Brief description of amendments: The amendments modified paragraph 2.E of the licenses to require compliance with the amended Physical Security Plan. This Plan was amended to conform to the requirements of 10 CFR 73.55. Consistent with the provisions of 10 CFR 73.55, search requirements must be implemented within 60 days and miscellaneous amendments within 180 days from the effective date of these amendments.

Date of issuance: October 17, 1988

Effective date: October 17, 1988

Amendment Nos.: 32 and 31

Facility Operating License Nos. DPR-80 and DPR-82: Amendments changed the licenses.

Date of initial notice in **Federal Register:** September 7, 1988 (53 FR 34609). The Commission's related evaluation of the amendments is contained in a Safeguards Evaluation dated October 17, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: California Polytechnic State University Library, Government Documents and Maps Department, San Luis Obispo, California 93407.

Pennsylvania Power and Light Company, Docket Nos. 50-387 and 50-388 Susquehanna Steam Electric Station, Units 1 and 2, Luzerne County, Pennsylvania

Date of application for amendments: December 18, 1987

Brief description of amendments: Miscellaneous Technical Specification Changes; (a) correct errors; (b) delete redundant information; and (c) change organizational nomenclature.

Date of issuance: October 20, 1988

Effective date: As of the date of issuance.

Amendment Nos.: 83 and 51

Facility Operating License Nos. NPF-14 and NPF-22. These amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** August 10, 1988 (53 FR 30141). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 20, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Osterhout Free Library, Reference Department, 71 South Franklin Street, Wilkes-Barre, Pennsylvania 18701.

Pennsylvania Power and Light Company, Docket No. 50-387, Susquehanna Steam Electric Station, Unit 1, Luzerne County, Pennsylvania

Date of application for amendment: June 3, 1988

Brief description of amendment: The amendment revised the Technical Specifications for material withdrawal schedule and lead factor ratio.

Date of issuance: October 31, 1988

Effective date: October 31, 1988

Amendment No.: 84

Facility Operating License No. NPF-14: This amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** August 10, 1988 (53 FR 30140). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 31, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Osterhout Free Library, Reference Department, 71 South Franklin Street, Wilkes-Barre, Pennsylvania 18701.

Philadelphia Electric Company, Docket No. 50-352, Limerick Generating Station, Unit 1, Montgomery County, Pennsylvania

Date of application for amendment: November 18, 1987

Brief description of amendment: This amendment modified Section 6 of the Technical Specifications to reflect (I) a new Corporate and (II) a new plant staff organizational structure and (III) a revised composition of the Plant Operations Review Committee.

Date of issuance: October 31, 1988

Effective date: October 31, 1988

Amendment No.: 10

Facility Operating License No. NPF-39. This amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** December 23, 1987 (52 FR 48589). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 31, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Pottstown Public Library, 500 High Street, Pottstown, Pennsylvania 19464.

Public Service Company of Colorado, Docket No. 50-267, Fort St. Vrain Nuclear Generating Station, Platteville, Colorado

Date of amendment request: December 2, 1986 as supplemented October 22, 1987 and July 15, 1988.

Brief description of amendment: The amendment modified paragraph 2.(D)(3) of the license to require compliance with the amended Physical Security Plan. The Plan was amended to conform to the requirements of 10 CFR 73.55. Consistent with the provisions of 10 CFR 73.55, search requirements must be implemented within 60 days and miscellaneous amendments within 180 days from the effective date of this amendment.

Date of issuance: October 24, 1988

Effective date: October 24, 1988

Amendment No.: 65

Facility Operating License No. DPR-34. Amendment revised the Technical license.

Date of initial notice in **Federal Register:** September 21, 1988 (53 FR 36673). The Commission's related evaluation of the amendment is contained in a Safeguards Evaluation Report dated October 24, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location. Greeley Public Library, City Complex Building, Greeley, Colorado

Public Service Electric & Gas Company, Docket No. 50-354, Hope Creek Generating Station, Salem County, New Jersey

Date of application for amendment: March 7, 1988

Brief description of amendment: This amendment deleted license condition 2.C.(3) concerning relief from certain pump and valve testing requirements.

Date of issuance: October 26, 1988

Effective date: October 26, 1988

Amendment No.: 20

Facility Operating License No. NPF-57. This amendment revised the License.

Date of initial notice in **Federal Register:** June 1, 1988 (53 FR 20045). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 26, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Pennsville Public Library, 190 S. Broadway, Pennsville, New Jersey 08070

Public Service Electric & Gas Company, Docket Nos. 50-272 and 50-311, Salem Generating Station, Unit Nos. 1 and 2, Salem County, New Jersey

Date of application for amendments: August 6, 1985 as supplemented on August 29, 1986 and August 16, 1988. The supplemental letters did not make technical changes to the original application.

Brief description of amendments: The amendments changed the Technical Specifications regarding air lock leakage testing.

Date of issuance: October 21, 1988

Effective date: October 21, 1988

Amendment Nos.: 89 and 62

Facility Operating License Nos. DPR-70 and DPR-75. These amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 25, 1985 (50 FR 38921). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 21, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Salem Free Public Library, 112 West Broadway, Salem, New Jersey 08079

South Carolina Electric & Gas Company, South Carolina Public Service Authority, Docket No. 50-395, Virgil C. Summer Nuclear Station, Unit No. 1, Fairfield County, South Carolina

Date of application for amendment: March 8, 1988 as supplemented August 31, and September 30, 1988.

Brief description of amendment: The amendment changes the Technical Specifications by revising Figures 3.9-1 and 3.9-2 of Section 3.9.12. These figures establish the minimum required fuel assembly exposure as a function of initial enrichment to permit storage of fuel assemblies in Regions 2 and 3 of the spent fuel assembly storage racks. In addition, the amendment revises Sections 5.3.1 and 5.6 of the Technical Specifications in terms of maximum initial enrichment of U-235 and minimum required burnup for Regions 2 and 3 of the spent fuel pool.

Date of issuance: October 28, 1988

Effective date: October 28, 1988

Amendment No.: 74

Facility Operating License No. NPF-12. Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register:** June 1, 1988 (53 FR 20046). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 28, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Fairfield County Library, Garden and Washington Streets, Winnsboro, South Carolina 29180.

South Carolina Electric & Gas Company, South Carolina Public Service Authority, Docket No. 50-395, Virgil C. Summer Nuclear Station, Unit No. 1, Fairfield County, South Carolina

Dates of application for amendment: May 20, 1988, as supplemented June 20, 1988, July 8, 1988, August 5, 1988, September 16, 1988, September 30, 1988, October 11, 1988, October 13, 1988, and October 24, 1988.

Brief description of amendment: The amendment changes the Technical Specifications to allow refueling and operating with (1) Vantage 5 (V5) improved fuel design in combination with the Westinghouse low parasitic fuel assemblies remaining in the core from Cycle 4 and (2) subsequent operating cycles with up to a full core of V5 fuel.

Date of issuance: October 28, 1988

Effective date: October 28, 1988

Amendment No.: 75

Facility Operating License No. NPF-12. Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register:** August 10, 1988 (53 FR 30144) The submittals dated August 5, 1988, September 16, 1988, September 30, 1988, October 11, 1988, October 13, 1988, and October 24, 1988 provided clarifying information that did not change the initial determination of no significant hazards consideration as published in the **Federal Register.** The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 28, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Fairfield County Library, Garden and Washington Streets, Winnsboro, South Carolina 29180.

Southern California Edison Company, et al., Docket No. 50-206, San Onofre Nuclear Generating Station, Unit No. 1, San Diego County, California

Date of application for amendment: May 26, 1988

Brief description of amendment: The amendment revised Technical Specification Section 3.5.2, "Control Rod Insertion Limits," to assure reactor operation is consistent with core design analysis, in that the Control Group I (Shutdown Group) is precluded from insertion during power operation.

Date of issuance: October 21, 1988

Effective date: This license amendment is effective the date of issuance and must be fully implemented no later than 30 days from date of issuance.

Amendment No.: 111

Provisional Operating License No. DPR-13. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** July 27, 1988 (53 FR 28295). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 21, 1988.

No significant hazards consideration comments received: No comments.

Local Public Document Room location: General Library, University of California, Post Office Box 19557, Irvine, California 92713.

The Cleveland Electric Illuminating Company, Duquesne Light Company, Ohio Edison Company, Pennsylvania Power Company, Toledo Edison Company, Docket No. 50-440, Perry Nuclear Power Plant, Unit No. 1, Lake County, Ohio

Date of application for amendment: June 9, 1988

Brief description of amendment: The amendment revises Table 3.8.4.1-1 of the Technical Specifications to delete spare

circuit breakers from the Table and correct typographical errors.

Date of issuance: October 24, 1988

Effective date: October 24, 1988

Amendment No.: 17.

Facility Operating License No. NPF-58. This amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 15, 1988 (53 FR 35941). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 24, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Perry Public Library, 3753 Main Street, Perry, Ohio 44081

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of application for amendment: June 28, 1988.

Brief description of amendment: The amendment changed the TS to reflect recent organizational changes. All references regarding the "Vice President, Nuclear" are changed to the "Senior Vice President, Nuclear." The position of General Manager, Engineering (Nuclear) has been deleted from the Nuclear Safety Review Board (NSRB) and the Manager, Licensing and Fuels, has been appointed Chairman of the NSRB.

Date of issuance: October 27, 1988.

Effective date: October 27, 1988.

Amendment No.: 39

Facility Operating License No. NPF-30. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** August 24, 1988 (53 FR 32299). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 27, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Callaway County Public Library, 710 Court Street, Fulton, Missouri 65251 and the John M. Olin Library, Washington University, Skinker and Lindell Boulevards, St. Louis, Missouri 63130.

Wolf Creek Nuclear Operating Corporation, Kansas Gas and Electric Company, Kansas City Power & Light Company, Kansas Electric Power Cooperative, Inc., Docket No. 50-482, Wolf Creek Generating Station, Coffey County, Kansas

Date of amendment request: December 2, 1986 as supplemented February 18 and August 2, 1988.

Brief description of amendment: The amendment modified paragraph 2.E of the license to require compliance with the amended Physical Security Plan. This Plan was amended to conform to the requirements of 10 CFR 73.55. Consistent with the provisions of 10 CFR 73.55, search requirements must be implemented within 60 days and miscellaneous amendments within 180 days from the effective date of the amendment.

Date of Issuance: October 24, 1988

Effective date: October 24, 1988

Amendment No.: 21

Facility Operating License No. NPF-42. Amendment revised the license.

Date of initial notice in **Federal Register:** September 21, 1988 (53 FR 36674). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 24, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room Location: Emporia State University, William Allen White Library, 1200 Commercial Street, Emporia, Kansas 66801 and Washburn University School of Law Library, Topeka, Kansas

Yankee Atomic Electric Company, Docket No. 50-029, Yankee Nuclear Power Station, Franklin County, Massachusetts

Date of application for amendment: June 27, 1988

Brief description of amendment: The amendment changes the Technical Specifications to permit an increase in the nitrogen pressure in the safety injection accumulator.

Date of issuance: October 25, 1988

Effective date: October 25, 1988

Amendment No.: 119

Facility Operating License No. DPR-3: Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register:** August 24, 1988 (53 FR 32304). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 25, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Greenfield Community College, 1 College Drive, Greenfield, Massachusetts 01301.

Yankee Atomic Electric Company, Docket no. 50-029, Yankee Nuclear Power Station, Franklin County, Massachusetts

Date of application for amendment: June 27, 1988

Brief description of amendment: The amendment revises the technical specifications to enable piping modifications needed to allow for installation of the Water Clean-Up System.

Date of issuance: November 1, 1988

Effective date: When the Water Clean-Up System is declared operable.

Amendment No.: 120

Facility Operating License No. DPR-3: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** August 24, 1988 (53 FR 32304). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 1, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Greenfield Community College, 1 College Drive, Greenfield, Massachusetts 01301.

NOTICE OF ISSUANCE OF AMENDMENT TO FACILITY OPERATING LICENSE AND FINAL DETERMINATION OF NO SIGNIFICANT HAZARDS CONSIDERATION AND OPPORTUNITY FOR HEARING (EXIGENT OR EMERGENCY CIRCUMSTANCES)

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Because of exigent or emergency circumstances associated with the date the amendment was needed, there was not time for the Commission to publish, for public comment before issuance, its usual 30-day Notice of Consideration of Issuance of Amendment and Proposed No Significant Hazards Consideration Determination and Opportunity for a Hearing. For exigent circumstances, the Commission has either issued a **Federal Register** notice providing opportunity for public comment or has used local media to provide notice to the public in the area surrounding a licensee's facility of the licensee's application and of the Commission's proposed determination of no significant hazards consideration. The Commission has provided a reasonable opportunity for the public to comment, using its best efforts to make

available to the public means of communication for the public to respond quickly, and in the case of telephone comments, the comments have been recorded or transcribed as appropriate and the licensee has been informed of the public comments.

In circumstances where failure to act in a timely way would have resulted, for example, in derating or shutdown of a nuclear power plant or in prevention of either resumption of operation or of increase in power output up to the plant's licensed power level, the Commission may not have had an opportunity to provide for public comment on its no significant hazards determination. In such case, the license amendment has been issued without opportunity for comment. If there has been some time for public comment but less than 30 days, the Commission may provide an opportunity for public comment. If comments have been requested, it is so stated. In either event, the State has been consulted by telephone whenever possible.

Under its regulations, the Commission may issue and make an amendment immediately effective, notwithstanding the pendency before it of a request for a hearing from any person, in advance of the holding and completion of any required hearing, where it has determined that no significant hazards consideration is involved.

The Commission has applied the standards of 10 CFR 50.92 and has made a final determination that the amendment involves no significant hazards consideration. The basis for this determination is contained in the documents related to this action. Accordingly, the amendments have been issued and made effective as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the application for amendment, (2) the amendment to Facility Operating License, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment, as indicated. All of these items 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 for the particular facility involved.

A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Reactor Projects.

The Commission is also offering an opportunity for a hearing with respect to the issuance of the amendments. By December 16, 1988, 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 petition for leave to intervene. Requests for a hearing and petitions 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. 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 fifteen (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 fifteen (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, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under consideration. 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.

Since the Commission has made a final determination that the amendment involves no significant hazards consideration, if a hearing is requested, it will not stay the effectiveness of the amendment. Any hearing held would take place while the amendment is in effect.

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 Service 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 ten (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) 325-6000 (in Missouri 1-(800) 342-6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to (*Project Director*): 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 the 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 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).

Public Service Electric & Gas Company, Docket No. 50-311, Salem Generating Station, Unit No. 2, Salem County, New Jersey

Date of Application for amendment: October 10, 1988

Brief description of amendment: The amendment changed the Technical Specifications to allow an alternate sampling method of steam generator tube inspections, limited to the fourth refueling outage. Telephone authorization was granted on an emergency basis on October 14, 1988, and confirmed by letter dated October 14, 1988.

Date of Issuance: November 1, 1988

Effective Date: October 14, 1988

Amendment No.: 63

Facility Operating License No. DPR-75: Amendment revised the Technical Specifications.

Public comments requested as to proposed no significant hazards consideration: No.

The Commission's related evaluation of the amendment, consultation with the State of New Jersey and final no significant hazards considerations determination are contained in a Safety Evaluation dated November 1, 1988.

Attorney for licensee: Conner and Wetterhahn, 1747 Pennsylvania Avenue, Washington, DC 20006

Local Public Document Room Location: Salem Free Public Library, 112 West Broadway, Salem, New Jersey 08079.

NRC Project Director: Walter R. Butler

Dated at Rockville, Maryland, this 9th day of November, 1988.

For the Nuclear Regulatory Commission

Bruce A. Boger,

Director, Division of Reactor Projects-I/II, Office of Nuclear Reactor Regulation

[Doc. 88-26331 Filed 11-15-88; 8:45 am]

BILLING CODE 7590-01-D

[Docket No. 50-155]

Consumers Power Co.; Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 93 to Facility Operating License No. DPR-6, issued to Consumers Power Company (the licensee), which revised the Technical Specifications (TSs) for operation of the Big Rock Point Plant (the facility), located in Charlevoix County, Michigan. The amendment became effective on October 14, 1988.

This amendment modifies the TSs by replacing the requirements to partial-stroke test the Reactor Depressurization System depressurizing valves quarterly with a requirement to full-stroke test all four depressurizing valves each refueling outage.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings, as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment and Opportunity for Hearing in connection with this action was published in the **Federal Register** on August 23, 1988 (53 FR 32123). No request for a hearing or petition for leave to intervene was filed following this notice.

Also in connection with this action, the Commission issued an Environmental Assessment and Finding of No Significant Impact.

For further details with respect to this action, see (1) the application for amendment dated July 5, 1988, as modified October 10, 1988, (2) Amendment No. 93 to License No. DPR-6, and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, Gelman Building, 2120 L Street, NW., Washington, DC, and at the North Central Michigan College, 1515 Howard Street, Petosky, Michigan 49770. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Reactor Projects—III, IV, V and Special Projects.

Dated at Rockville, Maryland, this 4th day of November 1988.

For the Nuclear Regulatory Commission.

Wayne E. Scott, Jr.,

Project Manager, Project Directorate III-1, Division of Reactor Projects—III, IV, V & Special Projects.

[FR Doc. 88-26442 Filed 11-15-88; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-302, License No. DPR-72, EA 88-34]

Florida Power Corp., Crystal River Unit 3, Crystal River, FL; Order Imposing Civil Monetary Penalty

I

Florida Power Corporation, Crystal River, Florida (licensee) is the holder of Operating License No. DPR-72 (license) issued by the Nuclear Regulatory Commission (Commission or NRC) on January 28, 1977. The license authorizes the licensee to operate the Crystal River facility in accordance with the conditions specified therein.

II

An NRC inspection of the licensee's activities under the license was conducted on November 30-December 4, 1987. The results of this inspection indicated that the licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the licensee by letter dated May 4, 1988. The Notice stated that nature of the violation, the provision of the NRC's requirements that the licensee had violated, and the amount of the civil penalty proposed for the violation. The licensee responded to the Notice of Violation and Proposed Imposition of Civil Penalty by letter dated June 2, 1988. In its response, the licensee admits the violation and does not take issue with the Severity Level, but requests mitigation of the civil penalty on the basis that the mitigation factors in 10 CFR Part 2, Appendix C, Section V.B. were not appropriately applied in assessing the penalty.

III

After consideration of the licensee's response and the statements of fact, explanations, and argument for mitigation contained therein, the Deputy Executive Director for Regional Operations has determined, as set forth in the Appendix to this Order, that the original penalty proposed for the violation designated in the Notice of Violation and Proposed Imposition of Civil Penalty should be mitigated by 50 percent.

IV

In view of the foregoing and pursuant to section 234 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2282, Pub. L. 96-295) and 10 CFR 2.205, it is hereby ordered that:

The licensee pay a civil penalty in the amount of Twenty-Five Thousand Dollars ($25,000) within 30 days of the date of this Order, by check, draft, or money order, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555.

V.

The licensee may request a hearing within 30 days of the date of this Order. A request for a hearing shall be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to the Assistant General Counsel for Enforcement, the Regional Administrator, Region II, and to the NRC Resident Inspector, Crystal River, Unit 3.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the licensee fails to request a hearing within 30 days of the date of this Order, the provisions to this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the licensee requests a hearing as provided above, the issue to be considered at such hearing shall be:

Whether on the basis of the violations set forth in the Notice of Violation and Proposed Imposition of Civil Penalty referenced in Section II above, which the licensee has admitted, this Order should be sustained.

For the Nuclear Regulatory Commission.

James M. Taylor,

Deputy Executive Director for Operations.

Dated at Rockville, Maryland, this 31st day of October 1988.

Appendix—Evaluation and conclusion

On May 4, 1988 a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection. Florida Power Corporation responded to the Notice on June 2, 1988. The licensee admits the violation, but requests mitigation of the civil penalty.

Restatement of Violation

10 CFR Part 50, Appendix B, Cirterion XVI, requires measures be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective materials and equipment, and non-conformances are promptly identified and corrected.

Contrary to the above, from May 1980 until October 1987, the licensee failed to assure that a condition adverse to quality, namely, a potentially overloaded emergency diesel generator (EDG), was promptly identified and corrected. Specifically: (a) The load on EDG/A, for certain design basis events, would have been approximately 3545 kw which is above the manufacturer's published 30-minute rating of 3300 kw; (b) on several occasions, the licensee performed the 18-month surveillance testing of both A and B diesel generators with loads above the 3000 kw rating, and the licensee failed to identify and perform, after each such run, the manufacturer's recommended inspection of certain critical components; and (c) the licensee had not identified that surveillance testing was performed at a maximum of 3100 kw even though the worst case design basis accident load given in the Final Safety Analysis Report is 3180 kw.

Summary of Licensee's Response

Florida Power Corporation (FPC) admits that the violation occurred and does not take issue with its Severity Level. However, FPC requests mitigation of the civil penalty on the basis that the mitigation factors in 10 CFR Part 2, Appendix C, Section V.B., were not appropriately applied in assessing the penalty. Its arguments in support of mitigation are that its corrective actions were timely and aggressive, that it identified the violation, and that proper credit was not given for its Configuration Management Program.

NRC Evaluation

Under the NRC's Enforcement Policy, in effect at the time of the violation was identified, reductions of up to 50% of the base civil penalty may be given when a licensee identifies the violation and promptly reports it to the NRC. In weighing this factor, consideration will be given to, among other things, the length of time the violation existed prior to discovery, the opportunity available to discover the violation, the ease of discovery and the promptness and completeness of any required report. In addition, the staff gives credit for effective comprehensive licensee programs for detection of problems that may constitute, or lead to violation of regulatory requirements.

With respect to the problem as described in the NOV, the staff credits the licensee with identifying the problem. The staff recognizes that the problem existed for approximately seven years as a result of a fundamental error that was incorporated at the time of a design modification (January 1980), but notes that there was not a reasonable opportunity to discover the problem prior to the time when the licensee began a detailed review of the EDG loading in June 1987. The staff has reconsidered the complexity of the problem as it related to the length of time that it took the licensee to fully realize and understand the extent of the problem, and the promptness and completeness with which the licensee submitted the required reports. While the licensee argues that mitigation for identification is appropriate based on their comprehensive Configuration Management Program (CMP), the NRC notes that in the case of this violation, the problem was not discovered from the CMP, but rather while determining the setting for an emergency diesel generator directional power relay which was being added to correct problems disclosed during an event described in LER 84-003-00. Nevertheless, the staff has concluded to mitigate the original civil penalty by 50% for this factor.

Mitigation of 50% may also be given for corrective actions which are unusually prompt and extensive. On the other hand, the civil penalty may be increased by as much as 50% if initiation of corrective action is not prompt or if the corrective action is only minimally acceptable. In weighing this factor, consideration will be given to, among other things, the timeliness of the corrective action, degree of licensee initiative, and the comprehensiveness of the corrective action—such as whether the action is focused narrowly to the specific violation or broadly to the general area of concern.

Although the special testing which was conducted to empirically confirm the loading calculations was an important part of the licensee's corrective action, the performance of these tests was only done at the insistence of the NRC to support the licensee's request for an exemption from the requirements of GDC-17. Furthermore, which the licensee is complying with the terms of the exemption, the licensee has not yet implemented the long-term solution to bring the facility into compliance with GDC-17. As noted in the staff's NOV, the CMP represents a positive commitment to programmatic configuration enhancement; however, weaknesses still exist and need to be remedied in your planned efforts to improve the effectiveness of the CMP for prompt corrective action in the resolution of design problems. Therefore, based on a review of the above considerations for the factor of corrective actions, the base amount was not mitigated or escalated.

NRC Conclusion

For reasons set forth herein, the NRC Staff has concluded that the licensee has provided an adequate basis for mitigation of the civil penalty by 50%. Consequently, the civil penalty in the amount of $25,000 should be imposed.

[FR Doc. 88-26443 Filed 11-15-88; 8:45 am]

BILLING CODE 7590-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-26263; File No. SR-Amex-88-26]

Self-Regulatory Organizations; Proposed Rule Change by American Stock Exchange, Inc. Relating to Amendments to Sections 712 and 713 of the Amex Company Guide To Modify the Circumstances Under Which Shareholder Approval Is Required as a Condition to Exchange Approval and Listing of Additional Stock Issuances

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on October 24, 1988, 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 Amex. 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 American Stock Exchange, Inc. is proposing to amend Sections 712 and 713 of the Amex Company Guide to modify the circumstances under which shareholder approval is required as a condition to Exchange approval and listing of additional stock issuances.

The text of the proposed rule change is available at the Office of the Secretary, 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 Amex included statements concerning the purpose of and basis for the proposed rule change and discussed 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 Amex 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

Under current Amex rules, shareholder approval is required pursuant to Section 712 of the Amex Company Guide as a condition to listing additonal shares of common stock (or securities convertible into common stock) where such shares are to be used:

(*1*) as the sole or partial consideration in acquiring the stock or assets of another company, if:

(a) the number of shares to be issued could increase the company's outstanding stock by 20% or more, or

(b) any single officer, director or substantial stockholder of the listed company has a 5% or greater interest (or such persons collectively have a 10% or greater interest) in the company or assets to be acquired or in the consideration to be paid in the transaction and the issuance could result in an increase in outstanding common shares of 50% or more; or

(*2*) pursuant to Section 713 of the Amex Company Guide for any other purpose, if:

(a) the sale or issuance by the company of common stock is to be effected at a price less than the greater of book or market value, and such sale, together with the sale of securities by officers, directors, or principal stockholders, equals 20% or more of the presently outstanding common stock, or

(b) if 20% or more of the company's outstanding common stock is to be sold for less than the greater of book or market value.

Representatives of the business and legal communities have from time to time commented that these requirements, and similar New York Stock Exchange requirements, are unnecessarily arbitrary and restrictive.[1]

The Exchange is now proposing to change its requirements. While the revision will result in fewer transactions being submitted for shareholder approval, other rules and policies, some of which were not fully developed when these requirements were first adopted, provide significant protection for investors. In this regard, it is noted that today's investors benefit from significantly enhanced corporate disclosure which is more comprehensive and timely than in the past. This is reflected in mandatory Commission filings, issuer press releases (which the Amex requires for every material event) and the rapid and independent dissemination of information by the various news services. Further, the great majority of Amex companies now have audit or comparable committees of disinterested directors which, under Amex rules, are required to approve transactions raising potential conflicts of interest.[2]

For these reasons, the Exchange believes that it would be appropriate to limit the extent to which its requirements intrude on corporate decision-making, and, therefore, proposes an increase of the present 20% threshold to 25%.

Similarly, it would also be appropriate to increase the triggering threshold for shareholder approval of acquisitions in which officers and directors have a financial interest from 5% individually (10% collectively) to 10% individually (20% collectively).

A new subsection is proposed to acknowledge the long-standing policy of the Exchange not to require strict application of the requirements to a transaction undertaken by a financially distressed company, where time is of the essence. Where a company ask for an exception based upon financial need, it would be required to (a) publicly acknowledge its financial difficulty at least ten days prior to the closing of the proposed transaction; and (b) obtain approval of the transaction either by its audit committee or by a similar committee of disinterested directors.

Finally, in the interest of simplicity and greater readability, we are proposing to combine Sections 712 and 713 into a single section.

(2) Basis

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 promotes just and equitable principles of trade, facilities transactions in securities and perfects the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change will impose no 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 Annex consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the

[1] *See e.g.*, SEC File No. SR-NYSE-88-19 where the New York Stock Exchange cited such criticism in connection with an analogous proposal to revise its threshold for requiring sharehold approval from 18½% to 25%.

[2] *See* Section 12 of the Amex Company Guide, and Form SD-1 Listing Agreement.

Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the Amex. All submissions should refer to the file number in the caption above and should be submitted by December 7, 1988.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

November 8, 1988.

[FR Doc. 88-26417 Filed 11-15-88; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-26266; File No. SR-PSE-88-23]

Self-Regulatory Organizations; Proposed Rule Change by The Pacific Stock Exchange Inc. Relating to a Policy for Allocating Booth Space on the PSE Options Trading Floor

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on October 11, 1988, the Pacific Stock Exchange Incorporated ("PSE" or the "Exchange") filed with the Securities and Exchange 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 Pacific Stock Exchange Incorporated ("PSE" or the "Exchange"), pursuant to Rule 19b-4 of the Securities and Exchange Act of 1934 ("the Act"), is submitting this rule filing for the purpose of adopting the following policy for the allocation of booth space on the options trading floor.

Options Floor Booth Allocation Policy Formula

The Booth Allocation Formula is comprised of three components: (1) Monthly trades; (2) monthly contracts; and (3) number of employees. The three components are averaged to obtain a percentage for each member firm (*e.g.*, If a particular firm executed 17.53% of the Exchange's monthly contracts, 16.16% of the trades and employed 9.45% of the floor personnel, the average would be 14.38% of all three components (17.53 + 16.16 + 9.45 / 3 = 14.38%)).

The booth figures for both clearing firms and retail/stock execution firms are compiled on a monthly as well as quarterly basis. A rolling six-month evaluation is used for purposes of determining the allocation of booth space. The quarterly figures constitute the primary data used for the evaluation of a booth space, which is done using the Booth Utilization Guidelines. Booth space for clearing firms and retail/stock execution firms is then allocated as follows:

Clearing Firms—The clearing firms' percentages are separated and adjusted to reflect the average number of booths allocated to the clearing firms. For example, a clearing firm entitled to an allocation of 30% of 200 booths available on the options floor (60 booths) would only be allocated 63.3% of the 60 booths (38 booths, or 19% of the 200 booths), based on the current booth space it is allocated. A particular clearing firm that has an overall average of 5% of the Booth Allocation Formula's three components is therefore entitled to 63.3% of the 5% or 6 booths. Assuming there is a 15% residual of the total 200 booths from the clearing firms, this 15% residual (30 booths) would be divided among the retail/stock execution firms according to the percentage within the group.

Retail/Stock Execution Firms—The same Booth Allocation Formula used for clearing firms is applied to retail/stock execution firms. In addition, the residual of the clearing firms' percentages is allocated among the retail/stock execution firms. For example, the clearing firm residual of 15% (30 booths) would be divided among the retail/stock execution firms based upon the percentages within the group. If a given retail/stock firm's three components have an average of 11%, the allocation is 11% of the residual 15% or 1.65%. The additional percentage would then provide the retail/stock firm with a 12.65% allocation. The retail/stock firm would be entitled to hold, based upon the formula, 25 booths (200 × 12.65%).

Booth Utilization Guidelines

The evaluation of booth utilization involves several factors applied only to the member firm leasing the booth space. First, effective use of the booth requires that it be occupied at least 50% of the trading day by the staff of the member firm that is leasing the booth.

Second, a booth must have at a minimum an operational phone. Further consideration is given to support equipment located in the booth space, such as Quotron, Bridge, inhouse systems and order support facilities. Each booth should have a minimum of between three to five working voice lines, not including any second party lines, as allowed under Subordinate Issues/Subleasing.

The evaluation of booth space utilization does not include a firm's use of the space for trade matching or any other type of trading support operation that may effectively be carried out elsewhere.

The aforementioned criteria are listed below in order of priority. They are:

1. Effective utilization of booth by personnel (50% occupancy).
2. Operational phone.
3. Member firm supported equipment (i.e., order machines).
4. Interrogation devices.
5. Three to five operating voice lines.

Booths which are not sufficiently utilized using the objective criteria listed above are subject to forfeiture and reassignment, notwithstanding any entitlement pursuant to the Booth Allocation Formula.

Subordinate issues

Subleasing—The subleasing of booth space by one member to another member firm is prohibited. The Exchange has established direct leasing agreements with all firms qualifying for booth space. This prohibits any arrangements with regard to booth rental occupancy, or use other than with a direct written agreement with the Exchange. A member firm may allow another member firm to install either a single phone or drop line in its booth space. Prior to installation of a single phone or drop line, the member firm wishing to install the telephone or drop line must seek written approval from the Exchange. Exchange approve phones or drop lines will not be considered in evaluating booth utilization of the member firm allocated the booth space. Phone or drop lines may not be staffed by the member firm that installed the phone or drop line.

Booth alterations—Booth alterations are made at the expense of the member firm leasing the booth, and the member firm, at its expense, is required to return the booth to its original condition upon vacating the space. Physical alteration of a booth requires the Exchange's prior approval.

Merger—Booth space occupied by a member firm that merges with another member firm will revert back to the Exchange. Any reallocation will be at the discretion of the Exchange. The surviving member firm will be considered for possible reallocation of booth space pursuant to the Booth Allocation Formula. The surviving

member firm will be given a higher degree of consideration for the reallocation of booth space.

Vacated booth space—Booth space that is vacated for any reason will automatically revert back to the Exchange for reallocation. Booth space that is vacated must be returned to its original condition by the vacating member firm before booth space fees are terminated.

Anticipated volume—A member firm may request additional booth space based upon the anticipation of increased volume (e.g., the merger of two firms, increased operational needs). A member firm's request for additional booth space will be evaluated by the Exchange. Any additional booth space that is allocated will be done so on a provisional basis. After a period not to exceed six months, the Exchange will conduct an evaluation of the member firm's booth space to determine if the additional booth space is being utilized pursuant to the booth utilization factors.

Stock firms—Booth space allocated to stock execution firms or to other firms that will be utilizing the booth space for stock execution will be at the discretion of the Exchange. Allocated booth space may not be contiguous.

Exchange allocation of space—The Exchange reserves the right to reallocate to member firms as needed 5% of the total booth space presently allocated to member firms. In reallocating booth space the Exchange will evaluate the utilization of a member firm's booth space.

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. 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

The purpose of the policy is to provide a fair and equitable procedure for allocating approximately 200 booth spaces to member firms on the PSE options trading floor. A majority of these booths are presently leased to member firms.

There have been increasing requests by member firms for additional booth space on the Exchange's options floor. The requests substantially outnumber the booth space that is now available. Many of the presently vacant booths are located in non-prime areas (prime area is defined as a booth either near a trading crowd, near posts that are active, or near a central passageway). There are also a number of booth spaces which are not being effectively utilized by member firms. In some cases, member firms are unwilling to vacate underutilized booth space for reallocation to other member firms that have shown a substantial business need for more booth space. Consequently, staff has found it necessary to formulate a policy that would allocate the booth space on the Exchange's options floor based on a member firm's utilization of such booth space.

The Booth Allocation Formula was devised to allocate booth space to member firms by taking into consideration historical trading data (number of trades and contracts) and the number of employees used to support each operation. The formula also takes into consideration the differing space requirements of the market maker clearing firms and the retail/stock execution firms. The formula is to be used in conjunction with Booth Utilization and Subordinate Issues.

The Booth Utilization Guidelines were devised to define effective use of booth space by specifying requirements such as the support equipment (e.g., Quotron), the number of operational phone lines, and the occupancy levels in each booth.

Additional issues are addressed in the Subordinate Issues section. The practice of one firm subleasing to another is prohibited in this section. Subleasing is considered ineffective utilization of booth space by the primary firm renting the space. However, a firm may place a telephone or drop line in another firm's booth space. The Exchange will control the placement of a member firm's equipment in a booth space it is not leasing, as well as charge an installation fee.

The Booth Alteration section allows the Exchange to control any alterations a lessee member firm may wish to make to its allocated booth space. It also requires that a member firm pay for booth space alterations and restore the booths to their original conditions when vacated.

If any member firms merge, the booth space of the member firm merging into the surviving firm, either operationally or otherwise, will revert back to the Exchange for reallocation as the Exchange deems appropriate.

Member firms may request booth space under the Anticipated Volume section when they are not entitled to it based upon the Booth Allocation Formula or the Booth Utilization Guidelines. The Exchange will determine if the reason for the request is warranted (i.e., new accounts, projected business growth, etc.). Any booth space allocation is subject to review by the Exchange at a later date.

The requirements of firms who primarily provide equity stock execution services to the market makers are lower than the retail or market maker clearing firms and must therefore be controlled so as to avoid the allocation of contiguous booth space whenever possible.

In addition to regular reviews of each member firm's order flow (trades, contracts), the Exchange expressly reserves the right to maintain or recall 5% of the total booth space available in order to satisfy any new or additional requests for booth space on the options floor. However, the Exchange will evaluate any recall of booth space based on the Utilization Guidelines. Any booth space vacated by a member firm will revert back to the Exchange for allocation.

The proposed Booth Allocation Policy is consistent with the requirements of the Securities and Exchange Act of 1934 ("the Act") and the rules and regulations thereunder applicable to the Exchange in that it will provide for an equitable allocation of booth space among its members utilizing the facilities of the PSE.

The PSE believes that this booth space alocation policy is consistent with section 6(b)(5) of the Act, which provides, in pertinent part, that the rules of the Exchange be designed to promote just and equitable principles of trade.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change imposes a burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

Written comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of the publication of this 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, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned, self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by December 7, 1988.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

Dated: November 9, 1988.

[FR Doc. 88-26475 Filed 11-15-88; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF STATE

[CM-8/1239]

Study Group 2 of the U.S. Organization for the International Radio Consultative Committee (CCIR); Meeting

The Department of State announces that Study Group 2 of the U.S. Organization for the International Radio Consultative Committee (CCIR) will meet on November 30, 1988 in Room 521J of the National Aeronautics and Space Administration (NASA), 600 Independence Avenue, SW., Washington, DC. The meeting will begin at 1:00 p.m.

Study Group 2 deals with communications for scientific satellites, space probes, exploration satellites (e.g., meteorological and geodetic) and with interference problems concerning the radio and radar astronomy services. The purpose of the meeting is to discuss preparations for the Final Meeting of Study Group 2 in the Fall of 1989.

Members of the general public may attend the meeting and join in the discussions subject to instructions of the Chairman. Requests for further information should be directed to Mr. Richard Shrum, State Department, Washington, DC 20520; telephone (202) 647-2592.

Date: November 9, 1988.

Richard E. Shrum,

Chairman, U.S. CCIR National Committee.

[FR Doc. 88-26512 Filed 11-15-88; 8:45 am]

BILLING CODE 4710-07-M

[CM-8/1237]

Study Group 7 of the U.S. Organization for the International Radio Consultative Committee (CCIR); Meeting

The Department of State announces that Study Group 7 of the U.S. Organization for the International Radio Consultative Committee (CCIR) will meet on December 2, 1988 at the U.S. Naval Observatory, Room 300, Building 52, 34th and Massachusetts Avenue, NW., Washington, DC. The meeting will begin at 9:30 a.m.

Study Group 7 deals with time-signal services by means of radiocommunications. The purpose of the meeeting is to discuss preparations for the Final Meeting of Study Group 7 in the Fall of 1989.

Members of the general public may attend the meeting and join in the discussions subject to instructions of the Chairman. Requests for further information should be directed to Mr. Roger E. Beehler, National Institute of Standards and Technology, 325 Broadway, Boulder, CO 70303; phone (303) 497-3281.

Dated: November 9, 1988.

Richard E. Shrum,

Chairman, U.S. CCIR National Committee.

[FR Doc. 88-26510 Filed 11-15-88; 8:45 am]

BILLING CODE 4710-07-M

[CM-8/1238]

Study Groups 10 and 11 of the U.S. Organization for the International Radio Consultative Committee (CCIR); Meeting

The Department of State announces that Study Groups 10 and 11 of the U.S. Organization for the International Radio Consultative Committee (CCIR) will meet on December 1, 1988 at the National Association of Broadcasters, 1771 N Street, NW., Washington, DC. The meeting of Study Group 11 will begin at 10:00 a.m.; Joint Groups at 12:00 noon; and 10 at 2:00 p.m.

Study Group 10 deals with sound broadcasting; Study Group 11 with television broadcasting; and the Joint Groups with program recording and the use of satellites for broadcasting. The purpose of the meeting is to discuss preparations for the Final Study Group Meetings in the Fall of 1989.

Members of the general public may attend the meeting and join in the discussions subject to instructions of the Chairman. Requests for further information should be directed to Mr. John W. Reiser, Federal Communications Commission, Washington, DC 20554; telephone (202) 254-3394.

Date: November 9, 1988.

Richard E. Shrum,

Chairman, U.S. CCIR National Committee.

[FR Doc. 88-26511 Filed 11-15-88; 8:45 am]

BILLING CODE 4710-07-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

[CGD 88-096]

Subcommittee on Marine Occupational Safety and Health, Chemical Transportation Advisory Committee; Meeting

AGENCY: Coast Guard, DOT.

ACTION: Notice of meeting.

SUMMARY: Notice is given here of a meeting of the Subcommittee on Marine Occupational Safety and Health of the Chemical Transportation Advisory Committee (CTAC). The meeting will be held on Tuesday, December 13, 1988, in Room 4234, U.S. Department of Transportation, Nassif Building, 400 7th Street, SW., Washington, DC. The meeting is scheduled to begin at 9:00 a.m. and end by 3:30 p.m. The Subcommittee is expected to discuss the application of marine occupational safety and health programs

recommended to the Coast Guard by Southwest Research Institute. In addition to these discussions, a presentation will be given on a national network of medical monitoring and hazard communication training services which are commercially available for the merchant marine industry.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Joseph Ocken, U.S. Coast Guard Headquarters (G-MTH-1), 2100 Second Street, SW., Washington, DC 20593, (202) 267-1577.

Dated: November 7, 1988.

M.J. Schiro,

Captain, U.S. Coast Guard, Acting Chief, Office of Marine Safety, Security and Environmental Protection.

[FR Doc. 88-26477 Filed 11-15-88; 8:45 am]

BILLING CODE 4910-14-M

Maritime Administration

[Docket S-838]

International Shipholding Corp.; Application for Permission To Acquire Waterman Marine Corp. and Waterman Industries Corp.

In connection with its planned acquisition of Waterman Marine Corporation and Waterman Industries Corporation, including certain of its subsidiaries (Waterman), International Shipholding Corporation and its subsidiaries (ISC) by letter dated November 4, 1988, requested all consents, waivers, and permissions required pursuant to sections 608, 804, and 805(a) of the Act. ISC further requested all other administrative approvals or waivers that the Maritime Administration (MARAD) may require pursuant to the Act or any provisions contained in the operating-differential subsidy (ODS) contracts held by Waterman Steamship Corporation, the vessel operating subsidiary of Waterman.

ISC is a publicly-held Delaware Corporation with its headquarters located in New Orleans, Louisiana. Through its subsidiaries, ISC also maintains principal offices in New York and Rotterdam, plus a network of agents in other major cities around the world. ISC states that it is a citizen of the United States as defined by section 905(c) of the Act for Title VI purposes.

ISC was formed in 1978 as a holding company and its only significant assets consist of the capital stock of its corporate subsidiaries. ISC's principal operating subsidiaries are Central Gulf Lines, Inc. (Central Gulf), a Delaware Corporation, and LCI Shipholdings, Inc. (LCI), a Liberian Corporation.

Central Gulf owns and operates eight U.S.-flag ocean-going vessels, including three LASH vessels and a full complement of U.S.-flag LASH barges, two pure car carriers, two breakbulk vessels and one RO/RO vessel. The two car carriers are under contract to carry Toyota Motor Corporation and Honda Motor Corporation vehicles from Japan to the United States. One of the Central Gulf LASH vessels is on charter to Waterman Steamship Corporation for operation on Trade Route (TR) 18/17, pending MARAD approval. Central Gulf's other five U.S.-flag ocean-going vessels are presently on charter to the Military Sealift Command (MSC). Central Gulf also owns three and charters-in 147 river barges, plus 14 U.S.-flag towboats.

LCI owns and operates a fleet of ten Liberian-flag ocean-going vessels, including three LASH vessels and a full complement of LASH barges, two pure car carriers, one breakbulk vessel, three LASH feeder vessels, and one self-propelled LASH feeder vessel. LCI's vessels generally operate around the world under medium to long-term contracts.

ICS, through its subsidiaries New Combo, Inc. and Second Probo, Inc. also owns a 50 percent interest in two foreign corporations that will own and charter-out three specialized product/bulk/ore vessels scheduled for delivery during the next four months. These vessels will be under long-term charter to a European marketing pool that primarily deals in foreign-to-foreign markets. ISC claims it will have no involvement in the operating or marketing of these vessels. ISC also owns a minority (one-third) investment in A/S Havtor (Havtor), a Norwegian company that in turn owns minority interests, through Norwegian limited partnerships, in highly-specialized ships that carry liquid petroleum gas, ethylene, and ammonia, plus several dry bulk ships. All of the Havtor ships are under long-term charter to European marketing pools.

ISC has several subsidiaries that provide chartering, brokerage, fleeting, loading, and husbanding services to their ISC affiliates, and a subsidiary that provides brokerage services to exporters. ISC also owns a minority equity interest in two management firms offering ship services in Norway, the Netherlands, and Singapore. ISC claims that these companies do not materially contribute to ISC's profits or revenues, but they facilitate vessel operations by avoiding reliance on unaffiliated third parties for services.

Through its subsidiary, Waterman Steamship Corporation, Waterman currently operates three U.S.-flag LASH vessels (two of which it charters under capitalized leases) and one C5-S-75a cargo vessel chartered from American President Lines, Ltd. on TR 18/17 between U.S. Atlantic and Gulf ports and ports in the Middle East and South and Southeast Asia. Under long-term agreements with unaffiliated vessel owners, Waterman also operates three U.S.-flag RO/RO vessels that are time chartered to the MSC under the TAKX Program. Waterman's TR 18/17 service is operated pursuant to a Waterman Operating-Differential Subsidy Agreement (ODSA), Contract MA/MSB-115, which expires on June 3, 1991. Waterman also is a party to two other existing ODSAs with MARAD, Contracts MA/MSB-378 and MA/MSB-450 which continue in effect until 1996 and 1998, respectively.

ISC states that following the proposed acquisition, Waterman will be separately operated, with separate accounting, under its own name, as a wholly-owned subsidiary of ISC. The membership of the Board of Directors of Waterman will be revised, but senior Waterman executives will retain their positions pursuant to the terms of 13 employment contracts for periods ranging from three to five years. Absent unforeseen changes in the ODS program or the TAKX programs, ISC has no current plans to alter significantly the operations of Waterman. However, ISC's subsidiaries have extensive experience operating vessels identical or similar to the vessels operated by Waterman, and ISC believes that its acquisition of Waterman will lead to long-term improvement in waterman's financial performance and stability. ISC believes that this, in turn, will serve to strength the overall standing and performance of the U.S. merchant marine.

Any person, firm, or corporation having any interest in the application for sections 608, 804, and 805(a) permission and desiring to submit comments concerning the application must file written comments in triplicate, to the Secretary, Maritime Administration, Room 7300, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590, by the close of business 5:00 p.m. on Wednesday, December 7, 1988. If such comments deal with section 805(a) issues, they should be accompanied by a petition for leave to intervene. The petition should state clearly and concisely the grounds of interest and the alleged facts relied on for relief.

If no petitions for leave to intervene on section 805(a) issues are received within the specified time, or if it is determined that petitions filed do not demonstrate sufficient interest to warrant a hearing, the Maritime Administration will take such action as may be deemed appropriate.

In the event petitions regarding the relevant section 805(a) issues are received from parties with standing to be heard, a hearing will be held, the purpose of which will be to receive evidence under section 805(a) relative to whether the proposed operations: (a) Could result in unfair competition to any person, firm, or corporation operating exclusively in the coastwise or international service, or (b) would be prejudicial to the objects and policy of the Act relative to domestic trade operations.

(Catalog of Federal Domestic Assistance Program Nos. 20.804 Operating-Differential Subsidies (ODS) and 20.800 Construction-Differential Subsidies (CDS))

By order of the Martime Administrator.

Dated: November 14, 1988.

Joel C. Richard,

Assistant Secretary.

[FR Doc. 88-26619 Filed 11-15-88; 8:45 am]

BILLING CODE 4910-81-M

[Docket No. M-009]

Identification of American Market Capacity for Marine Hull Insurance

On June 20, 1988, MARAD published in the **Federal Register** a final rule to govern the placement of marine hull insurance on subsidized and Title XI program vessels (53 FR 23112). This rule became effective July 20, 1988. Section 249.9 of the rule requires that the American insurance market be given an opportunity to compete for the placement of marine hull insurance on each vessel. This section requires that owners or insurance brokers certify to the Maritime Administration (MARAD) in certain situations that American markets have been offered the business. When more than 50 percent of the placement is foreign, the broker must now certify that at least 50 percent of the American market (measured in terms of capacity) was offered the risk. If more than 75 percent is placed foreign, the broker must certify that 75 percent of the American market was offered the risk.

This procedure requires MARAD to identify all qualified American underwriters and their respective capacities, and to make such information available to vessels owners and brokers. On August 2, 1988, a notice was published in the **Federal Register** for the purpose of soliciting this information from American underwriters. Shown below is a list of American market underwriters which MARAD has compiled from the responses received. The list indicates the separate capacities for Blue Water. Non Blue Water and Drill Rig marine hull insurance.

Date: November 9, 1988.

Joel C. Richard,

Assistant Secretary, Maritime Administration.

U.S. MARKET CAPACITY

	Blue water	Non blue water	Drill rigs
AIG Oil Rig Division			$50,000,000
American Home Assurance Company			
New Hampshire Insurance Company			
National Union Fire Insurance Company			
All American Marine Slip	$5,000,000	$5,000,000	27,500,000
Continental Insurance Company			
The fidelity Casualty Company of New York			
The Firemen's Insurance Company of Newark, N.J.			
Allianz Insurance Company		500,000	
American Hull Insurance Syndicate	30,000,000		
American International Marine Agency	5,000,000	5,000,000	
American Home Assurance Company			
New Hampshire Insurance Company			
National Union Fire Insurance Company			
Atlantic Mutual Companies		2,000,000	
Atlantic Mutual Insurance Company			
Centennial Insurance Company			
American Offshore Insurance Syndicate			25,000,000
Commercial Union Insurance Companies		2,000,000	
Donald H. Miller, Inc	10,000,000	10,000,000	
Peerless Insurance Company			
Excelsior Insurance Company			
The Netherlands Insurance Company			
Fireman's Fund Insurance Companies		5,000,000	
Firemans Fund Insurance Company			7,500,000
National Surety Corporation			
American Insurance Company thru Frank B. Wetzel & Company			10,000,000
Highlands Insurance Company	4,000,000	4,000,000	
The Home Insurance Company	7,000,000	7,000,000	
Houston Casualty Company	2,000,000	2,000,000	2,000,000
Insurance Company of North America	15,000,000	5,000,000	10,000,000
International Marine Underwriters	1,000,000	2,000,000	
United States Fire Insurance Company			
Marine Office of America Corp	1,250,000	5,000,000	
Mutual Marine office, Inc	8,000,000	2,000,000	14,000,000
Arkwright Mutual			
Utica Mutual			
New York Marine and General			
Navigators Management Corp	5,000,000		
Navigators Insurance Company			
Colonia Insurance Company—U.S. Branch			
New York Marine Managers Inc	6,000,000	2,000,000	15,000,000

U.S. MARKET CAPACITY—Continued

	Blue water	Non blue water	Drill rigs
Progressive Casualty Insurance Company			
Reinsurance Corporation of New York			
Christiania General Insurance Corp.			
Pennsylvania Lumbermans Mutual Ins. Co.			
Colonia Insurance Company—U.S. Branch			
United Reinsurance Corporation of N.Y.			
United Fire and Casualty Company			
Reliance Insurance Company		4,000,000	
Royal Insurance Company		25,000,000	
St. Paul Fire and Marine Insurance Company	2,500,000	2,000,000	
Talbot, Bird & Co., Inc		2,000,000	
Albany Insurance Company			
Texas Marine Underwriters Agency, Inc. (SEE New York Marine Managers Inc.)			
Wausau Insurance Companies	2,000,000	5,000,000	
Wm. H. McGee & Co., Inc		1,000,000	
Wm. H. McGee & Co., Inc		1,000,000	
Sun Insurance Company of New York			
	103,750,000	97,000,000	161,000,000

[FR Doc. 88-26418 Filed 11-15-88; 8:45 am]

BILLING CODE 4910-81-M

National Highway Traffic Safety Administration

Highway Safety Program; Amendment of Conforming Products List of Evidential Breath Testing Devices

AGENCY: National Highway Safety Administration (NHTSA), DOT.

ACTION: Notice.

SUMMARY: This notice amends the Conforming Products List of instruments which have been found to conform to the Model Specifications for Evidential Breath Testing Devices (49 FR 48854).

EFFECTIVE DATE: November 16, 1988.

FOR FURTHER INFORMATION CONTACT: Mrs. Robin Mayer, Office of Alcohol and State Programs, NTS-21, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590; Telephone: (202) 366-9825.

SUPPLEMENTARY INFORMATION: On November 5, 1973, the National Highway Traffic Safety Administration (NHTSA) published the Standards for Devices to Measure Breath Alcohol (38 FR 30459). A Qualified Products List of Evidential Breath Measurement Devices comprised of instruments that met this standard was first issued on November 21, 1974 (39 FR 41399).

On December 14, 1984 (49 FR 48854), NHTSA converted this standard to Model Specifications for Evidential Breath Testing Devices, and published in Appendix D to that notice (49 FR 48864), a conformig products list (CPL) of instruments that were found to conform to the Model Specifications. Amendments to the CPL have been published in the **Federal Register** since that time.

Since the last publication of the CPL, a number of devices have been tested in accordance with the Model Specifications. These tests indicate that four (4) evidential breath testing instruments, not previously on the CPL, conform to the Model Specifications. These instruments include: CMI, Inc.'s Intoxilyzer PAC 1200, Intoxilyzer 5000 (CAL DOJ), and Intoxilyzer 5000 (VA); and Intoximeters, Inc.'s Intoximeter 3000 (rev B1).

Further, since the manufacturer of the BAC Datamaster has changed from Verax Systems, Inc., to National Patent Analytical Systems, Inc., the agency has retested the instrument. This device remains in conformance with the Model Specifications, and the CPL has been revised to include both the previous and current manufacturer. In addition, several typographical errors found in prior Conforming Products Lists have been corrected.

The Conforming Products list is therefore amended as follows:

CONFORMING PRODUCTS LIST OF EVIDENTIAL BREATH MEASUREMENT DEVICES

Manufacturer and model	Mobile	Non-mobile
Alcohol Countermeasures System, Inc. Port Huron, MI:		
Alert J3AD	X	X
BAC Systems, Inc., Ontario, Canada:		
Breath Analysis Computer		X
CAMEC Ltd., North Shields, Tyne and Ware, England:		
IR Breath Analyzer	X	X
CMI, Inc., Mintum, CO:		
Intoxilyzer Model:		
4011	X	X
4011A	X	X
4011AS	X	X
4011AS-A	X	X
4011AS-AQ	X	X
4011 AW	X	X
4011A27-10100	X	X
4011A27-10100 with filter	X	X
5000	X	X
5000 (w/Cal. Vapor Re-Circ)	X	X
5000 (w/3/8" ID Hose option).	X	X
5000 (CAL DOJ)	X	X
5000 (VA)	X	X
PAC 1200	X	X
Decator Electronics, Decator, IL:		
Alco-Tector mode 500		X
Intoximeters, Inc., St. Louis, MO:		
Photo Electric Intoximeter		X
GC Intoximeter MK II	X	X
GC Intoximeter MK IV	X	X
Auto Intoximeter	X	X
Intoximeter Model:		
3000	X	X
3000 (rev B1)	X	X
3000 (rev B2)	X	X
3000 (rev B2A)	X	X
Alco-Sensor III	X	X
Alco-Sensor IIIA	X	X
RBT III	X	X
Komyo Kitagawa, Kogyo, K.K.:		
Alcolyzer DPA-2	X	X
Breath Alcohol Meter PAM 101B.	X	X
Lion Laboratories, Ltd., Cardiff, Wales, UK:		
Alcolmeter Model:		
AE-D1	X	X
SD-2	X	X
EBA	X	X
Auto-Alcolmeter		X
Luckey Laboratories, San Bernadino, CA:		
Alco-Analyzer Model:		
1000		X
2000		X
National Draeger, Inc., Pittsburg, PA		
Alcotest Model:		
7010	X	X
7110	X	X

CONFORMING PRODUCTS LIST OF EVIDENTIAL BREATH MEASUREMENT DEVICES—Continued

Manufacturer and model	Mobile	Non-mobile
Breathalyzer Model:		
900	X	X
900A	X	X
900BG	X	X
National Patent Analytical Systems, Inc., East Hartford, CT:		
BAC Datamaster	X	X
Omicron Systems, Palo Alto, CA:		
Intoxilyzer Model:		
4011	X	X
4011AW	X	X
Siemans-Allis, Cherry Hill, NJ:		
Alcomat	X	X
Alcomat F	X	X
Smith and Wesson Electronics, Springfield, MA:		
Breathalyzer Model:		
900	X	X
900A	X	X
1000	X	X
2000	X	X
2000 (no-Humidity Sensor)	X	X
Stephenson Corp.:		
Breathalyzer 900	X	X
Verax Systems, Inc., Fairport, NY:		
The BAC Verifier	X	X
BAC Verifier Datamaster	X	X
BAC Verifier Datamaster II	X	X

(23 U.S.C. 402; delegations of authority at 49 CFR 1.50 and 501.)

George Reagle,

Associate Administrator for Traffic Safety Programs.

[FR Doc. 88-26400 Filed 11-10-88; 11:49 am]

BILLING CODE 4910-59-M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

Date: November 9, 1988.

The Department of the Treasury has made revisions and resubmitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Pub. L. 96-511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2224, 15th and Pennsylvania Avenue NW., Washington, DC 20220.

Internal Revenue Service

OMB Number: 1545-0134
Form Number: 1128
Type of Review: Resubmission
Title: Application for Change in Accounting Period
Description: Form is needed in order to process taxpayers' requests to change their accounting period. All information requested is used to determine whether the application should be approved. Respondents are taxable and nontaxable entities including individuals, partnerships, corporations, estates, tax-exempt organizations and cooperatives.
Respondents: Individuals or households Farms, Businesses or other for-profit, Non-profit institutions, Small businesses or organizations
Estimated Number of Respondents: 20,000
Estimated Burden Hours Per Response:
Recordkeeping, 16 hours 1 minute
Learning about the law or the form, 6 hours 56 minutes
Preparing the form, 8 hours 5 minutes
Copying, assembling, and sending the form to IRS, 16 minutes
Frequency of Response: On occasion
Estimated Total Reporting Burden: 632,800 hours

OMB Number: 1545-1004
Form Number: 1120-REIT
Type of Review: Resubmission
Title: U.S. Income Tax Return for Real Estate Investment Trusts
Description: Form 1120-REIT is filed by a corporation, trust, or association electing to be taxed as a REIT in order to report its income and deductions and to compute its tax liability. IRS uses Form 1120-REIT to determine whether the REIT has correctly reported its income, deductions, and tax liability.
Respondents: Businesses or other for-profit
Estimated Number of Respondents: 250
Estimated Burden Hours Per Response:
Recordkeeping, 53 hours 49 minutes
Learning about the law or the form, 22 hours 38 minutes
Preparing the form, 63 hours 35 minutes
Copying, assembling, and sending the form to IRS, 11 hours 6 minutes
Frequency of Response: Annually
Estimated Total Reprting Burden: 37,820 hours

Clearance Officer: Garrick Shear, (202) 535-4297, Internal Revenue Service, Room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.
OMB Reviewer: Milo Sunderhauf, (202) 395-6880, Officer of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 88-26412 Filed 11-15-88; 8:45 am]

BILLING CODE 4810-25-M

Fiscal Service

1989 Fee Schedule for the Transfer of U.S. Treasury Book-Entry Securities Held at Federal Reserve Banks

AGENCY: Department of the Treasury, Fiscal Service, Bureau of the Public Debt.

ACTION: Notice.

SUMMARY: The Department of the Treasury has revised the schedule of fees that will be used in 1989 for assessing charges on the transfer of book-entry Treasury securities between accounts of depository institutions maintained at Federal Reserve Banks and Branches. The revised fee schedule is based on an anticipated increase in the cost of providing the Treasury book-entry securities transfer service.

EFFECTIVE DATE: January 3, 1989.

FOR FURTHER INFORMATION CONTACT: Carl M. Locken, Jr., Assistant Commissioner (Financing), Bureau of the Public Debt, Room 534, E Street Building, Washington, DC 20239-0001, (202) 376-4350.

Kerry Lanham, Government Securities Specialist, Bureau of the Public Debt, Room 534, E Street Building, Washington, DC 20239-0001, (202) 376-4350.

William A. Saunders, Government Securities Specialist, Bureau of the Public Debt, Room 534, E Street Building, Washington, DC 20239-0001, (202) 376-4350.

SUPPLEMENTARY INFORMATION: On October 1, 1985, the Department of the Treasury established a fee schedule for the transfer of Treasury book-entry securities between accounts of depository institutions maintained at Federal Reserve Banks and Branches. The fees, which have remained unchanged since 1985, apply to on-line Treasury transfers originated, off-line Treasury transfers originated, and off-line Treasury transfers received. Treasury transfer reversals are not currently assessed fees.

Based on a recent review of book-entry costs and volumes, the Treasury determined that the cost of providing the Treasury book-entry transfer service in 1989 will increase, even though the volume of Treasury book-entry transfers processed between accounts is expected to remain virtually unchanged. To the extent possible, Treasury attempts to establish fees that will recover the cost of processing book-entry transfers.

Consequently, effective January 3, 1989, the Treasury will: (1) Increase the fee for on-line Treasury transfers originated from $1.50 to $1.65 per

transfer; (2) increase the fee for off-line Treasury transfers originated and off-line Treasury transfers received from $6.25 to $6.40 per transfer; and (3) charge a fee to receivers of on-line and off-line Treasury transfer reversals ($1.65 per on-line Treasury transfer reversal received and $6.40 per off-line Treasury transfer reversal received).

No fees are currently proposed for: (1) On- and off-line reversals originated or (2) transfers to and from collateral accounts supporting borrowings from the Federal Reserve or Treasury deposits (i.e., transfers to and from Discount, Treasury Tax & Loan, and Circular 176 accounts).

The determination to charge fees for Treasury transfer reversals received is based on the premise that the purpose of transfer reversals is to enable the receiver (the original sender) to correct original transfers that were sent in error, and that the original sender should absorb the cost of processing the transfer reversal. Because the processing and associated costs of transfer reversals are identical to those of regular securities transfers, the Treasury intends to charge the same fee for transfer reversals received that it currently charges for regular securities transfers.

The cumulative effect of these developments is expected to be a net increase in total Treasury transfer fees for 1989 commensurate with the anticipated increase in the cost of providing the Treasury transfer service. The Treasury expects that the new fees will result in the full recovery of the costs associated therewith.

The fees described in this notice apply only to the transfer of Treasury book-entry securities. The Federal Reserve System assesses fees to recover the costs associated with the processing of the funds component of Treasury book-entry transfer messages, and the costs associated with providing book-entry services for Government agencies. The Federal Reserve fees for these services are set out in a separate notice published November 4, 1988, by the Board of Governors of the Federal Reserve System.

While Treasury book-entry tranfer fees will increase, Federal Reserve fees for the funds component of Treasury book-entry tranfers will decrease, leaving the combined fees for Treasury book-entry tranfers unchanged for 1989.

The following is the Treasury fee schedule that will be effective January 3, 1989, for the Treasury book-entry transfer service:

1989 Fee Schedule

On-line transfers originated: $1.65 per tranfer

Off-line transfers originated: $6.40 per tranfer

Off-line transfers received: $6.40 per tranfer

On-line reversal transfers received: $1.65 per tranfer

Off-line reversal transfers received $6.40 per tranfer

Gerald Murphy,

Fiscal Assistant Secretary.

Date: November 9, 1988.

[FR Doc. 88-26508 Filed 11-15-88; 8:45 am]

BILLING CODE 4810-40-M

Sunshine Act Meetings

Federal Register
Vol. 53, No. 221
Wednesday, November 16, 1988

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL COMMUNICATIONS COMMISSION:

November 10, 1988.

FCC to Hold Open Commission Meeting, Thursday, November 17, 1988

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, November 17, 1988, which is scheduled to commence at 9:30 a.m., in Room 856, at 1919 M Street, NW., Washington, DC.

Agenda, Item No., and Subject

Private Radio—1—Title: Report on the Status of Frequency Coordination in the Private Land Mobile Radio Services. Summary: The Report examines the current status of the frequency coordination process.

Common Carrier—1—Title: Contel ASC Request for Reassignment of its ASC-2 Satellite. Summary: The Commission will consider Contel ASC's application for reassignment of its ASC-2 Satellite from its current location at 83° W.L. to 99° W.L.

Agenda Item No. Subject

Common Carrier—2—Title: Authorization of New Domestic Fixed-Satellites and Assignment of Orbit Locations. Summary: The Commission will consider applications for authority to construct and launch new space stations in the Domestic Fixed-Statllite Service. It also will consider an orbit assignment plan for new and previously authorized space stations.

Common Carrier—3—Title: In the Matter of Filing and Review of Open Network Architecture (ONA) Plans, CC Docket No. 88-2, Phase I. Summary: The Commission will consider whether to approve the Open Network Architecture (ONA) plans filed by the Bell Operating Companies.

Common Carrier—4—Title: In the Matter of Filing and review of Open Network Architecture (ONA) Plans, CC Dock No. 88-2, Phase II. Summary: The Commission will consider whether to approve the Open Network Architecture (ONA) plan filed by AT&T.

This meeting may be continued the following work day to allow the Commission to complete appropriate action.

Additional information concerning this meeting may be obtained from Audrey Spivack, Office of Public Affairs, telephone number (202) 632-5050.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 88-26521 Filed 11-11-88; 11:17 am]

BILLING CODE 6712-01-M

FEDERAL ENERGY REGULATORY COMMISSION

November 9, 1988.

The following notice of meeting is published pursuant to section 3(a) of the Government in the Sunshine Act (Pub. L. No. 94-409), 5 U.S.C. 552B:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

TIME: November 16, 1988, 10:00 a.m.

PLACE: 825 North Capitol Street, NE., Room 9306, Washington, DC 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

* Note.—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Lois D. Cashell, Secretary, Telephone (202) 357-8400.

This is a list of matters to be considered by the Commission. It does not include a listing of all papers relevant to the items on the agenda; however, all public documents may be examined in the Public Reference Room.

Consent Power Agenda, 886th Meeting—November 16, 1988, Regular Meeting (10:00 a.m.)

CAP-1.
Project No. 2520-001, Great Northern Nekoosa Corporation

CAP-2.
Project No. 2680-007, Consumers Power Company and The Detroit Edison Company

CAP-3.
Project No. 6780-004, Enviro Hydro Incorporated

CAP-4.
Project No. 10405-004, Craig W. Scott

CAP-5.
Docket No. UL88-24-001, City of Martinsville, Virginia

CAP-6.
Project No. 2785-005, Wolverine Power Corporation

CAP-7.
Project No. 6456-005, Village of Green Island, New York

CAP-8.
Project No. 8763-003, Power Mining, Inc.

CAP-9.
Docket No. UL87-30-001, Kirkway Electric Corporation

CAP-10.
Project No. 7269-004, James B. Boyd and Janet A. Boyd

CAP-11.
Project No. 7707-001, Souhegan Hydropower Company
Project No. 8714-000, Pennichuck Water Works, Inc.

CAP-12.
Docket No. ER88-619-000, Gulf States Utilities Company

CAP-13.
Docket Nos. ER82-774-006 and 008, Nantahala Power and Light Company and Tapoco, Inc.

CAP-14.
Docket No. ER84-560-004, Union Electric Company

CAP-15.
Docket No. EC87-19-000, Southwestern Public Service Company and Black Mesa Power Company

CAP-16.
Docket No. EL87-55-001, City of Holyoke Gas and Electric Department, City of Westfield Gas and Electric Light Department, Marblehead Municipal Light Department, Middleborough Municipal Gas and Electric Department, North Attleboro Electric Department, Peabody Municipal Light Plant, Shrewsbury Electric Light Department, Templeton Municipal Light Plant, Town of Boylston Municipal Light Department, Town of Hudson Light and Power Department, Town of Littleton Municipal Light and Water Department, Town of Wakefield Municipal Light Department, and West Boylston Municipal Lighting Plant v. Boston Edison Company

CAP-17.
Docket Nos. ER87-72-003 and ER87-73-002, Orange & Rockland Utilities, Inc.

CAP-18.
Docket No. QF88-262-001, Everett Energy Corporation

CAP-19.
Docket Nos. ER81-179-025 and 026, Arizona Public Service Company

CAP-20.
Docket No. ER87-365-000, Sourhtern California Edison Company

CAP-21.
Docket No. ER88-261-000, Centel Electric-Kansas

CAP-22.
Docket No. EL88-14-000, Montaup Electric Company

CAP-23.
Docket No. EL88-1-000, Indiana and Michigan Municipal Distributors Association and City of Auburn, Indiana v. Indiana Michigna Power Company

Docket Nos. ER88-30-000, ER88-33-000 and ER88-34-000, Indiana Michigan Power Company

CAP-24.
Omitted

CAP-25.
Docket No. QF88-378-000, Empire Energy-Niagara Cogeneration, Inc.

Consent Miscellaneous Agenda

CAM-1.
Docket Nos. RM88-21-000 and RM86-5-002, Amendment to Regulations Governing Exemption of Small Hydroelectric Power Projects of 5 Megawatts or Less
CAM-2.
Docket No. RM88-27-001, Procedure for Filing Petitions for Review with the Federal Energy Regulatory Commission
CAM-3.
Docket No. GP88-13-000, Oklahoma Corporation Commission
CAM-4.
Docket No. GP87-77-000, Lowry Exploration, Inc.
CAM-5.
Docket No. GP84-23-029 (Phase 2), Stowers Oil & Gas Company, Panhandle Energy Corp., Prairie Oil Co., Sharon Oil Co., Almac Oil Co., Judy Oil Co., Kim Petroleum Co. Inc., Komanche Oil & Gas Co., Omega Energy, Tumbleweed Production, Panstar Oil & Gas, Inc., Dennis Mills Enterprises, Wy-Vel Corp., Walker Operating Corp. and 3W Oil, Inc.
CAM-6.
Docket No. GP86-51-001, Northern Natural Gas Company, Diviison of Enron Corp. v. Cabot Pipeline Corporation and Texaco Producing Inc.
CAM-7.
Docket No. GP84-56-008, Northwest Central Pipeline Corporation
Docket No. RP83-42-007, Midwest Gas Users Association v. Northwest Central Pipeline Corporation

Consent Gas Agenda

CAG-1.
Omitted
CAG-2.
Docket Nos. RP88-187-007, 001, 003, 004 and 005, Columbia Gas Transmission Corporation
CAG-3.
Docket No. RP88-223-001, Texas Eastern Transmission Corporation
CAG-4.
Docket Nos. RP89-4-000 and 001, Tennessee Gas Pipeline Company
CAG-5.
Docket No. RP88-81-003, Texas Eastern Transmission Corporation
CAG-6.
Docket Nos. RP88-197-003, RP88-236-000, TA88-1-49-002, TA88-3-49-002 and RP88-197-000, Williston Basin Interstate Pipeline Company
CAG-7.
Docket Nos. RP88-93-005 and RP88-40-005, Questar Pipeline Company
CAG-8.
Docket No. RP88-39-000, Williams Natural Gas Company
CAG-9.
Docket Nos. RP88-163-000, 001 and TA88-3-8-000, South Georgia Natural Gas Company
CAG-10.
Docket No. RP89-2-000, Natural Gas Pipeline Company of America
CAG-11.
Docket No. RP89-5-000, Northwest Pipeline Corporation
CAG-12.
Docket Nos. TA88-2-15-002 and TM89-1-15-001, Mid Louisiana Gas Company
CAG-13.
Docket Nos. RP88-138-001, 002, 003, TQ88-1-6-001, 002, 003, RP88-181-003, RP86-94-009 and TM89-1-6-000, Sea Robin Pipeline Company
CAG-14.
Docket No. RP88-248-001, Arkla Energy Resources Company
CAG-15.
Docket No. RP88-203-000, Panhandle Eastern Pipe Line Company
CAG-16.
Docket Nos. RP88-118-000, 001, 002 and 003, Mid Louisiana Gas Company
CAG-17.
Docket Nos. RP88-154-003 and RP88-154-004, Northwest Pipeline Corporation
CAG-18.
Docket Nos. RP88-127-001, 002, TQ88-1-63-000, 001, RP88-90-001, TA88-2-63-000, 001 and 002, Carnegie Natural Gas Company
CAG-19.
Docket No. RP87-15-024, Trunkline Gas Company
CAG-20.
Docket No. RP88-229-001, Southern Natural Gas Company
CAG-21.
Docket Nos. CP-81-107-028 and CP83-403-011, CNG Transmission Corporation
CAG-22.
Docket Nos. CP84-7-006 and 007, National Fuel Gas Supply Corporation
CAG-23.
Docket No. RP88-217-005, CNG Transmission Corporation
CAG-24.
Docket Nos. RP88-236-001 and RP88-197-004, Williston Basin Interstate Pipeline Company
CAG-25.
Docket No. RP88-44-011, El Paso Natural Gas Company
CAG-26.
Docket No. RP88-117-003, Northern Natural Gas Company, a Division of Enron Corp.
CAG-27.
Docket Nos. RP88-125-003, TQ88-1-22-003 and TA87-3-22-005, CNG Transmission Corporation
CAG-28.
Docket No. RP88-251-001, Texas Eastern Transmission Corporation
CAG-29.
Docket No. RP88-80-010, Texas Eastern Transmission Corporation
CAG-30.
Docket Nos. TQ88-2-17-001, TQ88-2-17-002, TM88-1-17-001 and RP88-67-010, Texas Eastern Transmission Corporation
CAG-31.
Docket No. TA88-4-29-002, Transcontinental Gas Pipe Line Corporation
CAG-32.
Docket Nos. TA85-1-16-006 and TA85-2-16-004, National Fuel Gas Supply Corporation
CAG-33.
Docket No. TA87-1-35-003, West Texas Gas, Inc.
CAG-34.
Docket No. RP88-201-002, East Tennessee Natural Gas Company
CAG-35.
Docket Nos. RP88-81-008, RP88-67-007 and RP88-175-001, Texas Eastern Transmission Corporation
CAG-36.
Docket No. RP86-142-001, Natural Gas Pipeline Company of America
CAG-37.
Docket No. RP86-42-002, El Paso Natural Gas Company
CAG-38.
Docket No. RP88-92-003, United Gas Pipe Line Company
CAG-39.
Docket No. RP88-92-001, United Gas Pipe Line Company
CAG-40.
Docket No. RP88-106-001, Northern Natural Gas Company, Division of Enron Corporation
CAG-41.
Docket Nos. RP88-210-001, 002, 000 and RP88-96-006, Southern Natural Gas Company
CAG-42.
Docket No. RP88-205-002, Alabama-Tennessee Natural Gas Company
CAG-43.
Docket No. RP88-80-009, Texas Eastern Transmission Corporation
CAG-44.
Docket No. RP85-122-012, Colorado Interstate Gas Company
CAG-45.
Docket Nos. RP87-70-011 and TA87-2-2-004, East Tennessee Natural Gas Company
CAG-46.
Docket Nos. RP85-122-006, 011 and RP87-30-014, Colorado Interstate Gas Company
CAG-47.
Docket No. RP87-34-004, United Gas Pipe Line Company
CAG-48.
Docket No. ST81-90-003, Natural Gas Pipeline Company of America
CAG-49.
Docket No. RP80-97-058, Tennessee Gas Pipeline Company
CAG-50.
Docket Nos. RP86-35-000, 004 and 005, Great Lakes Gas Transmission Company
CAG-51.
Docket No. RP85-194-000, Panhandle Eastern Pipe Line Company
Docket No. RP86-49-000, East Ohio Company v. Panhandle Eastern Pipe Line Company
CAG-52.
Omitted
CAG-53.
Docket Nos. TA83-1-37-003, TA83-2-37-003, TA84-1-37-004, TA84-2-37-010, TA85-1-37-004, TA85-2-37-007 and RP82-56-018, Northwest Pipeline Corporation
CAG-54.

Docket Nos. RP85-122-005 and RP87-30-010, Colorado Interstate Gas Company
CAG-55.
Docket No. RP87-87-000, Granite State Gas Transmission, Inc.
CAG-56.
Docket Nos. ST88-3342-000 and ST88-4552-000, Wintershall Pipeline Corporation
CAG-57.
Docket No. ST88-4360-000, Somerset Gas Service
CAG-58.
Docket No. IS85-15-000, Southern Pacific Pipe Lines, Inc.
CAG-59.
Docket No. IS88-24-000, Texas Eastern Products Pipeline Company
CAG-60.
Docket No. CP73-184-003, Colorado Interstate Gas Company, a Division of Colorado Interstate Company
Docket No. CI73-485-002, CIG Exploration, Inc.
CAG-61.
Docket Nos. CP86-578-015 and RP85-13-020, Northwest Pipeline Corporation
CAG-62.
Docket No. G-4579-057, Mobil Exploration and Producing North America Inc.
CAG-63.
Docket Nos. RI88-614-000 and RI88-934-000, DCD, Inc. and Samedan Oil Corporation
CAG-64.
Docket No. CP88-656-002, MexUS Interstate Pipeline Company, Inc.
CAG-65.
Docket No. CP88-519-001, Questar Pipeline Company
CAG-66.
Docket No. CP87-451-011, Northeast U.S. Pipeline Projects
CAG-67.
Docket No. GP88-11-001, Hadson Gas Systems, Inc.
CAG-68.
Docket No. CP88-286-001, Cascade Natural Gas Corporation v. Northwest Pipeline Corporation, Chevron Chemical Company, Intermountain Gas Company, Hadson Gas Systems, Inc., Llano, Inc., Corpus Christi Industrial Pipeline Company and Transco Energy Marketing Company
CAG-69.
Docket No. CP84-183-005, Transcontinental Gas Pipe Line Corporation
CAG-70.
Omitted
CAG-71.
Docket Nos. CP86-286-000 and 002, Williams Natural Gas Company
Docket Nos. CP86-606-000 and 001, Pacific Gas Transmission Company
CAG-72.
Docket Nos. CP86-531-002 and 003, Texas Gas Transmission Corporation
CAG-73.
Docket No. CP86-344-002, CNG Gas Transmission Corporation
CAG-74.
Docket No. CP87-547-001, Arkla Energy Resources, a Division of Arkla, Inc.
CAG-75.
Docket No. CP87-442-002, ANR Pipeline Company
CAG-76.
Docket Nos. CP85-511-002 and 003, Northern Natural Gas Company, Division of Enron Corp.
CAG-77.
Docket No. CP87-176-001, Panhandle Eastern Pipe Line Company
Docket No. CP63-159-001, National Helium Corporation
CAG-78.
Docket No. CP88-106-002, Transcontinental Gas Pipe Line Corporation
CAG-79.
Docket No. CP87-175-001, Texas Eastern Transmission Corporation
CAG-80.
Docket No. CP87-524-001, Texas Gas Transmission Corporation
CAG-81.
Docket No. CP87-174-001, Panhandle Eastern Pipe Line Company and Trunkline Gas Company
Docket No. CP87-455-001, KN Energy, Inc.
CAG-82.
Docket No. CP88-407-001, Illinois Power Company
CAG-83.
Docket No. CP88-415-000, Trunkline Gas Company
CAG-84.
Omitted
CAG-85.
Docket No. CP87-36-000, Colorado Interstate Gas Company
CAG-86.
Docket No. CP87-516-000, Washington Natural Gas Company
Docket No. CP88-200-000, Northwest Pipeline Company
CAG-87.
Omitted
CAG-88.
Omitted
CAG-89.
Docket Nos. CP87-224-000 and 001, Northwest Gas Pipeline Corporation
CAG-90.
Omitted
CAG-91.
Omitted
CAG-92.
Docket Nos. CP88-490-000 and CP88-548-000, Panhandle Eastern Pipe Line Company
CAG-93.
Omitted
CAG-94.
Docket No. CP88-367-000, Southern Natural Gas Company
CAG-95.
Docket No. CP87-451-015, Northeast U.S. Pipeline Projects
CAG-96.
Docket No. CP88-701-000, Amoco Gas Company
CAG-97.
Docket No. CP88-700-000, Windward Energy and Marketing Company and ARCO Oil and Gas Company
CAG-98.
Docket No. CP87-433-000, Oklahoma Natural Gas Company v. Williams Natural Gas Company and Quivira Gas Company
CAG-99.
Docket No. CP88-42-000, Kansas Power and Light Company v. Williams Natural Gas Company
Docket No. CP61-29-001, Williams Natural Gas Company
CAG-100.
Docket No. RP88-191-004, Tennessee Gas Pipeline Company

I. Licensed Project Matters

P-1.
Docket No. HB03-75-1-001, Alabama Power Company. Protest of headwater benefits determination regarding the treatment of costs and energy associated with pumped storage operations at the upstream project.

II. Electric Rate Matters

ER-1.
Reserved

Miscellaneous Agenda

M-1.
Docket No. FA84-15-002, Minnesota Power & Light Company. Order on court remand concerning fuel adjustment clause.
M-2.
Docket No. RM87-24-001, Procedures for the Assessment of Civil Penalties under section 31 of the Federal Power Act. Rehearing.
M-3.
Reserved
M-4.
Reserved
M-5.
Docket No. RM88-14-001, Interpretation of section 5 of the Outer Continental Shelf Lands Act. Rehearing.
Docket No. RM88-15-000, Regulations under section 5 of the Outer Continental Shelf Lands Act (OCSLA) Governing Transportation of Natural Gas by Interstate Natural Gas Pipelines on the Outer Continental Shelf. Final rule.

I. Pipeline Rate Matters

RP-1.
Docket No. RP88-182-000, Gas Research Institute. Opinion concerning 1989 funding unit.
RP-2.
(A) Docket No. RP88-27-003, United Gas Pipe Line Company. Order on rehearing concerning the take-or-pay cost passthrough.
(B) Docket Nos. RP88-68-003 and RP87-7-033, Transcontinental Gas Pipe Line Corporation. Order on rehearing concerning passthrough of Order No. 55 take-or-pay buyout and buydown settlement costs.
RP-3.
Docket Nos. RP81-85-000, RP83-93-003 and FA85-01-000, Trunkline LNG Company and Trunkline Gas Company. Opinion concerning prudence, AFUDC, deferred taxes, and cash working capital.
RP-4.
(A) Docket No. RP88-184-001, El Paso Natural Gas Company. Rehearing order concerning Order No. 500 prudence and El Paso's appeal.
(B) Docket Nos. RP88-198-001, 002 and 003, Transwestern Pipeline Company.

Rehearing order concerning Order No. 500, take-or-pay and direct billing.

II. Producer Matters

CI-1.
Reserved

III. Pipeline Certificate Matters

CP-1.
Reserved

Lois D. Cashell,

Secretary.

[FR Doc. 88-26582 Filed 11-14-88; 1:16 pm]

BILLING CODE 6717-01-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: 9:30 a.m., Monday, November 21, 1988.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED: .

1. Publication for comment of proposed amendment to Regulation Y (Bank Holding Companies and Change in Bank Control) regarding activities of nonbank subsidiaries of state bank subsidiaries of bank holding companies.

2. Any items carried forward from a previously announced meeting.

Note. —This meeting will be recoreded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's Freedom of Information Office, and copies may be ordered for $5 per cassette by calling (202) 452-3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, DC 20551.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204.

Dated: November 14, 1988.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 88-26557 Filed 11-14-88; 11:17 am]

BILLING CODE 6210-01-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: Approximately 11:30 a.m., Monday, November 21, 1988, following a recess at the conclusion of the open meeting.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Date: November 14, 1988.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 88-26558 Filed 11-14-88; 11:17 am]

BILLING CODE 6210-01-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: Notice forwarded to Federal Register on November 9, 1988.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10:00 a.m., Wednesday, November 16, 1988.

CHANGES IN THE MEETING: Change in the time of the open meeting to 9:30 a.m., Wednesday, November 16, 1988.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 4552-3204.

Date: November 10, 1988.

William W. Wiles,

Secretary of the Board.

[FR Doc. 88-26509 Filed 11-10-88; 5:03 pm]

BILLING CODE 6210-01-M

POSTAL RATE COMMISSION

Meeting

TIME AND DATE: Thursday, November 17, 1988 at 2:30 p.m.

PLACE: Conference Room, 1333 H Street, NW., Suite 300, Washington, DC 20268-0001.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Discuss the evidence and argument in Docket No. C87-2.

2. Discuss the Postal Service response to the Complaint, Docket No. C89-1, which is due on November 16, 1988.

CONTACT PERSON FOR MORE INFORMATION: Charles L. Clapp, Secretary, Postal Rate Commission, Room 300, 1333 H Street, NW., Washington, DC 20268-0001, Telephone (202) 789-6840.

Charles L. Clapp,

Secretary.

[FR Doc. 88-26519 Filed 11-14-88; 11:17 a.m.]

BILLING CODE 7715-01-M

Corrections

Federal Register
Vol. 53, No. 221
Wednesday, November 16, 1988

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents and volumes of the Code of Federal Regulations. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Food Stamp Program; Thrifty Food Plan (TFP) and Income Eligibility Standards and Deductions for the 48 States and DC, Alaska, Hawaii, Guam, and the Virgin Islands

Correction

In notice document 88-25419 beginning on page 44505 in the issue of Thursday, November 3, 1988, make the following corrections:

1. On page 44507, in the second table, under "Rural II Alaska", in the last entry, "+113" should read "+133". Also, in footnote 3, "138.52 percent" should read "128.52 percent".

2. On the same page, in the third column, beginning in the seventh line, remove the sentence, "The allotment for rural I areas is the higher of the allotment that was in effect in each area on October 1, 1985 or 100.79 percent of the Anchorage TFP."

3. On the same page, in the same column, in the third line under the footnotes to the table, "BLs" shoud read "BLS". Also, in the fourth line, "adjustments" was misspelled.

4. On page 44508, in the first column, in the first paragraph, in the second line, "amended" was misspelled. Also, in the ninth line, "disable" should read "disabled".

BILLING CODE 1505-01-D

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 655

Labor Certification Process for the Temporary Employment of Aliens in Agriculture in the United States; Adverse Effect Wage Rate Methodology

Correction

In proposed rule document 88-24954 beginning on page 43722 in the issue of Friday, October 28, 1988, make the following corrections:

1. On page 43722, in the second column, in the **SUMMARY**, in the 10th line, "employees" should read "employers".

2. On page 43723, in the first column, in the third complete paragraph, in the 16th line, "United States of Appeals" should read "United States Court of Appeals".

3. On the same page, in the second column, in the first complete paragraph, in the fourth line, "H-24" should read "H-2A", and in the 20th line, "H-2A should read "H-2".

4. On page 43724, in the second column, in paragraph (b), in the fourth line, "of" should read "or".

5. On the same page, in the third column, under "3. Post-war Program", in the 13th line, "information" should read "informally".

6. On page 43728, in the third column, in the last complete paragraph, in the second line, "eage rates" should read "wage rates".

Note: For a Department of Labor correction to this document see the Proposed Rules section of this issue.

BILLING CODE 1505-01-D

federal register

Wednesday
November 16, 1988

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 331

Antacid Drug Products for Over-the-Counter Human Use; Notice of Proposed Rulemaking

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR PART 331

[Docket No. 88N-0003]

Antacid Drug Products for Over-the-Counter Human Use; Proposed Amendment to the Monograph

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking to amend the final monograph for over-the-counter (OTC) antacid drug products to revise the conditions for marketing combination antacid/analgesic drug products, to add a section on the labeling of permitted combinations of active ingredients, and to redesignate the professional labeling section to conform to the format of other OTC drug final monographs. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Drug Products and public comments on the advance notice of proposed rulemaking for OTC internal analgesic, antipyretic, and antirheumatic drug products that was based on those recommendations. The agency's proposal concerning OTC internal analgesic, antipyretic, and antirheumatic drug products is published elsewhere in this issue of the **Federal Register**. These proposals are part of the ongoing review of OTC drug products conducted by FDA.

DATE: Written comments or objections by March 16, 1989.

ADDRESS: Written comments or objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 4, 1974 (39 FR 19862), FDA issued a final monograph for OTC antacid drug products (21 CFR Part 331). Section 331.15(b) (21 CFR 331.15(b)) of the monograph provides for the combination of an antacid and any generally recognized as safe and effective analgesic ingredient(s) if the combination is indicated for use solely for concurrent symptoms, e.g., headache and acid indigestion, and is marketed in a form intended for ingestion as a solution. These combinations were limited to administration in solution because all the evidence of safety submitted for review under the rulemaking for OTC antacid drug products was derived from studies and experience with products administered as solutions (39 FR 19869).

Subsequent to the publication of the final rule for OTC antacid drug products, the Advisory Review Panel for OTC Internal Analgesic and Antirheumatic Drug Products (Internal Analgesic Panel) reviewed data on OTC antacid/analgesic combinations and recommended conditions for their safe and effective use in its report on OTC internal analgesic, antipyretic, and antirheumatic drug products (July 8, 1977; 42 FR 35346). This Panel recommended that acetaminophen could be combined with a Category I antacid ingredient provided the product was labeled for the concurrent symptoms involved, e.g., "For the temporary relief of occasional minor aches, pains, and headache, * * *, and for acid indigestion." The Panel did not specify any specific dosage form. The Panel also recommended as Category I an antacid/aspirin combination, labeled only for analgesic-antipyretic indications. However, in this case the combination was limited to marketing as a highly buffered aspirin for use as a solution (42 FR 35370).

In the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products published elsewhere in this issue of the **Federal Register**, FDA states for the first time its position on the establishment of a monograph for these drug products. In formulating its proposals on conditions for marketing combinations of antacid and analgesic ingredients in the internal analgesic, antipyretic, and antirheumatic drug products tentative final monograph, the agency considered the recommendations of both the Antacid Panel and the Internal Analgesic Panel as well as all currently-available data on such combinations. As discussed in comments 47, 76, 94, 95, and 96 of the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products, the agency has determined that (1) acetaminophen may be combined with any antacid ingredient(s) and may be labeled only for concurrent symptoms, (2) aspirin may be combined with any antacid ingredient(s) when marketed in a form intended for ingestion as a solution and may be labeled for concurrent symptoms as well as analgesic indications alone, and (3) combinations of other proposed generally recognized as safe and effective internal analgesic-antipyretic ingredients (i.e., carbaspirin calcium, choline salicylate, magnesium salicylate, and sodium salicylate) and antacid ingredients have not existed previously in the marketplace and lack supporting data.

Based on these findings, the agency has determined that the antacid final monograph should be updated to be consistent with the proposals being made in Part 343 (the internal analgesic, antipyretic, and antirheumatic tentative final monograph), published elsewhere in this issue of the **Federal Register**. Therefore, the agency is proposing to revise § 331.15(b) of the antacid monograph to read as follows:

(1) *Antacid and acetaminophen combinations.* See § 343.20(b)(1) of this chapter.

(2) *Antacid and aspirin combinations.* See § 343.20(b)(3) of this chapter.

In addition, the agency is proposing the addition of new § 331.60 to the antacid final monograph in order to provide for the labeling of permitted combinations of active ingredients and is redesignating the professional labeling section from § 331.31 to § 331.80 in accordance with the format of other recently published tentative final and final monographs for OTC drug products. Further, the agency is revising the *Scope* section (21 CFR 331.1) of the antacid final monograph in accordance with the format of other recently published monographs. Because of the interrelationship of this amendment to the antacid final monograph and the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products, the agency does not intend to finalize this amendment until the comments to the internal analgesic, antipyretic, and antirheumatic tentative final monograph have been fully evaluated.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC antacid drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, Pub. L. 96-354. That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC antacid drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC antacid drug products. Comments regarding the impact of this rulemaking on OTC antacid drug products should be accompanied by appropriate documentation.

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 March 16, 1989, submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments or objections. Three copies of all comments or objections are to be submitted, except that individuals may submit one copy. Comments and objections are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments and objections 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 331

Antacid drug products, Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended in Part 331 as follows:

PART 331—ANTACID PRODUCTS FOR OVER-THE-COUNTER (OTC) HUMAN USE

1. The authority citation for Part 331 is revised to read as follows:

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.10 and 5.11.

2. Section 331.1 is revised to read as follows:

§ 331.1 Scope.

(a) An over-the-counter antacid drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

3. Section 331.15 is amended by revising paragraph (b) to read as follows:

§ 331.15 Combination with nonantacid active ingredients.

* * * * *

(b)(1) *Antacid and acetaminophen combinations.* See § 343.20(b)(1) of this chapter.

(2) *Antacid and aspirin combinations.* See § 343.20(b)(3) of this chapter.

* * * * *

4. Section 331.60 is added to Subpart D to read as follows:

§ 331.60 Labeling of permitted combinations of active ingredients.

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs.

(b) *Indications.* The labeling of the product states, under the heading "Indications," the indication(s) for each ingredient in the combination, as established in the indications sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (b). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For permitted combinations identified in § 331.15(b)(1).* The indications in § 343.60(b)(2) of this chapter should be used.

(2) *For permitted combinations identified in § 331.15(b)(2).* The indications in § 343.60(b)(4) of this chapter should be used.

(c) *Warnings.* The labeling of the product states, under the heading "Warnings," the warning(s) for each ingredient in the combination, as established in the warnings sections of the applicable OTC drug monographs.

(d) *Directions.* The labeling of the product states, under the heading "Directions," directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (d). When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC drug monograph.

§ 331.31 [Redesignated as § 331.80]

5. Section 331.31 *Professional labeling* is redesignated as § 331.80.

Dated: August 5, 1988.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 88-26156 Filed 11-15-88; 8:45 am]

BILLING CODE 4160-01-M

federal register

Wednesday
November 16, 1988

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 357

Orally Administered Menstrual Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; Notice of Proposed Rulemaking

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 357

[Docket No. 82N-0165]

Orally Administered Menstrual Drug Products for Over-the Counter Human Use; Tentative Final Monograph

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of a tentative final monograph that would establish conditions under which over-the-counter (OTC) orally administered menstrual drug products (drugs taken internally to relieve symptoms relating to a woman's menstrual period) are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and public comments on an advance notice of proposed rulemaking that was based on those recommendations. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by March 16, 1989. Because this document is being published concurrently with the notice of proposed rulemaking on OTC internal analgesic, antipyretic, and antirheumatic drug products elsewhere in this issue of the **Federal Register**, the agency is allowing a period of 120 days for comments and objections instead of the normal 60 days. New data by November 16, 1989. Comments on the new data by January 16, 1990. Written comments on the agency's economic impact determination by March 16, 1989.

ADDRESS: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 7, 1982 (47 FR 55076), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC orally administered menstrual drug products, together with the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products (Miscellaneous Internal Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by March 7, 1983. Reply comments in response to comments filed in the initial comment period could be submitted by April 6, 1983.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration (address above), after deletion of a small amount of trade secret information.

In response to the advance notice of proposed rulemaking, five drug manufacturers, two consulting firms, and the Panel chairman submitted comments. Copies of the comments received are on public display in the Dockets Management Branch.

In order to conform to terminology used in the OTC drug review regulations (21 CFR 330.10), the present document is designated as a "tentative final monograph." Its legal status, however, is that of a proposed rule. In this tentative final monograph (proposed rule) to establish Subpart K of Part 357 (21 CFR Part 357), FDA states for the first time its position on the establishment of a monograph for OTC orally administered menstrual drug products. Final agency action on this matter will occur with the publication at a future date of a final monograph, which will be a final rule establishing a monograph for OTC orally administered menstrual drug products.

This proposal constitutes FDA's tentative adoption of the Panel's conclusions and recommendations on OTC orally administered menstrual drug products as modified on the basis of the comments received and the agency's independent evaluation of the Panel's report. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications are reflected in the following summary of the comments and FDA's responses to them.

After reviewing and evaluating the Panel's recommendations regarding the use of OTC internal analgesic ingredients during the premenstrual and menstrual periods, the agency has decided to include premenstrual and menstrual claims for these ingredients as part of the rulemaking for OTC internal analgesic drug products rather than to retain them as part of the rulemaking for OTC menstrual drug products. In this way, the various conditions for which an OTC internal analgesic drug product is effective will be listed in one monograph. Elsewhere in this issue of the **Federal Register**, the agency is proposing in the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products to include premenstrual and menstrual claims. Final agency action on OTC internal analgesic ingredients for premenstrual and menstrual use will occur with publication of the final rule establishing a monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products. Comments relevant to OTC internal analgesics are discussed in that document.

Although this tentative final monograph contains indications for antihistamine and smooth-muscle relaxant active ingredients, no ingredients from either of these pharmacologic groups are included in Category I at this time. In the event that no new data are submitted to the agency during the allotted 12-month new data period or if submitted data are not sufficient to establish "monograph conditions" for these classes of ingredients, those classes will not be included in the final monograph. Should new data be sufficient to establish "monograph conditions" for these classes of ingredients, appropriate warnings and directions will be included in the final monograph.

The OTC drug procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II,

and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the **Federal Register**. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notices published in the **Federal Register** of November 16, 1973 (38 FR 31696) and August 27, 1975 (40 FR 38179) or to additional information that has come to the agency's attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Tentative Conclusions on the Comments

A. Comments on Orally Administered Menstrual Active Ingredients

1. One comment stated that, although the pharmacologic literature contains anecdotal evidence of the diuretic activity of ammonium chloride, the Panel did not consider or have available any quantitative data on ammonium chloride at the dosage of 1 gram (g) three times a day that it recommended as Category I.

The agency has reviewed the available data and information and believes that there is sufficient support for general recognition of ammonium chloride's effectiveness at the Panel's recommended dosage. The scientific literature contains several published clinical studies demonstrating ammonium chloride's mechanism of action as a diuretic (Refs. 1 through 5). Greenhill and Freed (Ref. 6) also reported that ammonium chloride is effective in relieving premenstrual and menstrual symptoms. In this study, ammonium chloride administered in doses of 1 g three times a day produced relief in 34 of 40 patients. Those patients who usually showed visible edema did not do so after therapy. Similar results have also been reported by Tecoz (Ref. 7) and Provenzano (Ref. 8). In addition, several pharmacology textbooks state that a dosage of 1 g of ammonium chloride three times a day is useful in treating premenstrual and menstrual symptoms (Refs. 9 through 12). Based on the above, the agency believes that ammonium chloride can be generally recognized as safe and effective for use as a diuretic in OTC menstrual drug products.

References

(1) Lyons, R.H., S.D. Jacobson, and N.L. Avery, "The Effect on the Plasma Volume of Dehydration Produced by a Low-Salt Diet and Ammonium Chloride," *American Heart Journal*, 27:353–359, 1944.

(2) Gamble, J.L., K.D. Blackfan, and B. Hamilton, "A Study of the Diuretic Action of Acid Producing Salts," *Journal of Clinical Investigation*, 1:359–388, 1925.

(3) Wiley, F.H., L.L. Wiley, and D.S. Waller, "The Effect of the Ingestion of Sodium, Potassium, and Ammonium Chlorides and Sodium Bicarbonate on the Metabolism of Inorganic Salts and Water," *Journal of Biological Chemistry*, 101:73–82, 1933.

(4) Folling, A., "On the Mechanism of the Ammonium Chloride Acidosis," *Acta Medica Scandinavica*, 71:221–257, 1929.

(5) Keith, N.M., C. W. Barrier, and M. Whelan, "The Diuretic Action of Ammonium Chlorid and Novasurol in Cases of Nephritis with Edema," *Journal of the American Medical Association*, 85:799–806, 1925.

(6) Greenhill, J.P., and S.C. Freed, "The Electrolyte Therapy of Premenstrual Distress," *Journal of the American Medical Association*, 117:504–507, 1941.

(7) Tecoz, R.M., "Traitement des Troubles Pre-Menstruels par Le Chlorure d' Ammonium," *Praxis*, 34:617–619, 1945.

(8) Provenzano, M.I., "Tensao Pre-Menstrual Seu Tratamento," *Revista de Ginecologia e D'Obstetricia*, 38:268–274, 1944.

(9) Beckman, H., "Pharmacology (The Nature, Action and Use of Drugs)," 2d Ed., W.B. Saunders Co., Philadelphia, pp. 466–467, 1961.

(10) Krantz, J.C., and C.J. Carr, editors, "The Pharmacological Principles of Medicinal Practice," 7th Ed., the Williams and Wilkins Co., Baltimore, pp. 639–640, 1969.

(11) "The Merck Manual," 11th Ed., Merck, Sharp, and Dohme Research Laboratories, Rahway, NJ, p. 659, 1966.

(12) Israel, S.L., "Diagnosis and Treatment of Menstrual Disorders and Sterility," 5th Ed., Harper and Row, New York, p. 158, 1967.

2. One comment stated that although the pharmacologic literature includes anecdotal evidence of the diuretic activity of caffeine, the Panel did not consider or have available any quantitative data for caffeine at the dose of 100 to 200 milligrams (mg) that it recommended as Category I. The comment noted that the results of the one study cited by the Panel to support its conclusions (Ref. 1) did show a significant increase in sodium output, but did not show a significant increase in urine volume following a 300-mg dose of caffeine. Another comment also noted an absence of data demonstrating caffeine's effectiveness in relieving subjective symptoms of the menstrual period.

The agency has reviewed the data and information cited by the Panel (Refs. 1 through 5), as well as other data and information in the scientific literature (Refs. 6, 7, and 8) and tentatively concludes that the data are adequate to support the effectiveness of the Panel's recommended dose of caffeine (100 to 200 mg) for use in OTC menstrual drug products.

The rationale for the use of diuretics during the premenstrual and menstrual periods was discussed by the Panel at 47 FR 55086. Although the Panel did not specifically discuss clinical studies that would support the recommended diuretic dose, the agency finds that caffeine's diuretic activity is well known and generally recognized (Refs. 2 through 5). Studies reported in the literature also support the Panel's conclusion regarding caffeine's diuretic action (Refs. 6, 7, and 8). In a double-blind, placebo-controlled, randomized, crossover study conducted by Robertson et al. (Ref. 6), 250 mg caffeine was found to produce a greater volume of urine in all patients as compared with placebo, with a mean increase of 29 percent. Eddy and Downs (Ref. 7) reported the minimum effective diuretic dose of caffeine to be 0.48 milligram per kilogram (mg/kg) in persons who were not coffee drinkers and 1.12 mg/kg in persons who were coffee drinkers (equivalent to 33 mg and 76 mg, respectively, in a 150-pound person). Victor, Lubetsky, and Greden (Ref. 8) reported that of 124 patients studied, 60 percent reported diuresis when

consuming less than 249 mg of caffeine per day.

As discussed in comment 3 below, in addition to caffeine's diuretic activity, its stimulant effect can provide additional benefit to persons suffering from fatigue during the premenstrual and menstrual periods.

Based on the above, the agency concurs with the Panel's recommendations and is including caffeine as an active ingredient in the tentative final monograph for OTC menstrual drug products.

References

(1) Dorfman, L.J., and M.E. Jarvik, "Comparative Stimulant and Diuretic Actions of Caffeine and Theobromine in Man," *Clinical Pharmacology and Therapeutics*, 11:869–872, 1970.

(2) Grollman, A., "Pharmacology and Therapeutics," 6th Ed., Lea and Febiger, Philadelphia, p. 555, 1965.

(3) de Stevens, G., "Diuretics, (Chemistry and Pharmacology)," Academic Press, New York, p. 12, 1963.

(4) Modell, W., editor, "Drugs of Choice, 1968–1969," C.V. Mosby Co., St. Louis, p. 88, 1967.

(5) Osol, A., R. Pratt, and M.D. Altschule, editors, "The United States Dispensatory," 27th Ed., Lippincott, Philadelphia, pp. 206–208, 1973.

(6) Robertson, D., et al., "Effects of Caffeine on Plasma Renin Activity, Catecholamines and Blood Pressure," *New England Journal of Medicine*, 298:181–186, 1978.

(7) Eddy, N.B., and A.W. Downs, "Tolerance and Cross-Tolerance in the Human Subject to the Diuretic Effect of Caffeine, Theobromine and Theophylline," *Journal of Pharmacology and Experimental Therapeutics*, 33:167–174, 1928.

(8) Victor, B.S., M. Lubetsky, and J.F. Greden, "Somatic Manifestations of Caffeinism," *Journal of Clinical Psychiatry*, 42:185–188, 1981.

3. One comment requested that the agency resolve certain inconsistencies relating to caffeine between the proposed rulemaking for OTC stimulant drug products and the advance notice of proposed rulemaking for OTC menstrual drug products. The comment noted that the stimulant tentative final monograph stated that caffeine could be expected to increase nervousness associated with premenstrual tension (43 FR 25561) and that the proposed labeling for caffeine included a warning advising that the use of caffeine may be associated with increased nervousness, anxiety, irritability, and other side effects (43 FR 25602). The comment pointed out that these same symptoms occur in the menstrual syndrome, a condition for which caffeine is being indicated for use as a diuretic. The comment implied that it is inappropriate to use a drug for a condition that includes symptoms that the drug itself caused as side effects.

The agency does not believe that the proposed rulemaking for OTC stimulant drug products and the advance notice of proposed rulemaking for OTC menstrual drug products are inconsistent with respect to caffeine. The agency notes that the proposed warning for caffeine in the tentative final monograph on OTC stimulant drug products (43 FR 25544) advises against excessive intake of caffeine, informs consumers to use caution when taking caffeine-containing drug products with other caffeine-containing products such as coffee or cola, and states that certain side effects such as anxiety, nervousness, and irritability may occur if the recommended dose is exceeded. The amount of caffeine that causes the side effects varies greatly among individuals, and the side effects are not expected to occur in most people from the usual stimulant or diuretic therapeutic dose of caffeine (100 to 200 mg).

As the Miscellaneous Internal Panel acknowledged in its report, caffeine can serve two purposes in OTC menstrual drug products (47 FR 55087). First, through its mild diuretic action, caffeine can relieve the symptoms of bloating, swelling, and water-weight gain during the premenstrual and menstrual periods. Second, the Panel acknowledged that fatigue is also a symptom of the premenstrual period, and caffeine's stimulant effect could relieve the fatigue. Although the premenstrual and menstrual syndrome may include the symptoms of nervousness, anxiety, and irritability, these symptoms do not necessarily occur in every individual (47 FR 55080). Even in those who are experiencing these symptoms, caffeine's diuretic effect may still provide a therapeuric benefit for the water-retention symptoms. Therefore, the agency does not believe it is inappropriate to use caffeine during the premenstrual and menstrual periods. However, to provide fully informative labeling to the consumer, the agency is proposing the following warning for OTC menstrual drug products containing caffeine: "The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart rate." The agency believes this warning is more appropriate for OTC menstrual drug products than the warnings recommended by the Panel in § 357.1054(c)(2) and is consistent with the warning in the final monograph for OTC stimulant drug products published in the **Federal Register** of February 29, 1988 (53 FR 6100).

4. Although phenyltoloxamine citrate was not reviewed by the Miscellaneous Internal Panel, one comment requested that products containing this ingredient in combination with acetaminophen or with acetaminophen and caffeine, which have been marketed for many years, be placed in Category III for relief of menstrual pain. The comment stated that the recommendations of the Miscellaneous Internal Panel concerning pyrilamine are equally applicable to other antihistamines and specifically to phenyltoloxamine because of their similarity in action. The comment pointed out that these products were reviewed by the Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Drug Products (Internal Analgesic Panel) and that clinical studies submitted to that Panel support this use of phenyltoloxamine. A reply comment stated that, whether or not other antihistamines share the effectiveness demonstrated by pyrilamine in relieving menstrual symptoms, all antihistamines should be subject to clinical investigations on an individual basis.

The agency has reviewed the administrative record of the rulemaking for OTC internal analgesic, antipyretic, and antirheumatic drug products and determined that products containing phenyltoloxamine in combination with acetaminophen or acetaminophen and caffeine have been marketed OTC for relief of menstrual pain. Therefore, the agency agrees with the comment that it is reasonable to include phenyltoloxamine citrate in Category III in the review of OTC menstrual drug products. However, the data are insufficient to demonstrate that phenyltoloxamine citrate in combination with acetaminophen or acetaminophen and caffeine provides any contribution to the product's effectiveness. The agency is placing phenyltoloxamine in Category III, and additional data will be necessary to establish the effectiveness of this ingredient for use in OTC menstrual drug products. (For a discussion of pyrilamine in OTC menstrual drug products, see comment 5 below.)

5. Two comments responded to the agency's concern that the Panel's conclusions on the use of pyrilamine maleate in OTC menstrual drug products may be inconsistent with the final order for OTC daytime sedative drug products. The comments contended that the agency's conclusions with respect to antihistamines in the daytime sedative final order (44 FR 36378) were not

relevant to the use of pyrilamine maleate in products for premenstrual syndrome because the pharmacological basis for pyrilamine's use in the premenstrual and menstrual syndrome relates to its effects as an H_1 histamine antagonist and possibly to its ability to reduce prolactin levels, with consequent reduction in prostaglandin synthesis, but not to its drowsiness side effect. The comments also argued that although a target population that could benefit from the drowsiness effect for use as a daytime sedative had not been demonstrated, the target population that can benefit from an effective menstrual drug product is well defined. The comments added that the results of two studies submitted to the Panel provide the necessary evidence demonstrating the effectiveness of pyrilamine maleate alone or in combination with pamabrom in relieving symptoms of the premenstrual and menstrual periods (Refs. 1 and 2).

The agency has reviewed all of the available data and acknowledges that the conclusions regarding antihistamines in the daytime sedative final rule may not be relevant to the use of pyrilamine maleate in products used for the premenstrual and menstrual syndrome. However, the agency does not believe the data are sufficient to establish the effectiveness of pyrilamine maleate alone or in combination for use in relieving symptoms of the premenstrual and menstrual syndromes. Therefore, the agency is classifying pyrilamine maleate (and its combinations) in Category III in this document.

Two studies were cited by the Panel in support of the effectiveness of pyrilamine maleate. The Boston study, a randomized, double-blind, crossover study, was conducted to compare the effectiveness of pyrilamine maleate vs placebo in the treatment of the premenstrual syndrome (Ref. 1). Although several parameters were analyzed, the sponsor indicated that water retention, negative affects (anxiety, irritability, depression, and tension), and pain were of primary concern. However, because the sponsor's statistical analysis of the study results (Ref. 3) did not take into consideration the crossover design of the study, the results cannot be relied upon as proof of effectiveness. In addition, patients should not have been excluded from the efficacy population for failing to receive each treatment for the same length of time.

The Wisconsin study, also a placebo-controlled, double-blind, randomized crossover study, was conducted to assess the effects of pamabrom and pyrilamine maleate alone and in a fixed combination in the treatment of the premenstrual syndrome (Ref. 2). As in the Boston study, the statistical analysis did not take into consideration the crossover design of the study (Ref. 4). Consequently, the results cannot be relied upon.

Although both of these studies appeared to be well-controlled clinical trials, the lack of sufficient data precluded a proper analysis of the studies. For example, in the Wisconsin study, although the raw data were submitted, the protocol was not included. In addition, the fact that the treatment order was based on whether the patient's study number was odd or even indicated that a proper randomization procedure was not employed. In the Boston study, individual patient data were not provided. The agency's detailed comments and evaluations of the data are on file in the Dockets Management Branch (address above) (Refs. 5 and 6). For the reasons above, the agency concludes that the studies are inadequate to establish effectiveness for pyrilamine maleate alone or in combination with pamabrom. Therefore, the agency is reclassifying pyrilamine maleate alone or in combination with pamabrom in Category III at this time.

In the preamble to the advance notice of proposed rulemaking for OTC menstrual drug products (47 FR 55076), the agency stated that it was not aware of any product on the OTC market containing pyrilamine maleate as the only ingredient and indicated for menstrual or premenstrual symptoms. The agency concluded that, because of its concerns regarding pyrilamine maleate, products containing pyrilamine maleate as a single ingredient and indicated for any menstrual or premenstrual symptoms should not be marketed at that time. The agency reaffirms in this document that products containing pyrilamine maleate as the sole ingredient and indicated for any menstrual or premenstrual symptoms should not be marketed as OTC menstrual drug products until the agency considers the ingredient to be generally recognized as safe and effective (Category I) for such use.

References

(1) "The Effect of Pyrilamine Maleate on the Relief of Symptoms Associated with the Premenstrual Syndrome (Boston Study 1981)," unpublished study, OTC Volume 170218.

(2) "Wisconsin Study (1978)," unpublished study, OTC Volume 170209 (pp. 163–186).

(3) OTC Volume 170224 (Section 4).

(4) OTC Volume 170221.

(5) Letter from W.E. Gilbertson, FDA, to C.N. Jolly, Chattem, Inc., dated February 22, 1985, coded LET009, Docket No. 82N-0165, Dockets Management Branch.

(6) Letter from W.E. Gilbertson, FDA, to C.N. Jolly, Chattem, Inc., dated July 29, 1988, coded LET011, Docket No. 82N-0165, Dockets Management Branch.

B. Comments on Labeling of Orally Administered Menstrual Drug Products

6. One comment noted that the Panel's recommended labeling for OTC menstrual drug products would provide for a distinction between products for use in the premenstrual and menstrual periods. The comment stated that because the Panel itself recognized that there was not a clear distinction between the symptoms occurring during these two periods, it would be simpler and less confusing to label all products in this category for relief of symptoms associated with "menstruation" or "the menstrual period," without attempting to distinguish between "premenstrual" and "menstrual" products.

The agency does not agree that the products should be indicated for "menstruation" only. Although the premenstrual and menstrual periods are two distinct syndromes, the symptoms that occur during these periods overlap significantly, and the ingredients used to relieve these symptoms would be the same whether the symptoms occurred during the menstrual or the premenstrual periods. Therefore, the agency does not believe it would be beneficial to the consumer to distinguish between these two periods in the indications. In this tentative final monograph, the agency is proposing that the products be indicated for the particular symptoms of the "premenstrual and menstrual periods" rather than distinguishing between the two periods. However, this would not preclude the selective use of these terms as part of the product name or as part of other promotional labeling statements, e.g., "premenstrual pain relief formula," "menstrual pain relief," etc. Such terms would be considered descriptive terms advising consumers of the product's benefits. While not included in the monograph, these terms are subject to the provisions of section 502 of the act (21 U.S.C. 352) relating to labeling that is false or misleading and will be evaluated by the agency in conjunction with normal enforcement activities relating to that section of the act.

In reviewing the labeling claims recommended by the Panel, the agency also notes that the Panel placed the term "dysmenorrhea" in Category I. The agency does not believe that "dysmenorrhea", when used alone, is a

word that is commonly understood by consumers, nor was this word used in any of the OTC drug product labeling submitted to the Panel. Therefore, the agency has not provided for its use as a sole indication but has provided for its optional use parenthetically with other terms, e.g., "For the relief of painful premenstrual and menstrual cramps" [which may be followed by: "(dysmenorrhea)."]

7. The Miscellaneous Internal Panel Chairman commented that the Panel's Category III classification of "skin-disorder" claims for antihistamine-containing ingredients (47 FR 55086) was an apparent oversight. He explained that although the classification accurately reflected the Panel's deliberations during the October 16–17, 1981 meeting, it was his personal opinion that such claims should be Category II. He was concerned that such claims would invite teenage girls to use these menstrual products to treat acne.

The agency has reviewed the administrative record for this rulemaking and has found no data to substantiate "skin disorder" claims for OTC menstrual drug products. Therefore, the agency concurs with the Panel Chairman. Skin disorder claims for OTC menstrual drug products are considered Category II.

C. Comments on Combinations

8. Two comments stated that the advance notice of proposed rulemaking for OTC menstrual drug products did not properly reflect all of the Panel's conclusions. The comments pointed out that at its October 16–17, 1981 meeting, the Panel classified the combination of a Category I analgesic and pyrilamine maleate in Category I, but the published document did not reflect this determination.

The agency has reviewed the transcripts of the meeting and concludes that the comments are correct in stating that the Panel classified the combination of a Category I analgesic and pyrilamine maleate as a Category I menstrual drug product. However, due to an editorial omission, the advance notice of proposed rulemaking did not reflect this conclusion. Nonetheless, as discussed in comment 5 above, the agency disagrees with the Panel's recommendation to include such a combination in Category I and has placed this combination in Category III. Therefore, the combination is not included in this tentative final monograph.

Criteria for establishing combinations as Category I are provided in the General Guidelines for OTC Drug Combination Products (Ref. 1). Paragraph 6 of these guidelines states, "In those cases where the data are sufficient to support a finding by the agency that several ingredients in a therapeutic category can be considered interchangeable for purposes of formulating combinations, the monograph will so state and list those ingredients. This is the preferred approach and will be done whenever supported by data and the opinion of experts." Therefore, the agency agrees with the Panel's concept of listing combination drug products by pharmacological class, but does not agree that sufficient data have been provided to allow for all of the ingredients in the various pharmacologic classes to be interchanged for the purpose of forming combinations. Therefore, only those combinations for which the agency has determined that adequate data exist have been included in the tentative final monograph. Data are necessary to establish the safety and effectiveness of other specific combinations or to demonstrate that the specific ingredients in a pharmacological class are chemically and pharmacologically interchangeable.

References

(1) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products, September 1978," Docket No. 78D–0322, Dockets Management Branch.

9. One comment requested that the combination of acetaminophen, pyrilamine maleate, ammonium chloride, caffeine, and iron be classified as a Category I combination for the relief of menstrual discomfort. The comment contended that this would be a reasonable combination because it is a merger of two Category I combinations recommended by the Panel, with the addition of iron. The comment added that the iron is included in the combination because of the "known menstrual iron losses" that were identified in the advance notice of proposed rulemaking for OTC vitamin and mineral drug products. (See the **Federal Register** of March 16, 1979; 44 FR 16183.)

One reply comment questioned whether this product would be intended for use even in the absence of symptoms, in order to provide iron supplementation, or whether the inclusion of iron in the formula has a symptom-specific role.

The comment did not provide any data, and the agency is unaware of any evidence, demonstrating that a suitable target population exists that could benefit from the short-term use of OTC menstrual drug products containing the four proposed ingredients plus iron. The Advisory Review Panel on OTC Vitamin and Mineral Drug Products stated in its report (44 FR 16183) that a daily extradietary iron supplement to supplement the dietary stores and to preserve iron stores seems reasonable because of the prevalance of iron deficiency in menstruating females. Menstrual drug products, however, are not taken daily for long-term dietary supplementation, but are intended for occasional short-term use to alleviate symptoms associated with the premenstrual and menstrual periods. Therefore, the addition of iron as a concurrent therapy in OTC menstrual drug products does not appear warranted.

In addition, pyrilamine maleate and the combinations containing pyrilamine maleate have been reclassified as Category III because of the lack of evidence of effectiveness. (See comment 5 above.) Therefore, the combination requested by the comment would also be considered a nonmonograph combination.

II. The Agency's Tentative Adoption of the Panel's Report

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. *Summary of ingredient categories.* The agency has reviewed all claimed active ingredients submitted to the Panel, as well as other data and information available at this time, and is proposing one change in the categorization of orally administered menstrual active ingredients recommended by the Panel. The agency has also reviewed the ingredient phenyltoloxamine citrate, which was not submitted to the Panel, and is proposing Category III status for this ingredient. (See comment 4 above.) As a convenience to the reader, the following list is included as a summary of the categorization of orally administered menstrual active ingredients recommended by the Panel and the proposed categorization by the agency.

Menstrual active ingredients	Panel	Agency
Analgesics: [1]		
Acetaminophen	I	
Aspirin	I	
Caffeine	III	
Carbaspirin calcium	I	
Choline salicylate	I	
Codeine	II	
Magnesium salicylate	I	
Sodium salicylate	I	
Antihistamines:		
Phenyltoloxamine citrate.	Not Reviewed	III

Menstrual active ingredients	Panel	Agency
Pyrilamine maleate	I	III
Diuretics:		
Ammonium chloride	I	I
Caffeine	I	I
Pamabrom	I	I
Theobromine sodium salicylate.	III	III
Theophylline	III	III
Smooth muscle-relaxants:		
Cinnamedrine hydrochloride.	III	III
Homatropine methylbromide.	II	II
botanical or vegetable herbs:		
Asclepias tuberosa (pleurisy root).	II	II
Cimicifuga racemosa (black cohosh).	II	II
Piscidia erythrina (Jamaica dogwood).	II	II
Senecio aureus (life root).	II	II
Taraxacum officinale (dandelion root).	II	II
Vitamins:		
Pyridoxine hydrochloride.	III	III
Other ingredients:		
Cnicus benedictus (blessed thistle).	II	II
Corn silk	II	II
Couch grass	II	II
Dog grass extract	II	II
Extract buchu	II	II
Extract uva ursi	II	II
Hydrastis canadensis (golden seal).	II	II
Oil of juniper	II	II
Pipsissewa	II	II
Triticum	II	II

[1] The agency's conclusions regarding the use of internal analgesic active ingredients for menstrual and premenstrual symptoms are presented elsewhere in this issue of the FEDERAL REGISTER.

2. *Testing of Category II and Category III conditions.* Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any orally administered menstrual active ingredient or condition included in the review by following the procedures outlined in the agency's policy statement published in the **Federal Register** of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Changes in the Panel's Recommendations

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the Panel's report and recommended monograph with the changes described in FDA's responses to the comments above and with other changes described in the summary below. A summary of the changes made by the agency follows.

1. Because of the changes summarized below, many of the section and paragraph numbers have been redesignated in this tentative final monograph.

2. The agency's conclusions regarding the use of internal analgesic active ingredients for menstrual and premenstrual symptoms are presented elsewhere in this issue of the **Federal Register.**

3. The word "precaution" has been deleted from the recommended warning for ammonium chloride in § 357.1052(c)(1)(ii). The agency considers the word "warning" alone to be the simplest, clearest signal to alert consumers and has routinely used the word "warning" in the labeling sections of other OTC drug tentative final and final monographs.

4. The recommended warnings relevant to the use of caffeine as an OTC menstrual drug have been revised. (See comment 3 above.)

5. Phenyltoloxamine citrate has been added to the menstrual rulemaking as a Category III ingredient. (See comment 4 above.)

6. Pyrilamine maleate as an individual ingredient and in combination has been reclassified from Category I to Category III. (See comments 5 and 8 above.)

7. The agency has modified the indications for OTC menstrual drug products to eliminate the distinction between the premenstrual and menstrual periods. (See comment 6 above.)

8. Skin disorder claims for OTC menstrual drug products have been reclassified from Category III to Category II. (See comment 7 above.)

9. The Panel recommended that the combination of ammonium chloride (650 mg) and caffeine (200 mg) given three times a day be classified in Category I. The Panel concluded this to be a rational combination because the diuretic mechanisms of action are different and adjunctive (47 FR 55095). The agency agrees that the combining of ingredients from the same therapeutic category with different mechanisms of action is rational and is provided for in the agency's general guidelines for OTC drug combination products (Ref. 1) which state that "* * * ingredients from the same therapeutic category that have different mechanisms of action may be combined to treat the same symptoms or condition if the combination meets the OTC combination policy in all respects and the combination is on a benefit-risk basis equal to or better than each of the active ingredients used alone at its therapeutic dose." However, the study cited by the Panel to support the combination of ammonium chloride (650 mg) and caffeine (200 &g) (Ref. 2) was not designed to assess the individual contribution of each ingredient to the combination. Such data are necessary to satisfy the requirements of 21 CFR 330.10(a)(4)(iv), i.e., that each active ingredient must make a contribution to the claimed effect of the product, particularly in light of the fact that the product contains 200 mg caffeine, which has been shown to be effective alone at this dose. The contribution of ammonium chloride in a subtherapeutic dose to a product already containing an effective ingredient at an effective dose level needs to be demonstrated. This is particularly important in this case because, as discussed in comment 1 above, the agency is unaware of any evidence of the effectiveness of ammonium chloride at doses less than the recommended dose of 1 g. Likewise, the agency is unaware of any evidence to establish that the addition of subtherapeutic amounts of ammonium chloride to caffeine would provide any effect above the caffeine alone. Therefore, the agency is classifying the combination of ammonium chloride (650 mg) and caffeine (200 mg) in Category III. However, because the agency considers ammonium chloride in combination with caffeine to be rational for use as an OTC menstrual drug product, the agency has no objections to a drug product that would contain each of these ingredients at their therapeutic dose. Therefore, provisions for ammonium chloride and caffeine in combination at their therapeutic dose have been included in the monograph.

References

(1) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products, September 1978," Docket No. 78D-0322, Dockets Management Branch.

(2) Hoffman, J.J., "A Double-Blind Crossover Clinical Trial of an OTC Diuretic in the Treatment of Premenstrual Tension and Weight Gain," Current Therapeutic Research, 26:575–580, 1979.

10. The agency has expanded the combination section of the monograph to provide for allowable combinations of analgesics (as identified in § 343.20(a)) to be combined with a diuretic.

11. The agency has not included several of the Panel's recommended indications statements for OTC menstrual diuretic drug products (§ 357.1054(b)(2) through (5)) in this

tentative final monograph because they duplicate information already contained in the statement of identity and the primary indications statement.

12. The Panel's recommended directions for OTC menstrual diuretic drug products containing pamabrom have been clarified to include a time interval as follows: Adult oral dosage is 50 milligrams four times a day, not to exceed 200 milligrams per day.

13. The Panel provided indications and directions for two specific combination products in § 357.1058 (a)(1) and (2) and (b)(1) of its proposed monograph. However, it did not provide labeling information for all of the combinations it recommended as Category I. Therefore, the agency is replacing the Panel's recommended § 357.1058 with a new general section (renumbered § 357.1060 in this tentative final monograph) for labeling of permitted combinations of active ingredients that conforms with the format of other recently published tentative final monographs. This combination labeling section contains provisions for combining duplicative words or phrases in the indications, warnings, and directions for each active ingredient in the combination, and contains a paragraph covering "Statement of identity," "Indications," "Warnings," and "Directions."

The information recommended by the Panel in § 357.1058(a) is not being included in this tentative final monograph because pyrilamine has been reclassified from Category I to Category III. (See comments 5 and 8 above.)

In the **Federal Register** of May 1, 1986 (51 FR 16258), the agency published a final rule changing its labeling policy for stating the indications for use of OTC drug products. Under 21 CFR 330.1(c)(2), the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED USES"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All other OTC drug labeling required by a monograph or other regulation (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under the OTC drug monograph where exact language has been established and identified by quotation marks in an applicable monograph or other regulation, e.g., 21 CFR 201.63 or 330.1(g). The proposed rule in this document is subject to the labeling provisions in § 330.1(c)(2).

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC orally administered menstrual drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, Pub. L. 96-354. That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC orally administered menstrual drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invited public comment in the advance notice of proposed rulemaking regarding any impact that this rulemaking would have on OTC orally administered menstrual drug products. No comments on economic impacts were received. Any comments on the agency's initial determination of the economic consequences of this proposed rulemaking should be submitted by March 16, 1989. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has 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 November 16, 1989, submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before March 16, 1989. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register**.

Interested persons, on or before March 16, 1989, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before January 16, 1990. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the **Federal Register** of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (HFA-305) (address above). Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on January 16, 1990. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the **Federal Register**, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 357

Labeling, Orally administered menstrual drug products, Over-the-counter drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended in Part 357 as follows:

PART 357—MISCELLANEOUS INTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR Part 357 continues to read as follows:

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.10 and 5.11.

2. A new Subpart K consisting of §§ 357.1001 through 357.1060 is added to read as follows:

Subpart K—Orally Administered Menstrual Drug Products

Sec.
357.1001 Scope.
357.1003 Definitions.
357.1010 Antihistamine active ingredients. [Reserved]
357.1012 Diuretic active ingredients.
357.1014 Smooth muscle-relaxant active ingredients. [Reserved]
357.1020 Permitted combinations of active ingredients.
357.1050 Labeling of orally administered menstrual drug products containing antihistamine ingredients identified in § 357.1010.
357.1052 Labeling of orally administered menstrual drug products containing diuretic ingredients identified in § 357.1012.
357.1054 Labeling of orally administered menstrual drug products containing smooth muscle-relaxant ingredients identified in § 357.1014.
357.1060 Labeling of permitted combinations of active ingredients.

Subpart K—Orally Administered Menstrual Drug Products

§ 357.1001 Scope.

(a) An over-the-counter menstrual drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 357.1003 Definitions.

As used in this subpart:

(a) *Diuretic.* A drug that increases the excretion of water.

(b) *Menstrual period.* The period of time from onset to stoppage of cyclic, physiologic uterine bleeding which (in the absence of pregnancy) normally recurs, usually at approximately 4-week intervals.

(c) *Menstruation.* The monthly flow of blood from the genital tract of women.

(d) *Premenstrual period.* The period of time approximately 1 week before onset of menstruation.

(e) *Premenstrual syndrome.* A recurrent symptom complex which begins during the week prior to menstruation and usually disappears soon after the onset of the menstrual flow. This symptom complex consists predominately of edema, lower abdominal pain (including cramps), breast tenderness, headache, abdominal bloating, fatigue, and the feelings of depression, irritability, tension, and anxiety.

§ 357.1010 Antihistamine active ingredients. [Reserved]

§ 357.1012 Diuretic active ingredients.

The active ingredients of the product consist of the following within the dosage limits established for each ingredient in § 357.1052(d):

(a) *Acidifying diuretic.* Ammonium chloride.

(b) *Xanthine diuretics.* (1) Caffeine.

(2) Pamabrom.

§ 357.1014 Smooth muscle-relaxant active ingredients. [Reserved]

§ 357.1020 Permitted combinations of active ingredients.

The following combinations are permitted provided each active ingredient is present within the established dosage limits and the product is labeled in accordance with § 357.1060.

(a) Any analgesic identified in § 343.10 of this chapter or any combination of analgesics identified in § 343.20(a) of this chapter and any diuretic identified in § 357.1012.

(b) Ammonium chloride identified in § 357.1012(a) with any one ingredient identified in § 357.1012(b).

§ 357.1050 Labeling of orally administered menstrual drug products containing antihistamine ingredients identified in § 357.1010.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "premenstrual/menstrual symptom reliever."

(b) *Indications.* The labeling of the product states, under the heading "Indications," any of the phrases listed in this paragraph (b). Other truthful and nonmisleading statements describing only the indications for use that have been established and listed in this paragraph, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) "For the relief of" ("emotional changes" or "mood changes") "related to the premenstrual and menstrual periods."

(2) "For the relief of" ("emotional changes" or "mood changes") "such as anxiety, nervous tension, and irritability related to the premenstrual and menstrual periods."

(3) "For the relief of water-retention symptoms related to the premenstrual and menstrual periods."

(4) "For the relief of temporary weight gain or swelling due to water retention during the premenstrual and menstrual periods."

(5) "For the relief of cramps and backache of the premenstrual and menstrual periods."

(c) *Warnings.* [Reserved]

(d) *Directions.* [Reserved]

§ 357.1052 Labeling of orally administered menstrual drug products containing diuretic ingredients identified in § 357.1012.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "diuretic."

(b) *Indications.* The labeling of the product states, under the heading "Indications," any of the phrases listed in this paragraph (b), as appropriate. Other truthful and nonmisleading statements describing only the indications for use that have been established and listed in this paragraph, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) "For the relief of temporary water-weight gain, bloating, swelling, and/or full feeling associated with the premenstrual and menstrual periods."

(2) In addition to the indication in paragraph (b)(1) of this section, products

containing caffeine identified in § 357 1012(b)(1) may also contain the following indication: "For the relief of fatigue associated with the premenstrual and menstrual periods."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) *For products containing ammonium chloride identified in § 357.1012(a).* (i) "Do not use if you have kidney or liver disease."

(ii) "This drug may cause nausea, vomiting, and gastrointestinal distress."

(2) *For products containing caffeine identified in § 357.1012(b)(1).* "The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally rapid heart rate."

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions":

(1) *For products containing ammonium chloride identified in § 357.1012(a).* Adult oral dosage is 1 gram three times a day for no longer than 6 days.

(2) *For products containing caffeine identified in § 357.1012(b)(1).* Adult oral dosage is 100 to 200 milligrams every 3 to 4 hours while symptoms persist.

(3) *For products containing pamabrom identified in § 357.1012(b)(2).* Adult oral dosage is 50 milligrams four times a day, not to exceed 200 milligrams per day.

§ 357.1054 Labeling of orally administered menstrual drug products containing smooth muscle-relaxant ingredients identified in § 357.1014.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "muscle relaxant."

(b) *Indications.* The labeling of the product states, under the heading "Indications," any of the phrases listed in this paragraph (b). Other truthful and nonmisleading statements describing only the indications for use that have been established and listed in this paragraph, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) "For the relief of painful premenstrual and menstrual cramps" [which may be followed by: "(dysmenorrhea)."]

(2) "For the relief of premenstrual and menstrual cramps."

(3) "For the relief of backache associated with premenstrual and menstrual cramps."

(4) "For the relief of cramps associated with the premenstrual and menstrual periods."

(c) *Warnings.* [Reserved]

(d) *Directions.* [Reserved]

§ 357.1060 Labeling of permitted combinations of active ingredients.

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs.

(b) *Indications.* The labeling of the product states, under the heading "Indications," the indication(s) for each ingredient in the combination, as established in the indications sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (b). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For the permitted combinations identified in § 357.1020(a).* "For the temporary relief of minor aches and pains and temporary water-weight gain, bloating, swelling, and full feeling associated with the premenstrual and menstrual periods."

(2) *For the permitted combinations identified in § 357.1020(a) that contain caffeine identified in § 357.1012(b)(1) the following indication may be used as an alternative to the one identified in § 357.1060(b)(1) above.* "For the temporary relief of minor aches and pains and temporary water-weight gain, bloating, swelling, full feeling, and fatigue associated with the premenstrual and menstrual periods."

(c) *Warnings.* The labeling of the product states, under the heading "Warning," the warning(s) for each ingredient in the combination, as established in the warnings sections of the applicable OTC drug monographs.

(d) *Directions.* The labeling of the product states, under the heading "Directions," directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs. When the time intervals or age limitations of administration of the individual ingredients differ, the directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC drug monograph. For example, an appropriate direction for a tablet containing 25 milligrams pamabrom and 325 mg aspirin would be "Two tablets every 4 to 6 hours not to exceed 8 tablets per day."

Dated: August 5, 1988.

Frank E. Young,

Commissioner of Food and Drugs.

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Wednesday
November 16, 1988

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 310, 343, and 369

Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; Notice of Proposed Rulemaking

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Parts 310, 343, and 369

[Docket No. 77N-0094]

Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of a tentative final monograph that would establish conditions under which over-the-counter (OTC) internal analgesic, antipyretic, and antirheumatic drug products are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the reports and recommendations of the Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Drug Products and the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and the public comments on the advance notices of proposed rulemaking for OTC internal analgesic, antipyretic, and antirheumatic drug products and OTC menstrual drug products that were based on the Panels' respective recommendations. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by May 16, 1989. Because of the length and complexity of this proposed regulation, the agency is allowing a period of 180 days for comments and objections instead of the normal 60 days. New data by November 16, 1989. Comments on the new data by January 16, 1990. Written comments on the agency's economic impact determination by May 16, 1989.

ADDRESS: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 8, 1977 (42 FR 35346), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products, together with the recommendations of the Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Drug Products (Internal Analgesic Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in these drug classes. Interested persons were invited to submit comments by December 5, 1977. Reply comments in response to comments filed in the initial comment period could be submitted by February 6, 1978.

In a notice published in the **Federal Register** of March 21, 1980 (45 FR 18401), the agency advised that it had reopened the administrative record for OTC internal analgesic, antipyretic, and antirheumatic drug products to allow for consideration of data and information that had been filed in the Dockets Management Branch after the date the administrative record previously had officially closed. The agency concluded that any new data and information filed prior to March 21, 1980 should be available to the agency in developing a proposed regulation in the form of a tentative final monograph.

In the **Federal Register** of December 7, 1982 (47 FR 55076), FDA published an advance notice of proposed rulemaking to establish a monograph for OTC orally administered menstrual drug products, together with the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products (Miscellaneous Internal Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by March 7, 1983. Reply comments in response to comments filed in the initial comment period could be submitted by April 6, 1983.

In accordance with § 330.10(a)(10), the data and information considered by the Panels were put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration (address above), after deletion of a small amount of trade secret information. Data and information received after the administrative record for OTC internal analgesic, antipyretic, and antirheumatic drug products was reopened have also been put on display in the Dockets Management Branch.

In response to the advance notice of proposed rulemaking for OTC internal analgesic, antipyretic, and antirheumatic drug products, two trade associations, several drug manufacturers, many health professionals, several consumers, a drug-standard-setting association, two health professional associations, a health foundation, and one consumer group submitted comments. Copies of the comments received are also on public display in the Dockets Management Branch.

In response to the advance notice of proposed rulemaking for OTC menstrual drug products, the agency received two comments from drug manufacturers relevant to OTC internal analgesic drug products.

After reviewing and evaluating the Miscellaneous Internal Panel's recommendations regarding the use of OTC internal analgesic ingredients during the premenstrual and menstrual periods, the agency has determined that it is appropriate to include premenstrual and menstrual claims for these ingredients as part of the rulemaking for OTC internal analgesic drug products rather than to retain them as part of the rulemaking for OTC menstrual drug products and has transferred the comments relevant to those claims to this rulemaking. In this way, the various conditions for which an OTC internal analgesic drug product is safe and effective will be listed in one monograph. The agency's proposed regulation in the form of a tentative final monograph for OTC orally administered menstrual drug products is published elsewhere in this issue of the **Federal Register.**

In order to conform to terminology used in the OTC drug review regulations (21 CFR 330.10), the present document is designated as a "tentative final monograph." Its legal status, however, is that of a proposed rule. In this tentative final monograph (proposed rule) to establish Part 343 (21 CFR Part 343) FDA states for the first time its position on the establishment of a monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products and the use of these products for premenstrual and menstrual symptoms. Final agency action on this matter will occur with the publication at a future date of a final monograph, which will be a final rule establishing a monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products.

This proposal constitutes FDA's tentative adoption of the Internal Analgesic Panel's conclusions and recommendations on OTC internal analgesic, antipyretic, and antirheumatic drug products and the Miscellaneous Internal Panel's conclusions and recommendations on the use of OTC internal analgesic drug products for premenstrual and menstrual symptoms,

as modified on the basis of the comments received and the agency's independent evaluation of the Panels' reports. Modifications have been made for clarity and regulatory accuracy and to reflect any new information that has come to the agency's attention. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications are reflected in the following summary of the comments and FDA's responses to them.

The Panel's conclusions and recommendations on the ingredient phenacetin are not addressed in this document. OTC drug products containing phenacetin are subject to the notice that FDA published on phenacetin in the **Federal Register** of October 5, 1983 (48 FR 45466), which requires removal of phenacetin from all prescription and OTC drug products (except for one prescription product on which a hearing request is pending).

The agency published an advance notice of proposed rulemaking on the reported association of the use of salicylates with Reye syndrome in the **Federal Register** of December 28, 1982 (47 FR 57886). Reye syndrome is a rare, acute, life-threatening condition, which primarily occurs in children or teenagers during the course of or while recovering from a mild respiratory tract infection, flu, chicken pox, or other viral illness. In the **Federal Register** of December 17, 1985 (50 FR 51400), the agency published a proposed rule to require the labeling of oral OTC aspirin and aspirin-containing drug products to bear a warning that such products should not be used to treat chicken pox or flu symptoms in children and teenagers before consulting a doctor about Reye syndrome. In addition to the warning statement, the agency proposed to prohibit OTC salicylate-containing drug products labeled solely for use by children (pediatric products) from recommending that the products be used in treating flu or chicken pox. The final rule was published in the **Federal Register** of March 7, 1986 (51 FR 8180). The final rule requires the labeling of orally or rectally administered OTC aspirin-containing drug products to prominently bear the following warning: "WARNING: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye syndrome, a rare but serious illness." In addition, the regulation states that OTC drug products covered by the rule and labeled solely for use by children (pediatric products) shall not recommend the product for use in treating flu or chicken pox. This required warning statement and restriction on use of the drug were scheduled to expire June 6, 1988 unless extended by the agency through publication for notice and comment in the **Federal Register**. In the **Federal Register** of January 22, 1988 (53 FR 1796) the agency published a proposal to make the labeling provision permanent. A final rule was published in the **Federal Register** of June 9, 1988 (53 FR 21633), which expanded the required warning sratement to make clear that aspirin use in children and teenagers has been reported to be associated with Reye syndrome and made the labeling provision permanent. Therefore, the agency will incorporate the Reye syndrome warning into the final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products. The agency notes that one provision of the Reye syndrome labeling regulation, i.e., 21 CFR 201.314(h)(3) states that OTC drug products subject to the regulation and labeled solely for use by children (pediatric products) shall not recommend the product for use in treating flu or chicken pox. Because the Reye syndrome warning in § 201.314(h)(1) applies to both children and teenagers, and teenagers may use other than pediatric products, the agency is not proposing to include flu in the labeling indication for any oral OTC aspirin and aspirin-containing drug products. In addition, FDA noted in the final rule (53 FR 21635) that scentific research to date focuses on the association between Reye syndrome and aspirin, rather than on the broader category of drug products containing nonaspirin salicylates. FDA stated that it will consider extending the warning to nonaspirin salicylates if warranted by further research. Therefore, at this time the agency is not proposing to include flu in the labeling indication for any salicylate preparation. However, the agency is including "flu" in the indications allowed for products containing acetaminophen.

The agency is also aware of the National Institutes of Health (NIH) Consensus Development Conference on analgesic-associated kidney disease held February 27 to 29, 1984. The NIH Conference issued a statement concluding that considerable evidence indicates that combinations of antipyretic analgesics, taken in large doses over a long period of time, cause a specific form of kidney disease and chronic renal failure. Persons so exposed may be more susceptible to the subsequent development of uroepithelial tumors. The Conference also concluded that, in contrast, there is little evidence that preparations containing a single analgesic ingredient have been similarly abused and similarly harmful. The Conference recommended that serious consideration should be given to limiting OTC drug products to those containing a single antipyretic-analgesic agent. The agency advises that the final Conference report is being included in this administrative record (see OTC volume 03BTFM), which has now been reopened with publication of this tentative final monograph. The agency invites specific comment on this issue and will address the Conference's recommendations in the final rule.

The OTC drug procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the **Federal Register**. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate

commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In the advance notice of proposed rulemaking for OTC internal analgesic, antipyretic, and antirheumatic drug products (published in the **Federal Register** of July 8, 1977 (42 FR 35346)), the agency suggested that the conditions included in the monograph (Category I) be effective 30 days after the date of publication of the final monograph in the **Federal Register** and that the conditions excluded from the monograph (Category II) be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph, regardless of whether further testing was undertaken to justify their future use. Experience has shown that relabeling of products covered by the monograph is necessary in order for manufacturers to comply with the monograph. New labels containing the monograph labeling have to be written, ordered, received, and incorporated into the manufacturing process. The agency has determined that it is impractical to expect new labeling to be in effect 30 days after the date of publication of the final monograph. Experience has shown also that if the deadline for relabeling is too short, the agency is burdened with extension requests and related paperwork.

In addition, some products will have to be reformulated to comply with the monograph. Reformulation often involves the need to do stability testing on the new product. An accelerated aging process may be used to test a new formulation; however, if the stability testing is not successful, and if further reformulation is required, there could be a further delay in having a new product available for manufacture.

The agency wishes to establish a reasonable period of time for relabeling and reformulation in order to avoid an unnecessary disruption of the marketplace that could not only result in economic loss, but also interfere with consumers' access to safe and effective drug products. Therefore, the agency is proposing that the final monograph be effective 12 months after the date of its publication in the **Federal Register**. The agency believes that within 12 months after the date of publication most manufacturers can order new labeling and reformulate their products and have them in compliance in the marketplace. If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notice published in the **Federal Register** of July 21, 1972 (37 FR 14633) or to additional information that has come to the agency's attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Tentative Conclusions on the Comments and Reply Comments

A. General Comments

1. Several comments contended that OTC drug monographs are interpretative, as opposed to substantive, regulations.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the **Federal Register** of May 11, 1972 (37 FR 9464), and in paragraph 3 of the preamble to the tentative final monograph for antacid drug products, published in the **Federal Register** of November 12, 1973 (38 FR 31260). FDA reaffirms the conclusions stated there. Subsequent court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. See, e.g., *National Nutritional Foods Association v. Weinberger*, 512 F.2d 688, 696–98 (2d Cir. 1975) and *National Association of Pharmaceutical Manufacturers v. FDA*, 487 F. Supp. 412 (S.D.N.Y. 1980), *aff'd*, 637 F.2d 887 (2d Cir. 1981).

2. One comment stated that FDA should provide better physician education on the treatment of drug toxicity, as well as on the potential toxicity of medications currently on the market. Other comments suggested that an educational program should be jointly initiated by FDA, the pharmaceutical industry, and the medical and pharmacy professions to better educate consumers on the appropriate use of analgesic products, e.g., the use of aspirin during pregnancy.

The agency supports and is actively engaged in educational programs for consumers, physicians, and health professionals. One way in which FDA provides information on drug interactions, toxicities, and other pertinent topics is through the "FDA Drug Bulletin." This publication is routinely mailed to physicians and other health professionals. One issue, for example, was devoted to alcohol-drug interactions, including possible interactions of alcohol with aspirin, other salicylates, and acetaminophen (Ref. 1). Another issue, which discussed the use of aspirin in patients with a previous myocardial infarction or unstable angina pectoris, included a discussion of adverse reactions that occurred from the doses of aspirin used in the studies (Ref. 2).

FDA also has consumer education programs on human drugs. Each program is implemented by FDA consumer affairs officers who provide health-related information, through talks, films, or slides, to diverse groups of people, such as health professionals, parents, teachers, and others. These groups, in turn, often help to disseminate the information further. The consumer education programs on human drugs consist of subprograms such as "Drugs and Pregnancy" and "Safe and Effective Use of Drugs," which include publications that provide information on the use of OTC internal analgesic drug products among others. Additional agency publications are also available to consumers. For example, "FDA Consumer" and "FDA Consumer Memo" have contained articles on drugs and pregnancy and the uses and dangers of OTC drugs that relieve pain (Refs. 3 through 6).

As new information becomes available, FDA updates these programs to assure continuing education of both consumers and health professionals. In addition, the agency participates in cooperative private-public programs through such organizations as the National Council on Patient Information and Education, which involves industry, health professionals, and consumers in a variety of education and information programs.

References

(1) Food and Drug Administration, "FDA Drug Bulletin," Vol. 9, No. 2, June 1979.

(2) Food and Drug Administration, "FDA Drug Bulletin," Vol. 15, No. 4, December 1985.

(3) Postotnik, P., "Drugs and Pregnancy," *FDA Consumer*, 12:6–10, 1978.

(4) Hecht, A., "Painkillers: Their Uses and Dangers," *FDA Consumer*, 2:6–11, 1977.

(5) Food and Drug Administration, "Nonprescription Pain Relievers," *FDA Consumer Memo*, HEW Publication No. (FDA) 78–3078.

(6) Food and Drug Administration, "Self-Medication," *FDA Consumer Memo*, HEW Publication No. (FDA) 73–3025.

3. One comment urged that future OTC drug monograph documents of more than 10 pages include a table of contents, an index, and boldface headings throughout the text for ease of

reading and locating information in the text.

In publishing documents in the **Federal Register**, FDA follows guidelines established by the National Archives and the Office of the Federal Register in an effort to make all government documents consistent in format and style.

Since the comment was written, **Federal Register** format has changed. The new format now includes headings in bold and italic type which make it easier to read and locate information in OTC Panel reports, tentative final monographs, and final monographs. However, no provision has been made for including either tables of contents or indexes in documents published in the **Federal Register**.

4. Two comments stated that neither a gastroenterologist nor a hematologist served on the Panel and that the expertise of such specialists was essential to the development of the Panel's report. Several other comments questioned the scientific validity of the Panel's report. These comments argued that the Panel frequently misinterpreted information and data to support its conclusions, reached conclusions contrary to the data submitted or testimony presented to it, and relied too heavily on references that are secondary, out-of-date, and unavailable to the scientific community (i.e., not published in scientific journals).

The agency points out that, although the Internal Analgesic Panel did not include a gastroenterologist or a hematologist, experts in the fields of gastroenterology and hematology appeared before the Panel to express their views and present data for the Panel's consideration. Thus, the Panel was not denied expertise in these areas in developing its report.

In evaluating the scientific validity of the Panel's report, the agency has considered the views expressed in the comments, reviewed current scientific literature, and consulted experts outside the agency when necessary. All data on which the Panel based its conclusions, including published and unpublished references, are available to interested persons, including the scientific community, through the Dockets Management Branch (address above).

5. Two comments believed that the Panel recommended changing the marketing status of aspirin products from OTC to prescription only. The comments opposed such a change and expressed concern that making aspirin products available by prescription only would limit consumers' access to these products and would greatly increase their cost. A third comment asserted that aspirin should be available only by prescription, but gave no reasons.

The Panel found aspirin to be safe and effective for OTC use as an analgesic and antipyretic and did not recommend making aspirin products available only by prescription. The agency agrees with this conclusion and emphasizes that aspirin products will continue to be available OTC.

6. One comment stated that the Panel should have deferred caffeine, as it deferred other ingredients in its report (42 FR 35350), to the Advisory Review Panel on OTC Sedative, Sleep-Aid, and Tranquilizer Drug Products (Sleep-Aid Panel) "for uses other than an analgesic adjuvant."

The Internal Analgesic Panel reviewed submissions for caffeine-containing analgesic products that were labeled as analgesics or as analgesic-stimulants. The Panel reviewed caffeine for its safety and effectiveness as an analgesic and as an analgesic adjuvant, but not as a stimulant because stimulant use was reviewed by the Sleep-Aid Panel in its report published in the **Federal Register** of December 8, 1975 (40 FR 57292). The agency presented its tentative conclusions on caffeine in the OTC nighttime sleep-aid and stimulant products notice of proposed rulemaking in the **Federal Register** of June 13, 1978 (43 FR 25544). In the **Federal Register** of February 29, 1988 (53 FR 6100), the agency published a final monograph for OTC stimulant drug products. Any OTC analgesic product containing caffeine for use in restoring alertness or wakefulness will have to follow the dosage and labeling requirements for caffeine established by the agency in that final monograph.

7. One comment from a pharmaceutical firm noted that the firm's name was not included in the list of submissions by firms (42 FR 35348 and 35349). The comment stated that, although this firm did not formally submit data, it presented oral evidence regarding OTC analgesics and underwrote the cost of statistical evaluation of several papers and editorials. To ensure that FDA is aware of the oral evidence that was presented, the comment provided copies of the transcripts of the sessions at which this company presented testimony.

The agency is aware that certain individuals appeared before the Panel to present testimony on behalf of this firm. Their names are included in the list of persons who presented their views to the Panel (42 FR 35347). Because this firm did not submit written data and information in response to the Panel's call-for-data and did not formally submit any data during the course of the Panel's deliberations, it is not included in the list of submissions by firms.

8. One comment, supporting the inclusion of "minor aches and pains of arthritis" in OTC drug analgesic labeling, argued that the Panel decided at an early stage of its review to limit the indications of antirheumatic products to "minor aches and pains" and remove all mention of the minor aches and pains of arthritis. The comment also stated that during the remainder of its review the Panel did not seriously consider any submission or presentation that was not in accord with the Panel's original decision.

The Panel considered the arthritis labeling issue several times during its review, including its April 1976 meeting. The Panel gave reasons for its recommendations on arthritis labeling under its general discussion of the labeling of OTC analgesic, antipyretic, and antirheumatic drug products and also in the discussion of antirheumatic agents (42 FR 35354 and 35453). However, because the agency has decided to allow the phrase "minor pain from arthritis" as an example in the monograph indication for OTC analgesic drug products, the comment's point is moot. (See comment 17 below.)

9. Two comments from the same source requested that the administrative record for the internal analgesic proposed monograph be kept open so that the transcripts or tapes of the closed meetings of the Panel could be reviewed and commented on. The comments stated that these transcripts and tapes were not released by FDA until after the comment period closed.

The original comment's request was dated December 1977. In response to a Freedom of Information (FOI) request (FOI file number F77-15,747), the transcripts and tapes of the Internal Analgesic Panel's closed meetings were made available to the comment source on May 17, 1978, after being reviewed by FDA for deletion of trade secrets, patient names, and other nondisclosable information. Since then the agency has not received from the comment source any new data or information relating to the transcripts or any petition to reopen the administrative record. Transcripts of panel meetings are not included in the administrative record. See 21 CFR 330.10(a)(10). The reasons for this are stated in the preamble to the "Proposal to Designate the Contents and the Time of Closing of the Administrative Record," published in the **Federal Register** of June 4, 1974 (39 FR 19878), and published as a final rule in the **Federal Register** of November 8, 1974 (39 FR 39556).

Because of the length of time since the FOI request was granted, the agency sees no reason at this point to consider having the record "kept open." All interested persons may submit written comments for a period of 180 days after the publication of this tentative final monograph. Any comments relating to the transcripts of the panel meetings should state the reasons that would warrant the agency's consideration of the transcripts, notwithstanding the reasons given by the agency for not ordinarily considering them.

B. Comments on Internal Analgesic, Antipyretic, and Antirheumatic Labeling

10. Several comments contended that there is no statutory authority for the codification of exact words to be used in describing the modes of action and the symptoms to be relieved by an OTC drug. The comments stated that existing statutory provisions (15 U.S.C. 1453(a), 21 CFR 201.61, and sections 508 and 502(e) of the Federal Food, Drug, and Cosmetic Act (hereafter referred to as the act) (21 U.S.C. 358 and 352(e)) do not show a congressional intent to authorize FDA to legislate the exact wording of OTC drug claims to the exclusion of other equally accurate and truthful claims for these products, and that section 502(c) of the Act (21 U.S.C. 352(c)) demonstrates a congressional intent to the contrary. The comments argued that any language fulfilling the statutory requirement should be satisfactory, and recommended that FDA provide for more flexibility of wording in OTC drug product labeling by adding the following statement to each list of approved indications: "or similar indication statements which are in keeping with the Panel's Report."

In the **Federal Register** of May 1, 1986 (51 FR 16258), the agency published a final rule changing its labeling policy for stating the indications for use of OTC drug products. Under 21 CFR 330.1(c)(2), the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED USES"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All other OTC drug labeling required by a monograph or other regulation (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under the OTC drug monograph or other regulation where exact language has been established and identified by quotation marks, e.g., 21 CFR 201.63 or 330.1(g). The proposed rule in this document is subject to the labeling provisions in § 330.1(c)(2).

11. One comment argued that the labeling proposed by the Panel contains extensive and complicated wording and may well be contrary to the intention of section 502(c) of the act (21 U.S.C. 352(c)), which states that OTC drug labeling is to be written in terms that consumers can easily understand.

In all of its decisions on labeling, the agency seriously considers the consumer's comprehension of the intended message in the labeling. The agency has thoroughly reviewed the Panel's recommended labeling and has modified it where necessary to make it clearer to consumers. Specific comment is invited on the labeling in this tentative final monograph, including comments on consumer understanding of the wording.

12. Two comments objected to the Panel's recommendation that all inactive ingredients be listed in the labeling of OTC analgesic, antipyretic, and antirheumatic drug products. The comments argued that a list of inactive ingredients in the labeling would be meaningless, confusing, and misleading to most consumers. The comments noted that the act does not require that inactive ingredients of drug products be included on a label and argued that listing these ingredients would crowd out information that is more meaningful to consumers.

The agency agrees that the Federal Food, Drug, and Cosmetic Act does not require the identification of all inactive ingredients in the labeling of OTC drug products. Section 502(e) of the act (21 U.S.C. 352(e)) does require disclosure of active ingredients and of certain ingredients, whether included as active or inactive components in a product. Although the act does not require the disclosure of all inactive ingredients in the labeling of OTC drug products, the agency agrees with the Panel that listing of inactive ingredients in OTC drug product labeling would be useful information for some consumers. Consumers with known allergies or intolerances to certain ingredients would then be able to identify substances that they may wish to avoid.

The Proprietary Association, the trade association that represents approximately 85 OTC drug manufacturers who reportedly market between 90 and 95 percent of the volume of all OTC drug products sold in the United States, has established guidelines (Ref. 1) for its member companies to list voluntarily inactive ingredients in the labeling of OTC drug products. Under another voluntary program begun in 1974, the member companies of The Proprietary Association have been including the quantities of active ingredients on OTC drug labels. The agency is not at this time proposing to require the listing of inactive ingredients in OTC drug product labeling. However, the agency commends these voluntary efforts and urges all other OTC drug manufacturers to similarly label their products.

References

(1) "Guidelines for Disclosure of Inactive Ingredients in OTC Medicines," The Proprietary Association, Washington, July 12, 1984, in OTC Volume 03BTFM.

13. One comment supported, while others objected to, the 10-day limitation on aspirin use recommended by the Panel in § 343.50(c)(1)(i): "Do not take this product for more than 10 days." The supporting comment stated that this recommended warning is consistent with the current medical knowledge of aspirin. Other comments objected to the warning on the grounds that it implies to consumers that aspirin products are unsafe or toxic if taken for more than 10 days; that there is no scientific, medical, or legal justification for the recommendation that chronic arthritis patients see a physician every 10 days; and that a delay of much longer than 10 days is needed before consulting a physician because early examination to rule out serious rheumatoid disease is expensive and does not yield results. The opposing comments also argued that many physicians recommend the use of aspirin beyond 10 days and that the consumer, after reading the 10-day warning, might be reluctant to follow the physician's advice. The following alternative wording was suggested, with the explanation that this warning directs that self-medication should not exceed 10 days: "If pain persists for more than 10 days . . . consult a physician immediately."

The agency points out that the 10-day warning was not intended to apply only to arthritic patients, as one comment appears to have interpreted it. As another comment stated, "* * * self-medication (with analgesic drug products) should not continue for more

than 10 days at one time." The intent of the 10-day warning is to inform all consumers, including arthritic patients, that analgesic drug products should not be taken for more than 10 days "unless directed by a doctor," so that serious conditions do not go undiagnosed and untreated. (See 42 FR 35351.) To reflect this intent, the agency is adding the words "unless directed by a doctor" to the warning for adults in § 343.50(c)(1)(i) and the corresponding warning for children in § 343.50(c)(2)(i). The agency does not believe that these warnings will imply to consumers that analgesic products are unsafe or toxic if taken for more than 10 days (or 5 days for children).

14. One comment supported, and others opposed, that portion of the recommended warning for analgesic and antipyretic products in § 343.50(c)(1)(i) that advises the consumer to consult a physician if symptoms persist or new ones occur. The comment that favored the warning stated that it is consistent with the state of medical knowledge concerning aspirin. One comment opposing the warning argued that informing the consumer to consult a physician if new symptoms occur may unduly alarm the consumer and could burden doctors with additional inquiries from consumers. Another comment stated that new but not unusual symptoms that respond to self-treatment may be expected during the normal course of a self-limited disease, e.g., the fever that develops during a stage of the common cold. The comments suggested the following alternative wording for § 343.50(c)(1)(i) and (ii): "If symptoms persist or get worse, consult your physician"; or "If symptoms persist, or new *unexpected* ones occur, consult your physician."

The agency agrees that worsening symptoms should be mentioned in the warning because this alerts the consumer to consult a doctor when one is needed, e.g., upon the development of secondary infection, rather than only after a 10-day (adults) or 5-day (children) maximum limit for self-treatment. The warning has been amended accordingly. The agency does not believe that informing the consumer to consult a doctor if new symptoms occur would unduly frighten consumers or further burden doctors. For clarity and precision, the agency is revising this portion of the warning to read, "If pain or fever persists or gets worse, if new symptoms occur * * *," in proposed § 343.50(c) (1)(i) and (2)(i). (See comment 18 below for further revision in the warnings.)

15. Two comments agreed with, and many comments objected to, the Panel's recommended Category I labeling indication for internal analgesic active ingredients in § 343.50(a)(1), "For the temporary relief of occasional minor aches, pains, and headache." The comments supporting this limited indication argued that indications that describe specific types of pain mislead the consumer because they imply a treatment of these conditions and encourage inappropriate self-diagnosis and self-treatment. The comments also argued that such labeling suggests to consumers that one product offers unique advantages over another for the specific indications stated on the label.

Some comments objected to the terms "occasional," "minor," or "temporary" because they are unnecessary, indefinite, or meaningless to consumers. Many comments that opposed the recommended indication supported more specific indications that currently appear on many OTC internal analgesic drug products, e.g., "for low back pain," "for muscular aches," "for sinusitis pain," "for pain of sprains," "for functional menstrual pain," "for the relief of minor sore throat pain," and "for pains caused by colds." A consumer survey was submithed to show the need for expanding the recommended indication (Ref. 1).

The comments argued that expanding the labeling would not imply treatment of these conditions, but would aid the consumer in selecting OTC internal analgesic drug products, thereby avoiding the expense of unnecessary visits to a physician and overburdening the health care system. The comments asserted that it is inconsistent for the Internal Analgesic Panel to prohibit the indication "For cold symptoms," while the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Products (Cough-Cold Panel) allows this indication for Category I combination products containing internal analgesics. Two comments contended that the use and effectiveness of analgesic ingredients in relieving the pain of sore throat is generally recognized and submitted excerpts of several references to support their statement (Ref. 2).

The Panel recommended a limited indication for OTC internal analgesic-antipyretic drug products in the belief that it was preferable to listing all of the various types of minor pain that these products could be used for. The Panel found that the various claims on the labels it reviewed were often vague and lacked clarity. The Panel was concerned that a plethora of claims would be confusing and misleading to the consumer (42 FR 35355). However, the agency does not believe that a statement describing one or more specific types of pain on an analgesic-antipyretic drug product properly labeled with the active ingredient and with the statement of identity (e.g., "pain reliever-fever reducer") would mislead consumers. Such labeling would be helpful to consumers to provide them with examples of the general types of pain for which OTC internal analgesic drug products are useful. Therefore, the agency is providing manufacturers the option of providing a limited or an expanded indications statement.

For the reasons described below, the agency is proposing the following indications for OTC internal analgesic drug products: "For the temporary relief of minor aches and pains" [which may be followed by one or more of the following: ("associated with" (select one or more of the following: "a cold," "the common cold," "sore throat," "headache," "toothache," "muscular aches," "backache," "the premenstrual and menstrual periods" (which may be followed by: "(dysmenorrhea)"), or "premenstrual and menstrual cramps" (which may be followed by: "(dysmenorrhea)"))), ("and for the minor pain from arthritis.")] (This statement is further expanded in comment 16 below to include fever labeling.) The types of pain described above are the only ones now being proposed to be allowed in the labeling of OTC internal analgesic drug products. A similar expanded indication is being proposed for products labeled for pediatric use. Minor pain from arthritis is not included as an example in the labeling for pediatric products because when this type of pain occurs in children, it should be treated by a doctor. For the same reason, minor pain associated with backache or muscular aches is not included in the labeling; the underlying cause of these kinds of pain in children should be determined by a doctor. Because the agency does not consider indications concerning premenstrual and menstrual pain appropriate for pediatric analgesic products, these claims are also not being included in the proposed labeling for products for pediatric use.

The terms "muscular aches" and "backache" adequately represent most musculoskeletal aches and pains and are preferable to listing all the specific areas of the body that could be involved. The Panel classified "low back pain" as Category II because it believed that the indication implied to consumers that OTC analgesic drug products could be used to treat arthritic conditions (42

FR 35454 and 35467). However, the agency recognizes that low back pain is not necessarily due to arthritis but may be due to causes amenable to OTC treatment such as minor strains or overexertion. The agency believes that low back pain amenable to treatment with OTC analgesic drug products is appropriately described by the terms "muscle aches" and "backache" in the proposed indication and therefore is not including the claim "low back pain" in the proposed monograph. Because the agency believes that consumers are familiar with the words "low back pain" and proposes to require labeling that would warn consumers against the use of OTC analgesic drug products for more than 10 days and to consult a doctor if symptoms persist or get worse or if new symptoms occur (in § 343.50(c)(1)(i)), the agency would not object to the use of the claim "low back pain" elsewhere on the label provided it is not intermixed with labeling established by the monograph. Similarly, the agency is not proposing to include the claim "pain of sinusitis" in the proposed monograph because it believes that this type of pain is adequately described by the term "headache" in the proposed indication. However, the agency also would not object to the use of this claim provided it is not intermixed with labeling established by the monograph.

Claims relating to sinusitis are addressed in the tentative final monograph for OTC cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products, published in the **Federal Register** of August 12, 1988 (53 FR 30522). (For a discussion of the agency's decision to include "minor pain from arthritis" in the statement of indications, see comment 17 below.)

Claims relating to menstrual pain were classified in Category II by the Panel (42 FR 35434). However, these claims were also reviewed by the Miscellaneous Internal Panel. The agency has reviewed that Panel's recommendations regarding OTC internal analgesic active ingredients for use during the premenstrual and menstrual periods and concurs with the Panel that any Category I OTC internal analgesic ingredient is safe and effective for the relief of pain associated with the premenstrual and menstrual periods and/or with premenstrual or menstrual cramps. In reviewing the various menstrual claims recommended by the Panel, the agency notes that the Panel placed in Category I a claim "for the relief of pain of dysmenorrhea." However, the agency does not believe that "dysmenorrhea," when used alone, is a word that is commonly understood by consumers. In addition, this word was not used in any of the OTC drug product labeling submitted to the Panel. Therefore, the agency has not provided for its use as a sole indication, but has provided for its optional use parenthetically with other terms, e.g., "* * * minor aches and pains * * * associated with the premenstrual and menstrual periods" (which may be followed by: "(dysmenorrhea)").

For the reasons discussed in comment 6 of the tentative final monograph for OTC menstrual drug products (published elsewhere in this issue of the **Federal Register**), the labeling being proposed for these products does not distinguish between the menstrual and premenstrual periods.

The agency is including the claim "sore throat" in the proposed indication after reviewing the various panels' recommendations, and applicable current and proposed regulations. The agency notes that sore throat in most cases is due to a self-limiting condition that resolves itself without treatment. However, the agency is aware that sore throat, mild as it may seem, may be a symptom of a more serious condition that is not amenable to self-diagnosis or self-treatment, such as a streptococcal infection ("strep throat"), which if left untreated may progress to rheumatic fever or acute glomerulonephritis (47 FR 22773). Because of the risk of serious illness if appropriate treatment of a sore throat is unduly delayed, the agency currently recommends that all OTC drug products indicated for the relief of sore throat display the following warning statement: "Warning—severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult physician promptly. Do not use for more than 2 days or administer to children under 3 years of age unless directed by physician," (21 CFR 369.20). Although the Internal Analgesic Panel did not specifically address this warning, the agency is proposing to include a modified version in § 343.50 (c)(1)(ii) and (c)(2)(ii) of this tentative final monograph. The agency is proposing to revise the current warning to make it consistent in format with warnings proposed in other current OTC drug tentative final monographs and is proposing that any analgesic drug product labeled for the relief of minor sore throat pain include the following warning. "If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly."

Because sore throat accompanied by rash could be indicative of several illnesses not amenable to OTC drug self-treatment, such as rheumatic fever or measles (Ref. 2), the agency believes that consumers should be warned against the use of aspirin when a rash is present. Therefore, the agency is proposing to include the word "rash" in the new proposed warning. The agency is not proposing to include the word "high" as descriptive of fever, as contained in the current warning in 21 CFR 369.20, because the agency believes that it is important for the consumer to recognize the presence of fever associated with sore throat regardless of whether the fever is high or low. The agency is also not proposing to include that portion of the current warning against administering the drug to children 3 years of age without consulting a physician. The Internal Analgesic Panel recommended labeling that provided for the use of analgesics in children 2 years of age. In the tentative final monograph for OTC oral health care drug products, the agency concluded that most Category I anesthetic/anaglesic ingredients, such as benzocaine and dyclonine hydrochloride, could be labeled for the temporary relief of minor sore throat in children 2 years of age or older (53 FR 2458). Therefore, the agency is proposing in this tentative final monograph for the labeling to provide for the use of analgesics for minor sore throat pain in children 2 years of age or older.

The agency is retaining the term "minor" to describe the aches and pains that are amenable to OTC treatment, as opposed to more severe symptoms that should be treated by a doctor. The term "temporary" remains in the indications statement to indicate the type of relief given by OTC internal analgesic drug products.

The term "occasional" is being deleted from the Panel's recommended labeling because the agency believes that the warnings included in the tentative final monograph are sufficient to warn consumers against the chronic use of OTC analgesics unless advised by a doctor.

References

(1) Comment No. C00043, Docket No. 77N-0094, Dockets Management Branch.

(2) Comment No. M00006, Docket No. 77N-0094, Dockets Management Branch.

(3) Berkow, R., editor, "The Merck Manual of Diagnosis and Therapy," 14th Ed., Merck and Co., Rahway, NJ, pp. 81-87, 1976.

16. Several comments objected to the antipyretic active ingredient labeling recommended in § 343.50(a)(2), "For the

reduction of fever," because it does not include the common cold and flu. The comments stated that fever associated with colds and flu is the most common type of fever for which self-medication is appropriate, and that eliminating the terms "common cold" and "flu" from the labeling would deny the consumer necessary information for safe and effective self-medication.

The agency believes that manufacturers should be able to inform consumers of the relationship between the common cold and fever, and is providing a number of options for labeling analgesic-antipyretic drug products so that this can be done if the manufacturer desires. With regard to the term "flu," the agency published a final rule on Reye syndrome and salicylate drug products entitled "Labeling for Oral and Rectal Over-the-Counter Aspirin and Aspirin-Containing Drug Products; Reye Syndrome Warning" in the **Federal Register** of June 9, 1988 (53 FR 21633). This rule provides that such products labeled solely for use by children (pediatric products) shall not recommend the product for use in treating flu or chicken pox. Because the warning required on all aspirin-containing products includes both children and teenagers (see discussion of final rule earlier in this document) and because of the possibility of teenagers using other than pediatric products, the agency has decided not to add "flu" to the label indications for any aspirin-containing product at this time.

In addition, while FDA noted in the final rule (53 FR 21635) that scientific research to date focuses on the association between Reye syndrome and aspirin, concerns have been raised about the use of the broader category of drug products containing nonaspirin salicylates in children and teenagers with "flu." Therefore, at this time the agency is not proposing to include flu in the labeling indication for any salicylate preparation. However, the labeling prohibition on this "flu" claim does not apply to the internal analgesic-antipyretic ingredient acetaminophen. Therefore, the agency is proposing to include the term "flu" in the indication for acetaminophen.

Section 343.50(a) (2) and (3), as recommended by the Panel, are being deleted, and the Panel's recommended indication for any Category I analgesic/antipyretic ingredient in § 343.50(a)(3) (redesignated § 343.50(b)(1)) is being revised as follows: "For the temporary relief of minor aches and pains" [which may be followed by one or more of the following: ("associated with" (select one or more of the following: "a cold," "the common cold," "sore throat," "headache," "toothache," "muscular aches," "backache," "the premenstrual amd menstrual periods" (which may be followed by: "(dysmenorrhea)"), or "premenstrual and menstrual cramps" (which may be followed by: "(dysmenorrhea)")))), ("and for the minor pain from arthritis"), and ("and to reduce fever.")] The labeling being proposed for products marketed exclusively for children is as follows: "For the temporary relief of minor aches and pains" [which may be followed by: ("associated with" (select one or more of the following: "a cold," "the common cold," "sore throat," "headache," or "toothache")) and/or ("and to reduce fever".)] The agency is also proposing that the term "flu" may be added to these revised indications for products containing acetaminophen.

In addition, the agency is proposing that all OTC analgesic-antipyretic drug products bear a statement of identity as a "pain reliever" or "analgesic (pain reliever)." If the product is also labeled to include the indication "to reduce fever," then the statement of identity is "pain reliever-fever reducer" or "analgesic (pain reliever)-antipyretic (fever reducer)."

17. One comment agreed with the Panel's recommendation that OTC analgesic drugs should not be labeled for the relief of pain from arthritis, adding that such labeling could be misleading to consumers. The comment stated that consumers may equate relief of pain with effective treatment of self-diagnosed "arthritis," thus preventing or delaying the diagnosis and proper treatment of a rheumatic disease and that OTC dosages of aspirin "rarely if ever" have anti-inflammatory activity.

Other comments disagreed with the Panel's recommendation and urged that labeling of OTC antirheumatic products include their use for the temporary relief of minor aches and pains from arthritis and rheumatism for the following reasons: (1) Consumers should not be denied such information, and to do so would place increasing demands on doctors and economic burdens on consumers and the health care system; (2) aspirin has an anti-inflammatory effect at OTC dosages, but the Panel's recommended labeling may lead some consumers to believe that aspirin products are unsuitable for relieving arthritis pain, and they may turn to undesirable treatment alternatives, such as diet fads or copper jewelry; (3) minor arthritic syndromes can be managed by self-medication with OTC internal analgesics without leading to serious medical consequences from delays in treatment of progressive diseases such as rheumatoid or gonococcal arthritis.

The agency agrees that arthritis cannot be self-diagnosed, but recognizes that OTC analgesics are effective in relieving "minor pain" associated with arthritic conditions. Descriptive labeling of this nature is now widely used in the labeling of OTC analgesic drug products, e.g., "for the temporary relief of minor arthritic pain." The agency does not believe that such labeling is misleading to consumers. As discussed in comment 15 above, the agency is proposing to expand the indications for OTC analgesic drug products to include examples of pain amenable to self-treatment, i.e., "headache," "toothache," "muscular aches," "backache," "sore throat," "pain associated with the common cold," "pain associated with the premenstrual or menstrual periods," or "minor pain from arthritis." Although the terms "arthritis" and "rheumatism" are used interchangeably by some consumers, the agency believes that "arthritis" is more accurate, more precise, and more readily understood by the majority of consumers.

Instead of denying consumers information on the use of OTC analgesics for relieving the minor pain from arthritis, the agency believes it would be more appropriate to provide such labeling. Consumers are warned against use for more than 10 days and to consult a doctor if pain persists or gets worse, if new symptoms occur, or if redness or swelling is present. These warnings should be sufficient to encourage consumers with persistent pain or inflammation who believe they have arthritis to consult a doctor for diagnosis and treatment. (See comments 18 and 19 below.)

18. One comment recommended a warning for OTC analgesic drug products that would alert consumers with symptoms of arthritis to consult a doctor if pain persists for more than 5 days or if redness is present.

Because the agency is expanding the indications labeling for analgesic ingredients to include minor pain from arthritis, the warnings recommended by the Panel in § 343.50(c)(1) (i) and (ii) are being revised to alert consumers to symptoms of inflammation (redness or swelling), which may appear in conditions such as arthritis and which signal the need to consult a doctor. Because the indications for pain and fever may be combined, the warnings are also being combined to inform consumers to consult a doctor if pain or fever persists or worsens and to include the 3-day limit for fever. The comment submitted no data to support its request

to shorten the limit of OTC analgesic use for symptoms of arthritis to 5 days. In the absence of such data, the agency proposes to retain the 10-day limit for self-medicating for pain.

Recognizing that certain OTC analgesic drug products may be labeled for use in adults and children, for use in children only, or for use in adults only, the agency is proposing the following warnings in the tentative final monograph to replace those recommended by the Panel in § 343.50(c)(1) and (2):

(1) *For products labeled for adults*—(i) *For products containing any ingredient in § 343.10.* "Do not take this product for pain for more than 10 days or for fever for more than 3 days unless directed by a doctor. If pain or fever persists or gets worse, if new symptoms occur, or if redness or swelling is present, consult a doctor because these could be signs of a serious condition.

(2) *For products labeled for children 2 years to under 12 years of age*—(i) *For products containing any ingredient in § 343.10.* "Do not give this product for pain for more than 5 days or for fever for more than 3 days unless directed by a doctor. If pain or fever persists or gets worse, if new symptoms occur, or if redness or swelling is present, consult a doctor because these could be signs of a serious condition."

(3) *For products labeled both for adults and for children 2 years to under 12 years of age* * * *. "Do not take this product for pain for more than 10 days (for adults) or 5 days (for children), and do not take for fever for more than 3 days unless directed by a doctor. If pain or fever persists or gets worse, if new symptoms occur, or if redness or swelling is present, consult a doctor because these could be signs of a serious condition. Do not give this product to children for the pain of arthritis unless directed by a doctor."

19. Several comments disagreed with the arthritis warning for OTC aspirin drug products recommended by the Panel in § 343.50(c)(3)(i): "Take this product for the treatment of arthritis only under the advice and supervision of a physician." The comments also disagreed with the warning for acetaminophen products recommended in § 343.50(c)(5)(ii): "Do not take this product for the treatment of arthritis except under the advice and supervision of a physician." One comment questioned why the warnings were different and recommended that the warning for aspirin in § 343.50(c)(3)(i) also be used for acetaminophen because both drugs are commonly recommended by physicians for the pain from arthritis.

Other comments opposed identical warnings for aspirin and acetaminophen, but also opposed the warnings recommended by the Panel for both drugs (i.e., § 343.50(c) (3)(i) and (5)(ii)), arguing that these warnings are so similar that consumers probably would not perceive their intended difference. These comments added that the Panel's recommended arthritis warning for acetaminophen may lead consumers to believe that acetaminophen is effective in treating arthritis. Emphasizing that acetaminophen, unlike aspirin, has no anti-inflammatory effect and cannot be used to treat arthritis, one comment suggested that the recommended warning in § 343.50(c)(5)(ii) be replaced with the following: "Do not take this product for the treatment of arthritis." As an alternative to this warning, a comment suggested the following warning: "Do not take this product for the relief of arthritis symptoms except under the advice and supervision of a physician." Another comment suggested that, because aspirin can be used to treat arthritis, the following statement be incorporated with the dosage schedule of OTC aspirin drug products in place of the recommended warning in § 343.50(c)(3)(i): "Dosage for arthritis and rheumatic conditions should be only under the advice and supervision of a physician."

The agency agrees that it may be difficult for consumers to distinguish between the warnings recommended by the Panel for aspirin and acetaminophen. Although aspirin is an anti-inflammatory agent, acetaminophen is not. Consumers might incorrectly interpret the Panel's acetaminophen warning (§ 343.50(c)(5)(ii)) to mean that acetaminophen is effective in the treatment of arthritis. To avoid misinterpretation and confusion, the agency is not including this warning in the monograph. Similarly, the agency does not believe that acetaminophen products should bear the warning recommended by the Panel for aspirin products in § 343.50(c)(3)(i), because consumers could also misinterpret this warning to mean that acetaminophen can be used to treat arthritis. An indication for the relief of "minor pain from arthritis" is being proposed for the labeling of both aspirin and acetaminophen products. However, an indication for the treatment of the arthritis itself is not being proposed for any OTC internal analgesic drug product because such treatment should be conducted only under the supervision of a doctor. Different labeling statements on aspirin and acetaminophen drug products regarding arthritis, as suggested by some of the comments, might encourage self-diagnosis and self-treatment of arthritis. The warning being proposed in § 343.50(c)(1)(i) of this document for all Category I ingredients should lead consumers with arthritis symptoms to consult a doctor for diagnosis and treatment of the condition. (See comments 17 and 18 above.) For these reasons, the agency proposes not to adopt the comments' suggestions and is not including either the Panel's recommended § 343.50(c)(3)(i) or § 343.50(c)(5)(ii) in the tentative final monograph.

20. Two comments maintained that the agency should permit the names of OTC analgesic drug products to reflect the uses of the products. The comments specifically requested permission to include the term "arthritis" in certain product names. One comment disagreed, arguing that product names which specifically refer to "arthritis," such as "arthritis strength," "arthritis pain formula," or "rheumatism preparation," imply that these products are uniquely effective for arthritis and will encourage improper self-diagnosis and inappropriate and potentially hazardous therapy.

The agency agrees that product names can be informative and that they should not be misleading. Medically descriptive product names, e.g., "arthritis pain formula," are not required and are not included in the monograph. These names are considered to be outside the scope of the OTC drug review, but are subject to the provisions in section 502 of the act (21 U.S.C. 352) relating to labeling that is false or misleading. Such terms will be evaluated by the agency in conjunction with normal enforcement activities relating to that section of the act.

21. One comment stated that the labels of OTC analgesic and antipyretic drug products should include a warning that these products suppress the body's defense mechanisms. The comment explained that, although the antipyretic and anti-inflammatory effects of aspirin cause a temporary relief of unpleasant symptoms, the disease process is disguised; valuable defense mechanisms such as inflammation and increased body temperature are impaired; and the illness is thereby prolonged.

The comment submitted no evidence to support the statement that analgesic and antipyretic drug products suppress the body's defense mechanisms and thereby prolong illness, and the agency is aware of none. Therefore, the agency is not proposing to include a warning in the monograph as suggested by the comment. The agency considers the

revised 10-day and 5-day warnings for analgesic drug products in § 343.50(c)(1)(i), (2)(i), and (3) in this tentative final monograph adequate to warn consumers to obtain professional help if symptoms persist or get worse or if new symptoms occur.

22. Two comments objected to the 5-day limitation of use of analgesic and antipyretic drug products by children under 12 years of age in the Panel's recommended warning statement in § 343.50(c)(1)(ii). The comments agreed with the Panel that the period of OTC use of analgesic and antipyretic drugs in children under 12 years of age should be limited, but disagreed over the length of time. Suggested alternatives were 2 or 3 days. One comment argued that this warning implies that OTC analgesic drug products are unsafe or toxic if used longer than 5 days.

The agency is proposing the following revised warning for children 2 years to under 12 years of age in § 343.50(c)(2)(i): "Do not give this product for pain for more than 5 days or for fever for more than 3 days unless directed by a doctor. If pain or fever persists or gets worse, if new symptoms occur, or if redness or swelling is present, consult a doctor because these could be signs of a serious condition," (see comment 18 above).

The comments submitted no data to support their suggestions for shorter time limitations. The Internal Analgesic Panel based its recommendation of a 5-day limitation for children on reports from poison control center data and on computer simulations that demonstrated that the plasma salicylate level could exceed 20 milligrams per 100 milliliters (mg/mL) (a toxic level) "among some smaller children of a particular age category following the recommended dosage schedule after 5 days" (42 FR 35368). The agency believes these data provide sufficient reason to propose the Panel's recommended 5-day use limitation for children.

23. Several comments opposed the number and length of warning statements the Panel recommended for OTC analgesic and antipyretic drug products. One comment expressed concern that an extensive list of warnings for products containing aspirin, compared to a shorter list for acetaminophen drug products, will lead consumers to conclude that aspirin drug products are more toxic and less useful than acetaminophen drug products. Other comments urged FDA to limit warning statements to those that are scientifically documented, clinically significant, and important to the appropriate use of the products by the average consumer. These comments further urged that the statements be combined and condensed for ease of consumer understanding and to avoid label clutter that may cause consumers to ignore cautions and warnings in the labeling. One comment suggested the use of supplementary circulars, etc.

FDA agrees that the warning statements for OTC drug products should be limited to those that are scientifically documented, clinically significant, and important for the safe and effective use of the products by consumers. The agency is requiring warning statements for each ingredient on this basis, not on the basis of a comparable number of warnings for each ingredient. Warning statements are also being combined and condensed whenever possible for ease of consumer understanding. In addition, manufacturers are free to design ways of incorporating all required information in labeling, e.g., using flap labels, redesigning packages, or using a package insert.

24. Many comments opposed warnings that cite organs of the body as possible sites of damage by internal analgesic drug products, with some comments referring specifically to the Panel's recommended liver warning for acetaminophen in § 343.50(c)(5)(i). These comments argued that naming an organ that may be injured from an acute overdose or from excessive use of an analgesic drug would place the responsibility of recognizing organ damage on the consumer, who would then be assuming the role of a physician. The comments further argued that this kind of label warning may be misunderstood and may either alarm or cause anxiety in consumers who use drugs rationally. On the other hand, the comments added, such labeling may provide information that may induce individuals to harm themselves.

The comments favored a single, more general warning for all OTC internal analgesic drug products, such as the following: "Do not take this product for more than 10 days unless directed by a physician. Excessive use over a long period of time may cause permanent injury." One comment suggested that, if such a general warning is not adopted, all OTC drug products should bear labeling which fully discloses the conditions under which damage may occur.

The agency is not proposing to include the general warning suggested by the comments in this tentative final monograph. FDA believes that the self-medicating consumer should be made aware of potential risks of a particular OTC drug product through label warnings. As discussed in comment 25 below, the agency agrees that the warnings need not specify the toxic effects on particular organs of the body that can be caused by acute overdose of a drug, as in a suicide attempt, and is not proposing the Panel's recommended liver warning for acetaminophen in this tentative final monograph. However, the agency concludes that the warnings should include specific information on the known side effects or adverse reactions that may occur from use of the drug according to labeled directions, as well as potential dangers that may occur if the labeled directions are exceeded.

The agency concludes that when medical evidence shows that toxicity is associated with the use of an OTC drug, either within its recommended dosage or when used beyond its recommended time limit or dosage (except for acute overdose), it is appropriate to warn consumers of the potential toxicity. In such cases it may be necessary to include organ-specific warnings as well as general labeling statements.

25. Many comments opposed the liver warning recommended by the Panel for acetaminophen drug products in § 343.50(c)(5)(i), "Do not exceed recommended dosage because severe liver damage may occur." Some comments argued that acetaminophen taken in recommended OTC dosage ranges shows no evidence of hepatotoxicity and that the labeling required in § 330.1(g), "Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately," provides sufficient warning to consumers. The comments expressed concern that the liver warning recommended by the Panel may discourage consumers from ever using acetaminophen and that this warning may also encourage suicidal persons to abuse acetaminophen drug products. The comments also argued that the liver warning is especially inappropriate for children's acetaminophen drug products because there is a lack of documented fatalities and serious liver damage in children from acute acetaminophen overdose. The comments stated there may be differences between the metabolism and pharmacokinetics of acetaminophen in children and adults that would cause children to be less vulnerable to acetaminophen toxicity.

Other comments endorsed the recommended liver warning and pointed out that there are no unique signs of acetaminophen toxicity, such as ringing in the ears (tinnitus), and that symptoms of acetaminophen toxicity do not appear until a few days after the overdose.

Noting that consumers are increasing their use of acetaminophen and that fatalities and liver damage have occurred in children, the comments argued that the recommended warning may discourage consumers from exceeding the recommended daily OTC dosage of acetaminophen and make consumers and doctors aware of the consequence of acetaminophen overdose. One comment, concerned about toxicity from the chronic use of acetaminophen in dosages of less than 4 grams (g) per day, suggested that the proposed liver warning be revised to place additional emphasis on the recommended limit of self-treatment with acetaminophen as follows: "Do not exceed recommended dosage or take for more than 10 days, because severe liver damage may occur." Another comment suggested that the recommended warning be revised to state the dosage that will cause hepatotoxicity, for example, 40 or more 325-mg tablets taken as a single dose.

After evaluating the data and information submitted, the agency has tentatively decided not to adopt the liver warning recommended by the Panel in § 343.50(c)(5)(i). The agency is aware that liver damage can occur from acetaminophen overdosage, as explained by the Panel (42 FR 35414). However, the agency believes that warnings need not include information on the specific toxic effects on organs of the body caused by acute overdose of a drug, as in suicide. (See comment 24 above.) The agency also considers it inadvisable to specify hepatotoxic dosage levels in consumer labeling, as one comment suggested, because such labeling could be suggestive to suicidal individuals.

The agency has noted two reports of hepatotoxicity in children who overdosed on acetaminophen. Arena, Rourk, and Sibrack (Ref. 1) described a 3-year-old girl who ingested 35 tablets of acetaminophen 325 mg and suffered decreased consciousness, vomiting, and enlargement of the liver and spleen. At that time the serum ammonia level was 82 micrograms per deciliter (μg/dL). She was admitted to the hospital about 24 hours after ingestion. The serum acetaminophen level was 94 micrograms per milliliter (μg/mL) 24 hours after ingestion; 48 hours after ingestion it dropped to 26 μg/mL. Seventy-two hours after the overdose, serum transaminase (liver enzyme) levels revealed a peak serum glutamic-oxaloacetic transaminase of 20,376 International Units (I.U.) and a peak serum glutamic-pyruvic transaminase of 13,303 I.U. The patient was alert and in good spirits by the second day in the hospital and was discharged 1 week later. Seven weeks after discharge her liver enzymes were normal.

Although this child weighed only 31 pounds and had ingested 11.375 g acetaminophen, resulting in phenomenal transaminase levels and a high plasma level of acetaminophen at 24 hours, she survived without any aftereffects. As one comment noted, this case suggests that a child's liver may be less vulnerable to the hepatotoxic effects of acetaminophen overdosage than an adult's. The agency points out, however, that before conclusions can be made on the potential toxicity of acetaminophen in children, more data are needed on the metabolism of acetaminophen and clinical observations in children (Ref. 2).

Carloss (Ref. 3) reported the death of a 3½-year-old girl who had an upper respiratory infection and was being treated with acetaminophen. The child was given 120 mg of acetaminophen syrup every 4 hours for three doses. Her doctor later increased the dose to 720 mg every 3 hours. During the next 24 hours she took 5.04 g acetaminophen and was hospitalized for nausea and vomiting. Fourteen hours after the last dose, the acetaminophen level was 5.3 mg/dL (therapeutic range, 1 to 3 mg/dL), well in the range of hepatotoxicity. The child was discharged from the hospital the next morning, but was readmitted 16 hours later with a serum glutamic-oxaloacetic transaminase level of 22,000 I.U. and subsequently died.

The child described by Carloss (Ref. 3) was approximately the same age as the one described by Arena, Rourk, and Sibrack (Ref. 1). Neither child had been treated with an antidote for acetaminophen poisoning, such as *N*-acetylcysteine. It is difficult to explain why the child who had ingested 5.04 g acetaminophen died, and the child who had ingested 11.375 g acetaminophen survived.

Regarding chronic use of acetaminophen within recommended OTC dosages, the agency at this time does not believe that the labeling suggested by the comment, "Do not exceed recommended dosage or take for more than 10 days, because severe liver damage may occur," is needed. The warnings proposed in § 343.50(c) (1)(i) and (3) in this tentative final monograph already state a 10-day limitation for adults on OTC analgesic self-medication. Furthermore, the agency is aware of only one somewhat convincing case report of acetaminophen hepatotoxicity associated with chronic acetaminophen usage in a normal individual (Ref. 4). A second case has been reported, but rechallenge results were inconsistent (Ref. 5). As discussed in detail in comment 27 below, Olsson (Ref. 4) described a 55-year-old male who was hospitalized for a flareup of hepatitis while taking a product containing acetaminophen and chlormezanone. He had no recent history of drug or alcohol use, but had a 1-year history of alcohol abuse 7 years before hospitalization. Because this individual developed hepatotoxicity on a low dose of acetaminophen, it is possible that some other problem was also present. (This patient was using a drug containing acetaminophen and chlormezanone, which could have induced the liver injury.) No similar report has appeared despite the wide use of acetaminophen.

A case of chronic use of 325 mg acetaminophen (12 tablets daily for 1 year) was described in which the patient's serum glutamic-oxaloacetic transaminase level was normal before acetaminophen use (Ref. 5). After 1 year of acetaminophen use, liver function tests showed an abnormal serum glutamic-oxaloacetic transaminase level and enlargement of the liver and spleen. After the drug was discontinued, the patient's serum glutamic-oxaloacetic transaminase level returned to normal. After being discharged from the hospital, the patient resumed using 12 tablets of 325 mg acetaminophen daily. Within 2 months he developed pain and was rehospitalized. A monitored rechallenge with one dose of 1,325 mg acetaminophen caused a rise in liver enzyme levels (serum glutamic-oxaloacetic transaminase and serum glutamic-pyruvic transaminase levels) within 12 to 18 hours. A liver biopsy revealed "bridging necrosis, spanning two portal and two central areas." After discontinuing acetaminophen for 4 months, the individual developed abdominal pain and enlargement of the spleen and had to be treated with azathioprine and prednisone. One year later, when liver function tests were back to normal, the individual again was rechallenged with 1,325 mg acetaminophen without any development of symptoms or rise in liver enzyme levels. This raises the possibility that this patient might have been developing chronic active hepatitis exacerbated by acetaminophen.

Rosenberg et al. (Ref. 6) described two individuals who had taken 3.6 g acetaminophen daily for 1 to 2 weeks. One person had a history of Gilbert's disease (characterized by mild jaundice). Both developed jaundice during a course of infectious mononucleosis. However, because

jaundice can occur in 5 to 10 percent of patients with infectious mononucleosis, the jaundice in these two patients could not definitely be attributed to acetaminophen.

Johnson and Tolman (Ref. 7) described a patient who had been taking 3 g acetaminophen daily and complained of fatigue and loss of appetite. The patient had used no other drugs and was not exposed to toxins other than unidentified cleaning solvents used occasionally. On medical examination there was liver tenderness, and a liver function test showed abnormal results. A liver biopsy revealed evidence of chronic active hepatitis with cirrhosis. The patient had a positive rechallenge, and the liver enzymes increased during the 2 weeks following the rechallenge, indicating that acetaminophen may have caused this elevation. It is possible that the patient had chronic active hepatitis and that acetaminophen exacerbated it. This case was also complicated by the concomitant occasional use of unidentified cleaning solvents.

The agency has noted instances where only a mild overdose of 5 to 7 g of acetaminophen may have produced hepatotoxicity. Ware et al. (Ref. 8) described a person who developed disorientation, jaundice, and fever after using acetaminophen and prescription drugs daily for headaches. Liver enzyme levels were elevated, and a liver biopsy showed centrilobular fibrosis and bridging necrosis with evidence of both an acute and a chronic process. The patient improved after 8 days of unspecified conservative treatment. This case does not prove acetaminophen hepatotoxicity because the other drugs the patient had been taking can cause hepatitis.

Toxic hepatitis was reported in three persons who were regularly ingesting acetaminophen in higher amounts than the recommended OTC dosage (Ref. 9). One patient was an alcoholic who for years had used up to 10 300-mg tablets of acetaminophen daily. During the 4 days before admission to the hospital, this individual drank no alcohol, but used about 100 tablets of acetaminophen. On admission to the hospital, the patient's liver enzymes were elevated, but they fell rapidly over the next 2 to 3 days. The amount of acetaminophen ingested and the subsequent pattern of serum liver enzyme abnormality found in this patient were consistent with a substantial overdose of acetaminophen 2 to 3 days before admission.

The second individual used as much as 5.2 g acetaminophen daily. This patient had disseminated bronchial cancer, with general ill health and malnutrition. This patient's liver enzymes were elevated while using acetaminophen. After the liver enzymes returned to normal, the patient was rechallenged. The rechallenge of 5.2 to 6.5 g acetaminophen daily produced elevated liver enzyme levels. The plasma acetaminophen level at 24 hours was 37 μg/mL, corresponding to an overdose of the drug.

The third individual had reportedly used 5.2 to 6.5 g acetaminophen daily for 3 weeks before hospitalization. Forty hours after the last dose, the plasma acetaminophen concentration was 15 μg/mL, consistent with an overdose.

Although it is not inconceivable that chronic use of acetaminophen within recommended OTC dosage ranges produces chronic active hepatitis in a very low percentage of people, and although it is possible that acetaminophen can exacerbate preexisting chronic active hepatitis, the agency concludes that the above data do not provide an adequate basis for requiring a labeling statement on liver damage from chronic use of acetaminophen, that is, within recommended daily OTC dosages for longer than 10 days.

Although the liver warning recommended by the Panel in § 343.50(c)(5)(i) is being deleted, the agency shares the comments' concern that symptoms of acetaminophen toxicity do not appear until a few days after an overdose. Following acetaminophen overdosage, there is a 24- to 48-hour period of relative well-being, when symptoms of hepatotoxicity do not appear despite the occurrence of liver damage. This "silent period" may create a false sense of security that could delay the use of an antidote, which must be administered promptly in order to be effective (Refs. 10 and 11). To alert consumers that prompt medical attention is essential to the proper management of acetaminophen overdose, the agency is proposing the following overdose warnings for acetaminophen drug products: For products labeled for adults (§ 343.50(c)(1)(iii)), "Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms," or for products labeled for children (§ 343.50(c)(2)(iii)), "Prompt medical attention is critical even if you do not notice any signs or symptoms." For products labeled both for adults and children, the warning for adults would apply, as described in § 343.50(c)(3). Both warnings would be required to follow the general overdose warnings in § 330.1(g) that are required for all OTC drugs.

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26. Several comments urged the adoption of a warning statement that advises consumers who have preexisting liver disease, such as hepatitis or infectious mononucleosis, or who may have Reye syndrome, against the use of acetaminophen unless directed by a doctor. The comments cited reports in the medical literature concerning acetaminophen toxicity in persons with liver disease (Refs. 1 through 13). Two comments asserted that there is no evidence to warrant a warning regarding acetaminophen and preexisting liver disease. One of these comments submitted two clinical studies (Refs. 14 and 15) and a report (Ref. 16) to support its position.

In reviewing and evaluating the data and information submitted by the comments, the agency has concluded that there is insufficient evidence at present to propose a warning against the use of acetaminophen at recommended OTC dosages by individuals with preexisting liver disease.

The data and information in Refs. 1 through 7, Refs. 9 through 13, and Ref. 16 presented no evidence to show that OTC dosages of acetaminophen cause

hepatotoxicity in persons with preexisting liver disease. Rosenberg et al. (Ref. 8) described two persons who developed jaundice during a course of infectious mononucleosis. As discussed in comment 25 above, the jaundice cannot be confidently ascribed to acetaminophen.

One of the clinical studies (Ref. 14) presents an open study of six male adults with chronic liver disease who were given 1 g acetaminophen every 4 hours four times a day. After 5 days of acetaminophen administration, there were no significant changes in liver enzyme laboratory values. The mean half-life of acetaminophen in these six subjects was 3.42±2.5. Ten hours after an initial dose of 1 g acetaminophen was administered on the first day, the plasma acetaminophen level was 1.9±1.5 μg/mL. There was no evidence of any significant accumulation of acetaminophen in the plasma of these individuals.

The other clinical study (Ref. 15) presents a placebo-controlled, double-blind, crossover study in which placebo or 4 g acetaminophen (1 g every 4 hours for four doses per day) was administered daily to 20 adults with preexisting liver disease of various types. The individuals were treated for 13 days and crossed over to the alternate regimen without a washout period. In comparing liver enzyme levels of the individuals during acetaminophen administration with those during placebo administration, no statistically significant differences were found. Three patients were excluded from the final analysis. One had changes in liver enzymes which could be attributed to the erratic course of his chronic active hepatitis. Although it is difficult to distinguish enzyme changes because of the erratic course of chronic active hepatitis versus drug-induced changes, the resulting rise in transaminases after rechallenge with acetaminophen raises the question of whether acetaminophen exacerbated this individual's chronic active hepatitis.

Additional data regarding the plasma half-life of acetaminophen in individuals with liver disease were presented at a meeting of FDA's Gastrointestinal Drugs Advisory Committee (Ref. 17). These data appeared to document prolonged serum half-life for acetaminophen in patients with liver disease. Nonetheless, the results of the placebo-controlled crossover study (Ref. 15) gave no evidence that this prolongation results in hepatotoxic levels of the drug. It should be pointed out, however, that prolonged acetaminophen half-life in the patients in this study was not documented, and thus it is not certain that the patients were at risk for possible adverse effects related to such prolongation.

Data pertaining to cytochrome P-450 enzyme levels in patients with liver disease may also be relevant to determining acetaminophen hepatotoxicity. Available data attribute the production of the hepatotoxic metabolite of acetaminophen to the cytochrome P-450 system. A reduction in activity of the cytochrome P-450 system then might result in reduced risk of hepatotoxicity.

The following data show decreased cytochrome P-450 levels in individuals with chronic liver disease. Farrell, Cooksley, and Powell (Ref. 18) showed that the cytochrome P-450 concentrations in patients taking enzyme-inducing drugs such as phenobarbital, phenytoin, and glutethimide are no different in control subjects than in persons with mild-to-moderate hepatitis or inactive cirrhosis. The patients with severe hepatitis or active cirrhosis who were taking enzyme-inducing drugs did have decreased cytochrome P-450 concentrations and may have lost the ability to respond to inducing agents.

Schoene et al. (Ref. 19) measured the cytochrome P-450 content in needle biopsies of the human liver and found that in individuals with severe hepatitis and cirrhosis, the cytochrome P-450 level was 50 percent of the control value. In individuals with either mild or moderate hepatitis, there was no change in the cytochrome P-450 level. Gabrielle et al. (Ref. 20) found no change in the cytochrome P-450 content in individuals with alcoholic steatosis and in those recovering from viral hepatitis compared with normal individuals. The cytochrome P-450 level in chronic persistent hepatitis was 10 percent of the level in the normal individuals. In chronic active hepatitis, the cytochrome P-450 level was 30 percent of that of a normal individual. Although these data suggest that the activity of the cytochrome P-450 system is reduced in individuals with severe liver disease, the relevance of this finding to acetaminophen hepatotoxicity in such individuals is not clear. It is possible that low cytochrome P-450 levels would protect against acetaminophen hepatotoxicity, but the evidence is conflicting on whether acetaminophen exacerbates liver disease.

In summary, the agency believes that at present there are insufficient data to support a warning against the use of acetaminophen by persons with preexisting liver disease such as hepatitis, liver function affected by infectious mononucleosis, or liver disease resulting from Reye syndrome.

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27. Several comments cited data to express concern that certain drugs which induce microsomal enzyme activity (e.g., alcohol and barbiturates) may increase the potential for acetaminophen-induced hepatotoxicity (Refs. 1 through 14). The comments recommended that warnings such as the following be required on the labeling of all products containing acetaminophen:

Do not take this product if you use alcohol or barbiturates unless directed by a physician.

Caution: Do not take this product if you are presently taking a prescription drug for epilepsy, barbiturates, or ethacrynic acid except under the advice and supervision of a physician.

A reply comment opposed the suggested warnings, stating that there is no evidence of any significant drug interaction of acetaminophen when used at recommended doses with drugs which induce microsomal enzyme activity.

The agency is not adopting the suggestion that consumers be warned against the use of ethacrynic acid with acetaminophen. The comments submitted no data to support such a warning, and the agency is not aware of data that indicate a need to warn consumers against the use of ethacrynic acid with acetaminophen.

After reviewing the data cited by the comments, the agency has determined that the results are conflicting and that there is insufficient evidence at this time to warrant a label warning against the use of OTC dosages of acetaminophen products with alcohol, barbiturates, or prescription drugs used for epilepsy.

One comment cited a commentary on acetaminophen which recommended that drugs such as phenobarbital and alcohol should not be used with acetaminophen because they appear to potentiate acetaminophen-induced hepatotoxicity (Ref. 1). However, no firsthand data were presented to support this recommendation. A report by Wilson et al. (Ref. 2) concerned a 13-year-old epileptic who took an overdose of acetaminophen and phenobarbital, subsequently developed hepatic encephalopathy, and died. These authors emphasized the seriousness of dealing with acetaminophen overdose, complicated in this case by the role of phenobarbital in potentiating the hepatotoxicity of acetaminophen.

Wright and Prescott (Ref. 3) retrospectively analyzed data on 16 individuals with hepatic necrosis following acetaminophen overdose. Eight of these individuals showed evidence of ingestion of either alcohol or barbiturates used in the treatment of epilepsy. Three individuals were chronic alcoholics. Wright and Prescott stated that their findings suggest that acetaminophen causes more severe hepatic necrosis in patients who have previously taken drugs that may cause induction of hepatic microsomal enzymes, such as barbiturates and alcohol. However, they conceded that their results must be interpreted cautiously because of the small number of individuals studied and because of uncontrollable factors such as age and nutritional state of the individuals, as well as the possibility of their ingesting other drugs.

Mitchell et al. (Ref. 4) concluded, as a result of their studies in rats and mice, that pretreatment of these animals with phenobarbital potentiates both the incidence and the severity of acetaminophen-induced hepatic necrosis. However, Prescott (Ref. 5) conducted a study on acetaminophen metabolism in 12 healthy volunteers and 15 individuals who were chronically using microsomal enzyme-inducing agents such as phenobarbital and diphenylhydantoin, drugs used in treating epilepsy. Prescott concluded that the production of hepatotoxic metabolites of acetaminophen was not increased in those individuals who used hepatic enzyme-inducing agents. These studies have produced conflicting results which are difficult to reconcile and from which firm conclusions cannot be drawn.

Scott and Stewart (Ref. 6) reported that most of the cases of acetaminophen overdose which they had seen were accompanied by some alcohol use and said that the time available for effective treatment of overdose may be "much reduced" in individuals with alcohol-damaged livers. Barker, de Carle, and Anuras (Ref. 7) observed severe liver damage in an alcoholic who had ingested "moderately excessive" amounts of acetaminophen (100 tablets of 300 mg acetaminophen 4 days before admission to the hospital). These investigators concluded that this individual's use of alcohol induced the formation of toxic acetaminophen metabolites, which made him more susceptible to liver injury from the "moderately excessive" dose of acetaminophen.

Emby and Fraser (Ref. 8) reported on two cases of acetaminophen overdose in alcoholics and concluded that "* * * the enhanced hepatotoxity of paracetamol (acetaminophen) in the presence of enzyme-inducing agents * * * has perhaps not been adequately emphasized." McClain et al. (Ref. 9) conducted studies in mice and also observed the clinical course of three chronic alcoholics who ingested therapeutic, rather than excessive, dosages of acetaminophen. McClain et al. stated that their findings "* * * suggest that alcohol enhances acetaminophen hepatotoxicity in mice and provides supportive evidence that these three alcoholic patients probably had a similar pathophysiological basis for their liver disease." Goldfinger et al. (Ref. 10) reported hepatic damage in an alcoholic who had ingested 9.75 g acetaminophen over a 2-day period prior to hospitalization. Vilstrup et al. (Ref. 11) reported on fulminant liver failure in a woman who was a known abuser of alcohol, diazepam, and barbiturates. The woman had taken a total of 5.4 g acetaminophen over a 2-day period for premenstrual pain and subsequently died.

The agency points out that the amount of acetaminophen ingested by the woman described by Vilstrup et al. is subject to question. It is also difficult to determine the exact daily dosage of acetaminophen ingested by those individuals observed by McClain et al. (Ref. 9) and Goldfinger et al. (Ref. 10). However, it appears that the individuals reported on by McClain et al. and Goldfinger et al. had ingested more than 4 g acetaminophen, which is the recommended maximum daily OTC dosage. In addition, the individual observed by Goldfinger et al. was using meprobamate, another hepatic microsomal enzyme inducer, in addition to alcohol and acetaminophen.

Olsson (Ref. 12) described an individual who had a 1-year history of alcohol abuse (occurring 7 years before hospitalization) and who was hospitalized with jaundice, hepatic cholestasis, and hepatic steatosis. This individual was using a drug containing acetaminophen and chlormezanone. Olsson acknowledged that it was impossible to obtain a reliable drug history from the patient. The role of alcohol is unclear, and chlormezanone could have induced the liver injury seen in this individual. Furthermore, no plasma acetaminophen determination was performed on this individual. Thus it is difficult to implicate acetaminophen and alcohol use positively as the causative factors in this case.

Shamszad et al. (Ref. 13) compiled data that suggest that the half-life of acetaminophen is significantly prolonged in patients with liver disease from alcohol use. However, these investigators noted that when alcohol is used simultaneously with acetaminophen the plasma disappearance curve of acetaminophen is unchanged.

In considering the wide use of acetaminophen in the United States, and after evaluating the above data, the agency concludes that the evidence available to warrant a label warning against the use of OTC dosages of acetaminophen with barbiturates, prescription drugs for epilepsy, or alcohol is conflicting and insufficient. However, if additional data demonstrate the need for such warnings in the future, the agency will reconsider its present position.

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28. Citing reports in the literature (Refs. 1 through 9) to substantiate their argument, several comments stated that acetaminophen has many adverse effects that should be included in label warnings for products containing this ingredient. These adverse effects include allergic reactions with clinical signs such as skin rashes, drug-induced fever, or asthma attacks associated with cross-sensitivity between aspirin and acetaminophen. Other adverse effects include blood dyscrasias, which are abnormal conditions of the blood. An example is thrombocytopenia, a decrease in the number of platelets. The comments attributed these adverse effects either to allergic reactions or idiosyncratic reactions, which are abnormal reactions peculiar to the individual. They also recommended a label warning to advise consumers who are allergic to acetaminophen not to use products containing that drug, and a label warning to advise consumers who have asthma or are sensitive or allergic to aspirin to consult their physician before using acetaminophen drug products.

Two reply comments disagreed, arguing that clinical experience and the medical literature indicate that adverse effects from acetaminophen are rare and do not support the need for such warning statements. These comments also maintained that some of the references cited are single-case, anecdotal reports and that there is insufficient evidence in most of the cases to establish a cause-and-effect relationship between acetaminophen and the reported reactions.

The agency believes that the warnings which the comments requested are not warranted at this time because there is insufficient evidence that these adverse effects are being caused by acetaminophen. However, if sufficient evidence is presented to warrant new warnings in the future, the agency will act accordingly.

Two of the reports on adverse effects of acetaminophen cited by the comments had also been cited by the Panel and presented no new data for the agency's consideration (Refs. 3 and 4). Some of the reports cited by the comments were single-case reports of thrombocytopenia, which may have resulted from a number of factors, including idiosyncracy, or which may have been caused by agents other than acetaminophen (Refs. 1, 3, and 7). There were three single-case reports of skin rash following the use of acetaminophen (Refs. 4, 5, and 9), but no cases of drug-induced fever.

Studies present conflicting data on the occurrence of cross-sensitivity between aspirin and acetaminophen (Refs. 2, 6, 8, 10, and 11). Fisherman and Cohen's study (Ref. 2) contained five cases of cross-sensitivity between aspirin and acetaminophen. These researchers calculated an "intolerance index," which can be used to compare the tendency of various drugs to produce allergic reactions. The index is based on the usual therapeutic dose divided by the minimal dose needed to produce clinical symptoms of intolerance. This result is multiplied by the percent of patients showing intolerance. The calculated "intolerance index" of aspirin was 368 compared with 13.5 for acetaminophen, indicating that there is a low degree of cross-reactivity to acetaminophen in aspirin-sensitive patients.

The Smith study (Ref. 8) also contained five cases of cross-sensitivity between aspirin and acetaminophen. A challenge dose of several common analgesics was given to five aspirin-sensitive patients, two of whom indicated they were sensitive to acetaminophen. Smith measured the change in forced expiratory volume, which is a measure of air flow and pulmonary function, and noted whether rhinitis was present. Three of the patients had statistically significant drops in forced expiratory volume, and four patients also developed rhinitis following acetaminophen administration. This study indicates a potential problem in a person who is highly sensitive to aspirin and who uses analgesic drugs, including acetaminophen, but it does not explain the clinical significance of changes in the forced expiratory volume.

Other studies, not cited by the comments, found no sensitivity to acetaminophen among aspirin-sensitive patients (Refs. 10 and 11). Sampter and Beers (Ref. 10) tested acetaminophen in 182 aspirin-sensitive patients and found no adverse reactions. Other investigators tested 11 aspirin-sensitive patients with therapeutic doses of acetaminophen and found no reaction to acetaminophen (Ref. 11).

Because of the conflicting data on the incidence of cross-sensitivity between aspirin and acetaminophen, the agency is not proposing a warning about cross-sensitivity to other analgesics on the acetaminophen label. Although the potential for allergic reactions to acetaminophen does exist, the agency believes that the following statement in the warnings in § 343.50(c) (1)(i), (2)(i),

and (3) will adequately inform consumers to consult a doctor if an allergic reaction, such as a rash, should occur following the use of acetaminophen: "* * * if new symptoms occur * * * consult a doctor because these could be signs of a serious condition."

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29. One comment suggested that the professional labeling recommended by the Panel (§ 343.80) be revised to include the indications that the Panel did not place in Category I because of its concern about self-diagnosis. The comment argued that, although self-diagnosis is a valid concern for consumer-oriented labeling, this concern is irrelevant to professional labeling. Another comment suggested that the Panel's recommended warnings listed below be moved from consumer labeling to professional labeling because these statements refer to conditions that should be diagnosed and supervised by a physician. The comment concluded that these warnings are irrelevant to a consumer with an undiagnosed condition, and are not needed once the condition is diagnosed because the consumer is then under the care of a physician who will recommend proper medication and advise against inappropriate medication.

The warnings recommended by the comment for inclusion in professional labeling are as follows:

Section 343.50(c)(3)(i): "Take this product for the treatment of arthritis only under the advice and supervision of a physician."

Section 343.50(c)(3)(iv): "*Caution:* Do not take this product if you have stomach distress, ulcers, or bleeding problems except under the advice and supervision of a physician."

Section 343.50(c)(3)(v): "*Caution:* Do not take this product if you are presently taking a prescription drug for anticoagulation (thinning the blood), diabetes, gout, or arthritis except under the advice and supervision of a physician."

Section 343.50(c)(4)(i): "This product contains aspirin. Do not take this product if you are allergic to aspirin or if you have asthma except under the advice and supervision of a physician."

Section 343.50(c)(4)(ii): "Do not take this product during the last 3 months of pregnancy except under the advice and supervision of a physician."

Section 343.50(c)(4)(iii): "Do not take this product for at least 7 days after tonsillectomy or oral surgery except under the advice and supervision of a physician."

The request made by the first comment did not specify the indications it was referring to; therefore, the agency cannot respond.

The agency disagrees with the second comment's suggestion that the warnings listed above be moved to the professional labeling section of the monograph. These warnings are essential for the safe and effective use by consumers of the products to which they apply (with the exception of § 343.50(c)(3)(i), which is being deleted for reasons stated in comment 19 above), and the agency proposes to require them in consumer labeling.

30. One comment stated that the following warnings recommended by the Panel in § 343.50(c) should be eliminated from OTC analgesic and antipyretic drug products that are marketed in children's dosage units as children's products: "Adults: Do not take this product for more than 10 days. If symptoms persist, or new ones occur, consult your physician." "Adults: Drink a full glass of water with each dose." "Do not take this product during the last 3 months of pregnancy except under the advice and supervision of a physician."

The comment contended that these statements, clearly intended for adults, are unnecessary and inappropriate for analgesic and antipyretic drug products labeled for children. The comment added that requiring these warnings on small containers (e.g., the 36-tablet size limitation for pediatric aspirin products) will result in smaller print that will make the labeling message less conspicuous, less legible, and less likely to be read and understood by the consumer.

The comment also stated that the words "Children under 12 years" should be eliminated from the recommended warnings in § 343.50 (c)(1)(ii) and (c)(3)(iii)(b), for the reasons given above as well as the reason that the statement is superfluous because pediatric products are defined by the Panel in § 343.3(e) as products for children under 12 years.

The pregnancy warning recommended by the Panel in § 343.50(c)(4)(ii) is obviously not needed in products intended only for use in children. In addition, the pregnancy-nursing warning required for all OTC drugs intended for systemic absorption specifically provides for an exemption for drugs that are labeled exclusively for pediatric use. (See 21 CFR 201.63(c)(2).)

The agency agrees that the warnings for adults limiting use to not more than 10 days and directing them to drink a full glass of water with each dose (§ 343.50(c)(1)(i) and (c)(3)(iii)(a)) are unnecessary in the labeling of products intended only for use in children, as the warnings in § 343.50(c)(1)(ii) and (c)(3)(iii)(b) provide the necessary information for children under 12 years of age. The warnings recommended by the Panel in § 343.50(c)(1)(i) and (c)(1)(ii) are being revised and expanded into three warnings appearing in the tentative final monograph under the following sections: § 343.50(c)(1)(i), for products labeled for adults; § 343.50(c)(2)(i), for products labeled for children 2 years to under 12 years of age; and § 343.50(c)(3), for products labeled both for adults and for children 2 years to under 12 years of age. (See comment 18 above.)

The agency agrees that products that are clearly identified for use in children, e.g., infant drops, children's aspirin or acetaminophen tablets, do not have to be labeled with a statement in the warnings or in the directions specifying that they are for children under 12 years, as had been recommended by the Panel. Because the directions for use for such products do not include dosages for people over 12 years of age or under 2 years of age, further labeling specifying

that these products are intended for use by children from 2 to 12 years of age appears to be unnecessary. Accordingly, new § 343.50(b)(4) is being proposed in the tentative final monograph as follows:

(4) *Other required statements*—(i) *For products labeled only for children 2 to under 12 years of age containing any ingredient identified in § 343.10.* (*A*) The labeling of the product contains, on the principal display panel, either of the following:

(*1*) "Children's (*trade name of product or generic name of ingredient(s)*)."

(*2*) "(*Trade name of product or generic name of ingredient(s)*) for Children."

(*B*) The labeling for adults in § 343.50(d) and the statement "Children 2 to under 12 years of age" in § 343.50(d)(3)(ii) are not required.

31. One comment supported and two comments opposed the part of the warning recommended by the Panel for aspirin drug products in § 343.50(c)(3)(iv) which states, "* * * Do not take this product if you have stomach distress * * * ."

The supporting comment stated that aspirin drug products cause gastrointestinal distress at therapeutic doses and that their labeling should bear a warning to this effect. The opposing comments recommended deleting the term "stomach distress," contending that it has little meaning to consumers. The term is so all-inclusive, the comment maintained, it may discourage consumers from using aspirin for symptoms for which it is indicated. The comments explained that "stomach distress" often accompanies symptoms such as headache or fever, as with the common cold or flu, and that the warning may discourage consumers from using aspirin for these concurrent symptoms. One comment suggested that, as alternative labeling, consumers be warned against the use of aspirin "in cases of stomach ulcer and related symptoms."

Because the agency shares the comments' concern that the general term "stomach distress" can be applied to various symptoms and may have little meaning to consumers, the agency is proposing to delete this term from the warning recommended by the Panel in § 343.50(c)(3)(iv).

Although the agency believes that alternative labeling is warranted, it is not adopting the alternative labeling suggested by one of the comments because the term "related symptoms" is vague and probably has little meaning to consumers. As the Panel pointed out, plain aspirin products can cause stomach discomfort or "stomach problems," such as heartburn, upset stomach, or stomach pain, in certain individuals (42 FR 35387). Plain aspirin can also exert adverse effects on the gastrointestinal tract (i.e., mucosal erosion, ulceration, minor occult bleeding, etc.) which may exacerbate stomach problems associated with underlying gastrointestinal disease. These effects can also be produced by salicylates other than aspirin (42 FR 35417 to 35421).

Regarding buffered aspirin products, the Panel stated that "* * * evidence seems to indicate that buffered aspirin produces a lower incidence of gastric intolerance in some patients but not in all patients who exhibit gastric intolerance with regular (plain) aspirin products" (42 FR 35470). However, the agency notes that the Panel also stated that this evidence is conflicting. In addition, the investigators of another study on the incidence of gastric lesions in rheumatic patients using plain, buffered, or enteric-coated aspirin concluded that buffered aspirin with an acid-neutralizing capacity of 1.9 milliequivalents (mEq) per 325 mg aspirin did not appear to prevent aspirin-induced gastric damage (Ref. 1). However, these investigators stated that more definitive studies are needed which compare various aspirin preparations before any final conclusions are reached.

Another study showed that OTC doses of buffered aspirin tablets containing 6.4 mEq of antacid, which exceeds the amount of buffering present in most currently marketed buffered aspirin products, produced gastric mucosal injury. The investigators of this study concluded that such products offer little protection to the gastric and duodenal mucosa (Ref. 2). Furthermore, the Panel stated that there is evidence that highly buffered aspirin for solution will reduce, but not eliminate, the acute gastric erosions and occult blood loss produced by the local effects of aspirin in animals and humans with no predisposing gastrointestinal disease (42 FR 35471).

For these reasons, the agency tentatively concludes that it is necessary to advise consumers who have persistent or recurring stomach problems (such as heartburn, upset stomach, or stomach pain), which may be symptoms of an underlying gastrointestinal disorder, against using products containing aspirin (plain or buffered) or other salicylates unless directed by a doctor. Accordingly, the Panel's recommended warning in § 343.50(c)(3)(iv) (redesignated § 343.50(c)(1)(v)(B)) is being revised as follows: "Do not take this product if you have stomach problems (such as heartburn, upset stomach, or stomach pain) that persist or recur, or if you have ulcers or bleeding problems, unless directed by a doctor." This warning is also being revised in § 343.50(c)(2)(v)(B) for products labeled for children 2 years to under 12 years of age.

References

(1) Silvoso, G.R., et al., "Incidence of Gastric Lesions in Patients with Rheumatic Disease on Chronic Aspirin Therapy," *Annals of Internal Medicine*, 91:517–520, 1979.

(2) Lanza, F.L., G.L. Royer, Jr., and R.S. Nelson, "Endoscopic Evaluation of the Effects of Aspirin, Buffered Aspirin, and Enteric-Coated Aspirin on Gastric and Duodenal Mucosa," *New England Journal of Medicine*, 303:136–138, 1980.

32. One comment asserted that warning statements for aspirin drug products should be stated separately. The comment stated that the following warning is the most important warning to the consumer and should be displayed alone on the label so that its effect is not diminished: "Warning: Keep this and all medicines out of children's reach. In case of accidental overdose, contact a physician immediately." The comment stated that all other cautions on the use of aspirin drug products should be under a section designated "Cautions."

The agency agrees that the general warnings quoted above are among the most important provided for all OTC drugs to consumers. These warnings are required for OTC drug products in § 330.1(g) (21 CFR 330.1(g)). The agency agrees that manufacturers should consider displaying these warnings separately from other label warnings or highlighting them to attract consumers' attention.

Concerning the use of the terms "warning" and "caution," section 502(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(f)(2)) states, in part, that any drug marketed OTC must bear in labeling "* * * such adequate warnings * * * as are necessary for the protection of users * * *." Section 330.10(a)(4)(v) of the OTC drug regulations provides that labeling of OTC drug products should include "* * * warnings against unsafe use, side effects, and adverse reactions * * *."

The agency notes that historically there has not been consistent usage of the signal words "warning" and "caution" in OTC drug labeling. For example, in §§ 369.20 and 369.21 (21 CFR 369.20 and 369.21), which list "warning" and "caution" statements for drugs, the signal words "warning" and "caution" are both used. In some instances either

of these signal words is used to convey the same or similar precautionary information.

FDA has considered which of these signal words would be most likely to attract consumers' attention to that information describing conditions under which the drug product should not be used or its use should be discontinued. The agency concludes that the signal word "warning" is more likely to flag potential dangers so that consumers will read the information being conveyed. Therefore, FDA has determined that the signal word "warning," rather than the word "caution," will be used routinely in OTC drug labeling that is intended to alert consumers to potential safety problems. Accordingly, the signal word "caution" is being deleted from the Panel's recommended warnings in § 343.50(c)(3) (iv) and (v), redesignated § 343.50(c)(1)(v) (B) and (C) in this proposed monograph.

33. One comment stated that the first sentence of the aspirin hypersensitivity warning recommended in § 343.50(c)(4)(i), "This product contains aspirin," is redundant for products that display the word "aspirin" in the product name or are clearly labeled as containing "aspirin." The comment stated that part of the next sentence in the warning, "Do not take this product if you are allergic to aspirin * * *," is adequate to warn consumers and that the first sentence should be deleted.

The agency agrees with the comment. Because section 502(e)(1) of the act (21 U.S.C. 352(e)(1)) requires that the established name of the active ingredients contained in a product be included in the label, the statement, "This product contains aspirin," would be redundant. Therefore, in the tentative final monograph this statement is being deleted from the warning.

34. Two comments urged that all children's aspirin products be labeled to include a warning that salicylate intoxication can occur from a therapeutic overdose when "aspirin is repetitively administered to infants and young children *at commonly recommended doses and time intervals.*" The comments argued that parents have been inadequately alerted to the hazards associated with the cumulative effects of salicylate in infants and young children and that parents frequently ignore recommended dosage schedules for aspirin because they think this drug can be administered with relative impunity. The comments further argued that parents will often continue to give aspirin to relieve a child's fever when the fever actually may be due to aspirin toxicity. One comment noted that ringing in the ears (tinnitus) has no value as a warning of toxicity in the pediatric age group because it is subjective, and infants and young children cannot alert the parent to its occurrence. For these reasons the following warning was suggested for all aspirin drug products for children: "Do not exceed recommended doses unless directed by your physician. More than six consecutive doses at four-hour intervals can lead to serious complications in a feverish dehydrated infant or young child."

Two reply comments disagreed with these comments. One argued that the Panel's pediatric dosage schedule and its recommended warnings in § 343.50 (c)(1)(ii) and (c)(2) contain instructions that, when heeded by parents, are adequate to prevent overdosage. These comments also stated that overdoses may occur with any drug and that parents must be alerted not to exceed the recommended dosages of aspirin as well as other drugs. The comments agreed that tinnitus has no value as a warning symptom because it cannot be adequately described by infants and children. However, the comments pointed out that there are observable symptoms of aspirin toxicity, such as hyperpnea, which can be described in labeling as "deep and rapid breathing." The reply comments also stated that dehydration should not be included in the labeling because parents cannot diagnose this condition, which is rare and should be diagnosed by a doctor. The comments also maintained that such labeling would confuse the consumer and obscure other necessary information on the label.

The agency does not believe that children's aspirin drug products should be labeled with a warning stating that salicylate intoxication can occur when aspirin is taken in doses within the recommended dosage schedule (therapeutic overdose). The reports of overdose of salicylates cited by the comments showed that poisoning from accidental ingestion occurs more commonly in children over 2 years of age and that therapeutic overdose is more likely to affect children under 2 years of age (Refs. 1, 2, and 3). The label directions recommended by the Panel for aspirin state, "For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician." Thus, parents are alerted to consult a physician before giving aspirin to children under 2 years of age. The physician is responsible for giving parents specific dosage instructions for aspirin given to children under 2 years of age and for warning parents of the potential dangers of exceeding the recommended dose.

For children 2 years of age and older, the Panel developed a new dosage schedule to help prevent therapeutic salicylate overdose. This dosage schedule not only is based upon a maximal dose that provides effective plasma levels for analgesic and antipyretic effects, but also has a safety margin in case of an inadvertent 50-percent increase in dosage. The agency believes that this children's dosage schedule, which has been slightly revised (see comment 58 below), and the revised warnings in § 343.50(c) (2)(i) and (3) provide adequate guidance to parents to prevent overdosage.

As for the additional labeling suggested by the comments, the agency believes that terms such as "dehydrated" and "deep and rapid breathing" have little meaning to consumers and are not appropriate for consumer labeling of aspirin drug products, although they may be used by doctors in diagnosing conditions due to toxicity. The information in the suggested labeling, "Do not exceed recommended doses unless directed by your physician," is provided in the directions for use by the phrase "or as directed by a doctor" or "unless directed by a doctor" after the usual recommended OTC dosage of the product.

References

(1) Craig, J.O., I.C. Ferguson, and J. Syme, "Infants, Toddlers, and Aspirin," *British Medical Journal*, 1:757–761, 1966.

(2) Done, A.K., and A.R. Temple, "Treatment of Salicylate Poisoning," *Modern Treatment*, 8:528–551, 1971.

(3) Tschetter, P.N., "Salicylism," *American Journal of Diseases of Children*, 106:134–146, 1963.

35. One comment contended that the warning not to take aspirin if taking a prescription drug for arthritis should not be included in the Panel's recommended warning in § 343.50(c)(3)(v). The comment further contended that the major responsibility of warning the consumer of drug interactions should rest with the prescribing physician and that the following statement by the Panel (42 FR 35372) should apply: "* * * physicians always carefully control the patient's use of all other medications, thereby negating the need for a warning."

The agency believes that many consumers who take prescription drugs will also use OTC analgesics and antipyretics, such as salicylates, without a physician's advice. These consumers may be unaware of possible interactions between the salicylates and prescription

drugs and need to be alerted to this possibility in the labeling. Based upon the Panel's discussion of the increased potential for gastric ulceration if aspirin is taken along with another anti-inflammatory agent (42 FR 35409), the agency tentatively concludes that the warning on the concurrent use of salicylates with prescription drugs for arthritis is needed and therefore should be retained. The warning is not intended to prohibit such concurrent use, but to alert consumers to consult a doctor first.

36. Two comments objected to the Panel's recommended warning in § 343.50(c)(3)(v) that advises against the use of salicylates concurrently with prescription drugs for the treatment of gout. The comments asserted that the warning should be modified to apply only to the use of salicylates and uricosuric drugs, which are drugs that promote the excretion of uric acid in the urine. The comments argued that allopurinol, commonly prescribed for gout, is a nonuricosuric drug and is compatible with salicylates.

The agency endorses the labeling recommended in § 343.50(c)(3)(v) to alert consumers to consult a physician before using OTC salicylates with several types of prescription drugs, including those used in the treatment of gout. The agency concludes that differentiating between uricosuric and nonuricosuric drugs in the warnings for OTC salicylate drug products would be meaningless and confusing to consumers. Because the agency believes that it is important for consumers to understand the reason for this warning, it is proposing in the tentative final monograph that the information in § 343.50(c)(3)(v) (redesignated § 343.50(c)(1)(v)(C) in this monograph) be identified as a drug interaction precaution and appear as follows: "*Drug Interaction Precaution.* Do not take this product if you are taking a prescription drug for anticoagulation (thinning the blood), diabetes, gout, or arthritis unless directed by a doctor." This precaution has been modified in § 343.50(c)(2)(v)(C) for products labeled for children 2 years to under 12 years of age. For products labeled both for adults and children, the precaution for adults will apply. (See § 343.50(c)(3).)

37. One comment objected to the warning recommended by the Panel for aspirin and salicylate products in § 343.50(c)(3)(v), asserting that the potential for drug interaction is greater than that expressed in this labeling. The comment explained that because the information on drug interactions is increasing, the consumer who is using prescription medication should consult a physician before using any pain reliever. The comment suggested the following alternative labeling, explaining that it is broader and more inclusive than the Panel's labeling and will provide safer coverage to the consumer: "If you are taking any prescription medication, consult your physician before using any pain reliever."

Another comment suggested the general drug interaction warning, "If you are taking any prescription medications, consult your physician before taking this medication."

The agency believes the labeling suggested by the comments is too general, and consumers might completely ignore its message. In addition, the suggested warnings would not alert consumers to the specific types of drugs that may interact with OTC analgesics. As discussed in comment 35 above, the agency will propose specific drug interaction warnings to consumers when necessary for the safe use of an OTC drug product.

38. Some comments opposed and others favored the Panel's recommended warning in § 343.50(c)(4)(i) against the use of aspirin drug products by consumers who have asthma. The opposing comments stated that the references the Panel cited to support the need for the warning were outdated and included no reports of fatal asthma attacks. The comments argued that the warning is unnecessary because only about 2 percent of asthmatics experience an adverse reaction to aspirin. Asthmatics are under a doctor's care, the comments stated, and the doctor should warn them of possible adverse reactions.

A comment from a consumer, who suffers from asthma and had been unaware that aspirin could precipitate asthma attacks, supported the Panel's warning. The comment insisted that it is necessary to warn asthmatics who may also be unaware that an asthma attack may occur with the use of aspirin drug products. Another supporting comment suggested the following alternative warning to avoid creating consumer anxiety: "If you have asthma * * * consult your physician before using any pain reliever."

The agency is proposing the following warning in § 343.50(c)(1)(iv) for products containing aspirin or carbaspirin calcium: "Do not take this product if you are allergic to aspirin or if you have asthma unless directed by a doctor." The Panel stated that aspirin has long been associated with allergic-type reactions, such as asthma in hypersensitive individuals. In certain instances these reactions can be life-threatening and even fatal (42 FR 35397). The consumer's comment reaffirmed the need to warn asthmatic consumers who may not always be alerted to this danger by a doctor.

The agency is not proposing the warning suggested by one comment because it refers to "any pain reliever" and is thus too broad. The medical literature includes a few reports that certain pain relievers other than aspirin may precipitate asthmatic attacks in aspirin-sensitive patients. However, these reports do not agree on the analgesic drugs implicated and the mechanism of action involved (Refs. 1 through 7). The agency concludes that more data and information are needed to determine the need for an asthma warning for pain relievers other than aspirin drug products.

References

(1) "Analgesics and Asthma," *British Medical Journal*, 3:419–420, 1973.

(2) Assem, E.S.K., "Immunological and Non-Immunological Mechanisms of Some of the Desirable and Undesirable Effects of Anti-Inflammatory and Analgesic Drugs," *Agents and Actions*, 6:212–218, 1976.

(3) Fisherman, E.W., and G.N. Cohen, "Aspirin and Other Cross-Reacting Small Chemicals in Known Aspirin Intolerant Patients," *Annals of Allergy*, 31:476–484, 1973.

(4) Smith, A. P., "Response of Aspirin-allergic Patients to Challenge by Some Analgesics in Common Use," *British Medical Journal*, 2:494–496, 1971.

(5) Szczeklik, A., R. J. Gryglewski, and G. Czerniawska-Mysik, "Relationship of Inhibition of Prostaglandin Biosynthesis by Analgesics to Asthma Attacks in Aspirin-Sensitive Patients," *British Medical Journal*, 1:67–69, 1975.

(6) Szczeklik, A., and C. Czerniawska-Mysik, "Prostaglandins and Aspirin-Induced Asthma" (letter to the editor), *Lancet* 1:488, 1976.

(7) Weinberger, M., "Analgesic Sensitivity in Children With Asthma.," *Pediatrics*, 62:910–915, 1978.

39. One comment disagreed with the wording in the Panel's recommended warning for aspirin and other salicylate products in § 343.50(c)(3)(ii), "Stop taking this product if ringing in the ears or other symptoms occur." The comment argued that the consumer should not be advised to stop taking the product if tinnitus develops because many doctors use tinnitus as a guideline for adjusting a patient's dosage level of aspirin to a therapeutically effective and tinnitus-free level. The comment stated that the phrase "or other symptoms occur" should be deleted from the warning because it is vague and confusing to the consumer. The comment suggested the following alternative: "If ringing in the

ears develops, consult your physician before taking any more medication."

The agency agrees that it is more appropriate to direct consumers with tinnitus to consult a doctor before taking more medication than to "stop taking" the product. The warning is being revised accordingly in the tentative final monograph. In addition, the phrase "or other symptoms occur" is being deleted from the warning because this phrase is synonymous with the phrase "if new symptoms occur," which has been included in the warnings in § 343.50(c)(1)(i), (2)(i), and (3).

The Panel noted that because aspirin or other salicylates produce a reversible ototoxicity manifested by deafness, it is important that patients who are regularly receiving salicylates at higher dosages be monitored by a physician for hearing loss as well as tinnitus. It is particularly important that patients with preexisting hearing loss be frequently monitored because they will not report tinnitus as plasma salicylate levels increase to toxic levels. An example of this was shown in a report from a consumer with a preexisting hearing loss who described a severe additional loss of hearing after using 50 grains (3,250 mg) of enteric-coated aspirin daily for a month (Ref. 1).

In view of the above considerations, the agency proposes to revise the warning, "Stop taking this product if ringing in the ears or other symptoms occur," to read as follows in § 343.50(c)(1)(v)(A) and (2)(v)(A): "If ringing in the ears or a loss of hearing occurs, consult a doctor before taking (giving) any more of this product."

Reference

(1) Letter from a consumer, included in OTC Volume 03BTFM.

40. One comment suggested that the term "bleeding problems" in the Panel's recommended warning in § 343.50(c)(3)(iv) be changed to "blood clotting problem." The comment argued that the term "blood clotting problem" is more accurate medically and would be more useful to consumers than "bleeding problems," which could be interpreted to include a minor cut that bleeds somewhat longer than usual. The comment provided three references to support its position (Refs. 1, 2, and 3).

The references provided by the comment do not suggest that the term "blood clotting problem" has more meaning to consumers than the term "bleeding problems." Two discuss bleeding time and other laboratory measurements (Refs. 1 and 2); the third discusses the side effect of gastrointestinal bleeding from aspirin use (Ref. 3).

The agency believes that the term "bleeding problems" as used in the warning in § 343.50(c)(3)(iv) (redesignated § 343.50(c)(1)(v)(B)) is accurate and useful to consumers. The Panel recommended the wording in this section to warn persons who have bleeding problems that they should not take aspirin except under the advice and supervision of a physician. Persons with bleeding problems such as hemophilia, von Willebrand's disease, thrombosthenia, or thrombocytopathia may react to aspirin drug products with a markedly prolonged bleeding time that might lead to a significant loss of blood in the gastrointestinal tract or elsewhere.

References

(1) Ingelfinger, F. J., "The Side Effects of Aspirin," *New England Journal of Medicine*, 290:1196–1197, 1974.

(2) Kaneshiro, M. M., et al., "Bleeding Time After Aspirin in Disorders of Intrinsic Clotting," *New England Journal of Medicine*, 281:1039–1042, 1969.

(3) Sanfelippo, M. J., and C. V. Hussey, "Thrombopathy; Identification and Distribution," *American Journal of Clinical Pathology*, 61:628–638, 1974.

41. One comment urged that the labeling of aspirin tablets direct consumers to take these products with food or milk. The comment personally attributed an incident of gastrointestinal bleeding to taking aspirin tablets with water rather than with milk or food, and maintained that food or milk would have coated the stomach and prevented the bleeding.

The comment submitted no data to support its viewpoint. The Panel considered whether salicylates should be taken with food, but concluded that it was most important that solid, oral dosage forms containing salicylates be taken with water to lessen the chance of gastric irritation (42 FR 35356). In fact, the Panel recommended the following warnings in § 343.50(c)(3)(iii): (*a*) "Adults: Drink a full glass of water with each dose," and (*b*) "Children under 12 years: Drink water with each dose."

The Panel specified a full glass of water for adults for each dose of salicylates. At gastric pH, 8 ounces or more of water is required to dissolve a dose of aspirin, the most commonly used salicylate. Undissolved salicylate in contact with the gastric mucosa is one cause of gastric irritation following salicylate ingestion. Although salicylate solution is less irritating than undissolved salicylate, the solution could also be irritating to the highly sensitive individual (42 FR 35387). Solid foods would delay the dissolution of salicylates, allowing the undissolved salicylate to remain in contact with the gastric mucosa longer, but liquid foods, such as juice or milk, dissolve salicylate. However, the agency is concerned that, because of their acidity, taking some juices with aspirin may cause more irritation to the stomach than taking aspirin with water. Also, the agency is unaware of any data showing that milk will lessen the gastric irritation caused by aspirin. Therefore, the agency concurs with the Panel that consumers should be advised to take solid, oral dosage forms of salicylates with water to lessen the chance of gastric irritation. The agency believes that these statements belong under the directions for use, rather than in the warnings. Consequently the warnings recommended by the Panel in § 343.50(c)(3)(iii) (*a*) and (*b*) have been designated as directions in § 343.50(d)(3)(i) and (ii) of this tentative final monograph.

42. Two comments urged Category II status for the following labeling claims for buffered aspirin: "Buffering agents to help make the pain reliever more gentle to the stomach," "helps prevent the stomach upset often caused by plain aspirin," "* * * provides ingredients that may prevent the stomach distress that plain aspirin occasionally causes but should not be taken by certain individuals with stomach disorders as cautioned elsewhere on the label," "faster to the bloodstream than plain aspirin," and claims implying more rapid analgesia as a result of an increased absorption rate.

The comments pointed out that the Panel concluded that there is insufficient evidence to substantiate the claims that buffered aspirin or highly buffered aspirin for solution (aspirin and antacid) can be safely used by persons who should not use plain aspirin. The comments stated that these claims may lead consumers to think that buffered aspirin products either give faster or greater pain relief than plain aspirin or cause less or no stomach distress. The comments expressed concern that reliance on claims relating to less stomach distress with buffered aspirin products could lead to a clinical danger in alcoholics and in persons who are prone to ulcers. Referring to claims such as "gets to the bloodstream faster than plain aspirin," the comments argued that blood level studies do not constitute acceptable scientific evidence to show that buffered products of this type are therapeutically superior to plain aspirin.

Other comments urged Category I status for the above labeling claims for buffered aspirin, stating that consumers should be informed of the purpose of buffering, and requested that the agency

provide specific information on the criteria for achieving Category I status for these Category III labeling claims. The comments noted that the Panel stated that the evidence, although conflicting, seems to show a lower incidence of stomach upset produced by buffered aspirin in some patients who exhibit gastric intolerance to plain aspirin (42 FR 35470). The comments also noted that such labeling claims are qualified or modified by the words "may" and "occasionally" and the phrase "* * * but should not be taken by certain individuals with stomach disorders as cautioned elsewhere on this label." The comments contended that the Panel classified stomach upset claims for buffered aspirin as Category III because the Panel believed that the benefits from the use of buffered aspirin in such instances affect only a few consumers, and not because such claims imply that buffered aspirin products have a therapeutic advantage over plain aspirin.

The comments also contended that there is no proof of a lack of relationship between variations in bioavailability of aspirin products and their resultant clinical effect. The comments argued that if a buffered aspirin product is absorbed more rapidly than plain aspirin and provides the consumer with some therapeutic advantage, labeling claims regarding faster absorption, such as "faster to the bloodstream than plain aspirin," would not be misleading to consumers and should be allowed.

The agency's response to these comments covers all buffered aspirin products, including aspirin with antacid products (such as highly buffered aspirin for solution), because the labeling claims apply to all such products.

The Panel found (1) "Comparisons of the most commonly used plain and buffered aspirin show that salicylate blood levels are twice as high in the first 10 to 20 minutes for the buffered aspirin product compared to regular aspirin," (2) "The basic problem is that there are no well-controlled clinical studies that unequivocally prove or disprove that these differences in absorption will result in clinically important differences in the onset, intensity or incidence of relief of pain or fever," and (3) Category III should be used to classify claims which cannot be fully evaluated with present data but have some reasonable basis and can probably be evaluated by further testing, perhaps involving more sensitive methodology." (See 42 FR 35480.) The Panel also expressed concerns that such claims could be confusing to the public.

The agency concurs that the studies submitted to the Panel are inconclusive to support a claim of more rapid action. The agency concludes that although there were apparent higher blood salicylate levels for buffered aspirin in some studies, there remains insufficient evidence on the basis of controlled clinical analgesic studies, that buffered aspirin products provide a more rapid onset, greater peak intensity, or a more prolonged duration of analgesia than unbuffered aspirin. Because no new data have been submitted to answer the Panel's concerns, claims such as "faster to the bloodstream than plain aspirin" remain classified in Category III.

Further, based upon the data submitted to the Panel, the agency concludes that there is not sufficient evidence to clearly demonstrate that buffered aspirin may help those individuals subject to stomach upset associated with aspirin ingestion. The Panel noted that the results, of the clinical studies comparing buffered aspirin to plain aspirin in which the symptom of gastric intolerance was evaluated, appear to be conflicting, but that the data seemed to indicate that buffered aspirin produces a lower incidence of gastric intolerance in some sensitive individuals. (See 42 FR 35480.) Accordingly, the Panel classified the following label claim in Category III: "Provides ingredients that may prevent the stomach distress that plain aspirin causes but should not be taken by certain individuals with stomach disorders as cautioned elsewhere on the label."

Citing the significant variation in dissolution rates among marketed formulations of buffered and unbuffered aspirin products, the Panel stated that the clinical evidence for a given buffered aspirin product could not necessarily be extrapolated to other buffered aspirin formulations. In addition, the Panel noted studies that suggest that an adequately buffered aspirin product may not have an advantage over a well formulated unbuffered product (42 FR 35375). The Panel recommended that specific standards be established for both buffered and unbuffered aspirin products (42 FR 35469). The Panel was uncertain about whether the observed decrease in gastric intolerance of buffered aspirin products was due to the buffering effect on the pH of the microenvironment surrounding the dissolving particles on the stomach lining, the increased dissolution rate, or both. Based on these uncertainties, the Panel stated its opinion that the Category III label claim could be used provided the minimum requirements for buffering capacity (1.9 mEq of acid neutralizing capacity per 325 mg aspirin) are met and the product had a dissolution rate similar to the buffered aspirin used in most of the clinical studies reviewed by the Panel (42 FR 35469 and 35470).

At this time, based upon the data that have been reviewed, the agency agrees that the clinical evidence is inconclusive to support a claim of better gastrointestinal tolerance for buffered aspirin products. However, industry has provided additional data in the form of three new clinical studies (Ref. 2). Detailed information on the disolution profiles and acid neutralizing capacity of the formulations used in these studies were also provided. These data are currently undergoing review by the agency, and will be discussed in the preamble to the final rule for OTC internal analgesic, antipyretic, and antirheumatic drug products.

It should be further noted that after the Panel's report was published, standards for acid neutralization (which is the Panel's recommended standard for acid neutralization for buffered aspirin products) and dissolution rates of buffered aspirin tablets were added to the United States Pharmacopeia (U.S.P.) (Ref. 1). As discussed in comment 98 below, the agency is proposing to incorporate these standards in the internal analgesic monograph. Products that meet these U.S.P standards are identified as "Buffered Aspirin." Accordingly, for buffered aspirin products meeting these standards, the agency is providing for the optional statement "contains buffering ingredients" in this tentative final monograph.

The agency agrees with the comment that consumers should be informed of the purpose of buffering. However, the clinical studies reviewed by the Panel and the Agency, are inconclusive. Until the new data (Ref. 2) are fully evaluated, claims regarding decreased gastric irritation are classified in Category III.

References

(1) "United States Pharmacopeia XXI—National Formulary XVI," Supplement 4, United States Pharmacopeial Convention, Inc., Rockville, MD, p. 2131, 1986.

(2) Comment No. SUP00032, Docket No. 77N-0094, Dockets Management Branch.

43. One comment requested that the claim "faster to the bloodstream than plain aspirin" be allowed for powder dosage forms of aspirin. The comment noted that the Panel acknowledged the rapid absorption of powders by stating: "They [powders] are rapidly absorbed however, often reaching peak blood levels more rapidly than the tablet dosage form" (42 FR 35376). The comment stated that clinical studies

comparing the absorption of an aspirin powder with absorption of aspirin tablets were submitted to the Panel, but there is no indication in the monograph that the Panel considered these studies. The comment also provided a more recent clinical study to support its contention that aspirin in powder form is more quickly absorbed than plain aspirin tablets (Ref. 1).

The studies to which the comment referred were reviewed by the Panel (Ref. 2). Based on these studies and other information, the Panel stated that powders, because of their large surface area, are rapidly absorbed and may often reach peak blood levels more rapidly than tablets.

The additional study submitted by the comment compares the rate of absorption of five different oral aspirin formulations—three in tablet form and two in powder form (Ref. 1). Three minutes after dosing, blood concentrations were higher with the powdered formulations than the tablet formulations. Over a 15-minute period, the powdered aspirin formulations and one buffered aspirin tablet formulation provided the highest blood levels of aspirin.

After considering the above data and information, the agency concurs with the Panel's statement that powders may often reach peak blood levels more rapidly than a tablet dosage form. However, the Panel also concluded that there was a lack of clinical studies that would prove or disprove that such differences in absorption will result in clinically important differences in the onset, intensity, or incidence of relief of pain or fever (42 FR 35480). As discussed in comment 42 above, the agency agrees with the Panel. Because the comment provided no clinical data that demonstrate a relationship between faster absorption and faster or enhanced pain relief, the claim "faster to the bloodstream than plain aspirin" is classified in Category III for powder dosage forms of aspirin. The agency has determined that for this claim to have clinical significance to consumers and to be included in the monograph, data are needed that establish that this effect makes a difference in the onset, intensity, or incidence of relief of pain or fever.

References

(1) Babish, J.G., "A Blood Absorption Study on Aspirin Formulation," draft of unpublished report in Comment No. C00032, Docket No. 77N-0094, Dockets Management Branch.

(2) OTC Volume 030058.

44. One comment requested that the following Category III labeling claims for buffered aspirin products be allowed for carbaspirin calcium: "Faster to the bloodstream than plain aspirin" and "provides ingredients that may prevent the stomach distress that plain aspirin occasionally causes but should not be taken by certain individuals with stomach disorders as cautioned elsewhere on the label." To support its request, the comment pointed out that the Panel concluded that carbaspirin calcium (formerly calcium carbaspirin) has a more rapid dissolution rate than aspirin and that slightly less gastrointestinal bleeding may result from its use (42 FR 35417).

Although carbaspirin calcium may produce slightly less gastrointestinal bleeding than aspirin, the agency notes that the Panel found no evidence that gastric bleeding is related to gastric upset (see comment 46 below); therefore, decreased gastrointestinal bleeding is not sufficient evidence to prove that carbaspirin calcium may be indicated when aspirin cannot be tolerated. With regard to rate of dissolution, the Panel reported on a study by Levy and Hayes that showed that the dissolution half-time of calcium acetylsalicylate carbamide complex (carbaspirin calcium) is the same as that of aspirin buffered with aluminum glycinate and magnesium carbamide (Ref. 1). The authors stated that the incidence of local gastric irritation and the absorption rate of a drug is a function of its dissolution rate (in its particular dosage form). While the results of the study by Levy and Hayes (Ref. 1) are indicative of the rapid dissolution of the product used in the study, an in vitro dissolution test alone is not adequate to support the use of the stomach distress claim for this ingredient. Moreover, because dissolution rates can be significantly influenced by product formulation, the results cannot be extrapolated to other formulations containing carbaspirin calcium. In the absence of any supporting clinical data, the agency is not proposing to include the claim, "provides ingredients that may prevent the stomach distress that plain aspirin occasionally causes but should not be taken by certain individuals with stomach disorders as cautioned elsewhere on the label" for this ingredient in the tentative final monograph and classifies the claim in Category III.

As discussed in comment 42 above, the agency agrees with the Panel that there is a lack of clinical studies to demonstrate that differences in absorption will result in clinically important differences in the onset, intensity, or incidence of the relief of pain or fever. Similarly, the agency concludes that the data are not sufficient to demonstrate that differences in dissolution will result in a clinically important difference in analgesia. Therefore, the agency classifies the claim "faster to the bloodstream than plain aspirin" in Category III for this ingredient. The agency has determined that for this claim to have clinical significance to consumers and to be included in the monograph, data are needed that establish that this effect makes a difference in the onset, intensity, or incidence of relief of pain or fever.

Reference

(1) Levy, G., and B.A. Hayes, "Physicochemical Basis of the Buffered Acetylsalicylic Acid Controversy," *New England Journal of Medicine*, 262:1053–1058, 1960.

45. One comment requested that the following claims for choline salicylate be permitted as Category I labeling: "Acts five times faster than aspirin," "reaches peak action twelve times faster than aspirin," "does not cause the gastrointestinal bleeding associated with the administration of aspirin and other salicylate compounds," "causes less gastric irritation," and "may be taken on an empty stomach and may prevent the stomach distress that aspirin occasionally causes but should not be taken by certain individuals with stomach disorders as cautioned elsewhere on the label." The comment pointed out that the Panel referred to studies showing that choline salicylate does not cause as much gastric bleeding as aspirin and that there is a lower incidence of gastrointestinal distress after choline salicylate administration than after aspirin administration (42 FR 35418). The comment noted that the claims "acts five times faster than aspirin" and "reaches peak action twelve times faster than aspirin" are included in the approved new application (NDA) labeling of choline salicylate.

The OTC drug product referred to by the comment as being the subject of an NDA was approved in 1959. The product was further evaluated under the Drug Efficacy Study Implementation (DESI) Program by the Panel on Neurological Drugs and the Panel on Drugs Used in Rheumatic Diseases. The agency published the Panels' findings in the **Federal Register**, of April 20, 1972 (37 FR 7820). The Panel on Neurological Drugs concluded that adequate studies showed that blood salicylate levels after choline salicylate administration were 5 times as high in 12 minutes and twice as high in 30 minutes but that there were no clinical studies to show that the onset of analgesic action was sooner, greater, or

more prolonged than with aspirin (37 FR 7823). In the same **Federal Register**, the agency stated that any further action on the product was deferred pending completion of the OTC drug review (37 FR 7820).

The Internal Analgesic Panel reported on several studies that indicated that choline salicylate is more rapidly absorbed than aspirin. However, the Panel reached the same conclusion as the DESI Panel on Neurological Drugs that there is a lack of clinical studies to demonstrate that more rapid absorption will result in a significant clinical effect (42 FR 35418). As discussed in comment 42 above, the agency concludes that the claim "faster to the bloodstream than plain aspirin" is a Category III claim because of the lack of such clinical data. Similarly, the agency concludes that the data are not adequate to support the claims "acts five times faster than aspirin" and "reaches peak action twelve times faster than aspirin." The agency notes that the Panel concluded that such claims should be classified in Category II. However, the Panel also concluded that Category III should be used to classify claims that have a reasonable basis and probably can be evaluated by further testing (42 FR 35435 and 35480). The agency concludes that such a reasonable basis exists and that such claims should be classified in Category III. The agency has determined that for this claim to have clinical significance to consumers and to be included in the monograph, data are needed that establish that this effect makes a difference in the onset, intensity, or incidence of relief of pain or fever.

Regarding the claims concerning the effect of choline salicylate on the stomach, the Internal Analgesic Panel concluded that based on its review of the submitted data further testing was required to substantiate claims such as "may be taken on an empty stomach and may prevent the stomach distress that aspirin occasionally causes" and proposed a Category III classification for such statements (42 FR 35418). The Panel did note that choline salicylate like highly buffered aspirin is ingested as a solution and may have a performance action similar to highly buffered aspirin for that reason. In the absence of any new supporting clinical data, the agency is placing the above labeling statement and the related claim "causes less gastric irritation" in Category III.

The agency is not proposing to include in the monograph the claim "does not cause the gastrointestinal bleeding associated with the administration of aspirin and other salicylate compounds." This statement refers to occult bleeding. The agency believes that allowing this claim may confuse or unduly alarm consumers by implying that aspirin frequently or commonly causes overt bleeding (or hemorrhaging) from the gastrointestinal tract. The agency believes that this claim is not appropriate for use in the labeling of OTC internal analgesic drug products containing choline salicylate and therefore proposes that this claim be classified as Category II.

46. One comment requested that products containing magnesium salicylate be allowed to claim that this ingredient has less potential to cause irritation of the gastrointestinal tract than aspirin. The comment contended that a submission to the Panel contained enough data to justify this claim (Ref. 1) and provided a letter from a physician stating that his clinical experience shows that patients tolerate magnesium salicylate better than aspirin. The comment also cited magnesium salicylate's physicochemical characteristics as additional support for the claim that it produces less gastrointestinal irritation than aspirin, explaining that magnesium salicylate goes into solution at a higher pH than aspirin and the magnesium ions may provide some buffering capacity.

The data reviewed by the Panel and cited by the comment included a human study in which a gastrocamera showed that both magnesium salicylate and aspirin caused some irritation of the mucous membranes of the stomach. However, the Panel concluded that the results of the study showed no significant difference in the degree of irritation between the ingredients. From other human studies, using radioactive chromate labeling of red blood cells, the Panel concluded that magnesium salicylate might produce less gastrointestinal bleeding than aspirin (42 FR 35419). However, the Panel concluded that there is no evidence that gastric bleeding is related to gastric upset and that these studies are not sufficient to prove that magnesium salicylate may be indicated when aspirin cannot be tolerated. The agency agrees with the Panel's conclusions. Because no new information has been submitted, the agency is placing the claim that magnesium salicylate has less potential for causing gastrointestinal irritation than does aspirin in Category III. Adequate clinical studies are necessary to support such a claim.

Reference

(1) OTC Volume 030042.

47. Several comments supported the Panel's recommendation against concurrent analgesic-antacid labeling claims for highly buffered aspirin for solution and urged adoption of the stomach distress warning recommended in § 343.50(c)(3)(iv). The comments stated that highly buffered aspirin for solution can cause gastrointestinal distress (stomach distress), peptic ulceration, and massive gastrointestinal bleeding and that the risk of gastrointestinal bleeding increases when this product is used with alcohol. The comments cited a "personal communication" and published studies (Refs. 1 through 5) to support this concern.

Other comments opposed the Panel's recommendation and argued that highly buffered aspirin for solution can be safely used to relieve concurrent symptoms of headache and upset stomach. The comments stated that this drug product does not cause mucosal erosions, and does not cause massive gastrointestinal bleeding, with or without alcohol. The comments stated that the "stomach distress" warning would preclude the marketing of these products for concurrent symptoms of headache and upset stomach. One comment expressed concern that if a highly buffered aspirin for solution cannot be marketed for concurrent symptoms of headache and upset stomach, consumers will substitute less widely used and tested products containing acetaminophen and antacid.

Highly buffered aspirin for solution contains a sufficient quantity of buffering ingredients to conform to the specifications for antacids established in the final monograph for OTC antacid drug products (21 CFR 331.10). Such products have been marketed for consumers with symptoms that require both an analgesic and an antacid, such as headache with heartburn or headache with "upset stomach."

In the final monograph for OTC antacid drug products published in the **Federal Register** of June 4, 1974 (39 FR 19869), the agency concluded that there is a significant target population for which a combination product containing a salicylate and an antacid provides rational concurrent therapy. The agency further concluded that because the safety evidence for the use of analgesic-antacid combination products is derived from studies and experience with products intended for administration as a solution, the use of these combinations for concurrent symptoms should be limited to these types of products (39 FR 19869 and 19875). When the final monograph for OTC antacid drug

products was published, the agency had received no data to show that such a combination product would be unsafe to use for concurrent symptoms, nor have such data been received since publication of the advance notice of proposed rulemaking for OTC internal analgesic drug products. The agency has also not received any data showing that highly buffered aspirin for solution presents the risk of massive gastrointestinal hemorrhage or that using these products with alcohol increases the risk of massive gastrointestinal bleeding in normal individuals. References 1 through 5, cited by one comment, discuss the association of alcohol and aspirin products with gastrointestinal bleeding, but do not provide sufficient evidence that the use of highly buffered aspirin and alcohol is associated with massive gastrointestinal bleeding. The agency could not assess the "personal communication" because the comment did not provide a copy.

The agency concurs with the Internal Analgesic Panel's recommendation that aspirin products should not be used by consumers who have ulcers, bleeding problems, or recurring or persistent stomach problems. This recommendation is supported by the findings of a study on gastrointestinal hemorrhage in persons with stomach problems who used an aspirin-antacid for solution combination product (Ref. 6). However, the agency finds a lack of data to preclude the use of aspirin-antacid products as an analgesic-antacid for concurrent symptoms of headache and heartburn, etc., provided the product is intended for ingestion as a solution and provides at least 5 mEq of acid-neutralizing capacity (as specified in § 331.10(a)). Therefore, the agency is proposing that any highly buffered aspirin for solution or other aspirin-antacid product for solution be identified as a "pain reliever-fever reducer" (or the variation permitted in § 343.50(a)) and "antacid." (Products containing acetaminophen with antacid, identified in § 343.20(b)(1) in the tentative final monograph, are also being identified in the same manner.) However, the agency is not proposing to restrict acetaminophen-antacid products to dosage forms intended for ingestion as a solution because acetaminophen does not have the adverse effects on the gastrointestinal tract that are associated with aspirin (see 42 FR 35413).

The agency recognizes that in addition to a target population which uses highly buffered aspirin for solution and other aspirin with antacid products for concurrent symptoms of minor aches and pains and acid indigestion, there are consumers who also use such products just for analgesic-antipyretic use alone. The agency concludes that these products are safe and effective for both uses and that the labeling of these products should provide for use of the product for either concurrent symptoms or analgesic-antipyretic use alone. The agency notes that currently marketed products are labeled for both uses.

Therefore, the agency is proposing the following statements of indications for products containing aspirin with antacid, based on the indications for analgesic-antipyretic ingredients in § 343.50(b)(1) and the indications for antacids in § 331.30(b). New § 343.60(b)(4) for aspirin with antacid products (aspirin and antacid combinations) is being added to the tentative final monograph as follows:

(4) *For permitted combinations identified in § 343.20(b)(3).* The indications are the following: "For the temporary relief of minor aches and pains with" (select one or more of the following: "heartburn," "sour stomach," or "acid indigestion") [which may be followed by: "and upset stomach associated with" (select one of the following, as appropriate: "this symptom" or "these symptoms")] and "Also may be used for the temporary relief of minor aches and pains alone" [which may be followed by one or more of the following: ("such as associated with" (select one or more of the following: "a cold," "the common cold," "sore throat," "headache," "toothache," "muscular aches," "backache" "the premenstrual and menstrual periods" (which may be followed by: "(dysmenorrhea)"), or "premenstrual and menstrual cramps" (which may be followed by: "(dysmenorrhea)")]), ("and for the minor pain from arthritis"), and ("and to reduce fever.")]

Although the above indications apply to aspirin with antacid products, such products should not be used by persons who have persistent or recurring stomach problems, such as acid indigestion, or who have ulcers or bleeding problems, as stated in the warnings in § 343.50(c) (1)(v)(8) and (2)(v)(8). (See comment 31 above.)

The agency is proposing that products containing acetaminophen with antacid be identified according to §§ 331.30 and 343.50 and bear labeling indications in accordance with § 343.60(b)(2). The agency believes that the proposed labeling for acetaminophen with antacid products and for aspirin with antacid products (including highly buffered aspirin for solution products) provides for the safe and effective OTC use of both combinations.

The agency is aware that the Antacid Panel recommended that any generally recognized as safe and effective analgesic ingredient could be combined with any antacid for concurrent symptoms (38 FR 8724) and that this recommendation is included in the final monograph for OTC antacid drug products (21 CFR 331.15(b)). However, this recommendation was based on data submitted for an aspirin-antacid combination product and an acetaminophen-antacid combination product both in forms intended for ingestion as a solution. No data were submitted to either the Antacid Panel or the Internal Analgesic Panel to support combinations of other Category I analgesics, especially non-aspirin salicylates, e.g., magnesium salicylate with an antacid. Because there are not sufficient data to support such combinations and because of a lack of evidence of the marketing of these combinations, the agency is not proposing to include combinations of non-aspirin salicylates (i.e., choline salicylate, magnesium salicylate, and sodium salicylate) and carbaspirin calcium with antacids in this tentative final monograph and is classifying such combinations in Category III. The final monograph for OTC antacid drug products currently provides for antacid-analgesic combinations marketed in a form intended for ingestion as a solution only (21 CFR 331.15(b)). That monograph, which was developed many years ago, provides for an antacid to be combined with any generally recognized as safe and effective analgesic ingredient(s). However, as discussed above, certain possible combinations have never been marketed and lack supporting data. Therefore, elsewhere in this issue of the **Federal Register**, the agency is proposing to amend the antacid final monograph so that it and the internal analgesic monograph will be consistent.

References

(1) Needham, C.D., et al., "Aspirin and Alcohol in Gastrointestinal Haemorrhage," *Gut*, 12:819–821, 1971.

(2) Jennings, G.H., "Causal Influences in Haematemesis and Melaena," *Gut*, 6:1–13, 1965.

(3) Astley, C.E., "Gastritis, Aspirin, and Alcohol" (letter to the editor), *British Medical Journal*, 4:484, 1967.

(4) Mould, G., "Faecal Blood-Loss after Sodium Acetylsalicylate Taken with Alcohol" (letter to the editor), *Lancet*, 1:1268, 1969.

(5) Croft, D.N., "Gastritis," *British Medical Journal*, 4:164–166, 1967.

(6) Innes, J.A., M.J. Ford, and J.F. Munro, "Gastro-Intestinal Haemorrhage Following

Ingestion of 'Alka-Seltzer,'" *Scottish Medical Journal*, 25:105–106, 1980.

48. One comment asserted that the terms "extra strength" and "extra pain relief" should be allowed in describing products containing 500 mg acetaminophen. The comment contended that these terms are justified because 1,000 mg (two 500-mg tablets) acetaminophen provides greater pain relief than 650 mg acetaminophen (two 325-mg tablets). Other comments opposed the use of such labeling claims. One comment proposed that the labeling of products containing nonstandard dosage units contain a statement denying the therapeutic advantage of products labeled in this manner.

The agency recognizes, as the Panel did, that the OTC drug market currently includes many different products containing analgesic-antipyretic drugs, either as single active ingredients or in combination with other active ingredients. Most of these products contain either aspirin or acetaminophen in varying amounts of active ingredients(s) per dosage unit.

The Panel believed that the availability of products containing different amounts of aspirin per dosage unit is confusing to consumers and encouraged the current use of claims such as "higher levels of pain reliever." To inform the consumer more fully of the contents and therapeutic capabilities of these products and to minimize confusion, the Panel recommended that products be clearly labeled as to the amount of active ingredient per dosage unit. The Panel further recommended the establishment of standard dosage units for aspirin, acetaminophen, and sodium salicylate (42 FR 35357). Based on these criteria, the Panel proposed that these ingredients and comparable analgesic drugs be labeled as containing either a "standard" or "nonstandard" dosage unit. As discussed in comment 53 below, the agency will not require the terms "standard" and "nonstandard" in labeling.

The Panel did not specifically address the terms "extra strength" and "extra pain relief," but did recommend a wide dosage range for which OTC analgesic-antipyretic drug products are safe and effective. The Panel recommended a 325-mg minimum effective dose, but also recognized 650 mg as the usual single dose. Furthermore, the Panel found that there may be circumstances when more than the usual single dose may be needed for an adequate effect, provided the daily dosage does not exceed 4,000 mg in a 24-hour period (42 FR 35360), and thus recommended OTC dosage ranges of 325 to 650 mg every 4 hours, more than 325 mg to 500 mg every 3 hours, or 842 to 1,000 mg every 6 hours.

In general, the agency concurs with the Panel's recommended dosage schedule, which is flexible and which provides for a wide dosage range per dosage unit. (See comment 53 below for further discussion.) Terms such as "extra strength" may be helpful to consumers by alerting them to the fact that products bearing such labeling may not necessarily contain the quantity of analgesic-antipyretic that is contained in other products they have purchased. However, the agency tentatively concludes that "extra strength," "maximum strength," "extra pain relief," and similar terms that are only peripherally related to product safety and effectiveness are outside the scope of the OTC drug review. Therefore, these terms will not be included in labeling required by the monograph, but may be used elsewhere in labeling, but not intermixed with monograph labeling, subject to the provisions of section 502 of the act. The agency encourages drug manufacturers voluntarily to provide consumers with an explanation of terms such as "extra strength" and "maximum strength" when they are used in labeling.

49. One comment requested that the professional labeling recommended in § 343.80 be amended to include an indication for the use of aspirin for transient ischemic attacks. Another comment requested that buffered aspirin also be included in this indication. The comments presented data to support their requests (Ref. 1).

A transient ischemic attack is a sudden onset of a focal neurologic dysfunction that may precede a stroke. It affects the brain or retina and clears after a period lasting from a few seconds up to 24 hours. The data submitted by the comments included two multicenter clinical studies as follows: a 37-month trial conducted by Fields et al. (Ref. 2) and a 55-month trial conducted by The Canadian Cooperative Study Group (Ref. 3).

The study by Fields et al. was a randomized, double-blind trial comparing aspirin with placebo in 178 patients to determine the incidence of subsequent transient ischemic attack, death, cerebral infarction, or retinal infarction. Only persons with episodes of monocular blindness or hemispheric-type transient ischemic attacks were eligible for admission to the study. Persons with symptoms in the carotid area were included, and those with only vertebrobasilar symptoms were excluded. Another requirement was that the most recent transient ischemic attack had occurred not more than 3 months prior to randomization. The absolute endpoints studied were mortality, retinal infarctions, and cerebral infarctions.

The analysis of the absolute endpoints, i.e., death or cerebral or retinal infarction, failed to show a statistically significant differential between aspirin and placebo. However, because the primary objective of the study was to determine whether aspirin would result in a reduction of transient ischemic attacks, a second class of endpoints was used to evaluate the patients' experience during the first 6 months of follow-up (after randomization). Endpoints included not only infarctions (cerebral or retinal) but also the number of transient ischemic attacks reported. When the absolute endpoints were coupled with the occurrence of transient ischemic attack in the first 6 months of follow-up, there was a statistically significant differential (p 0.01) in favor of aspirin. When the patients were separately grouped according to whether they had a single carotid transient ischemic attack or multiple attacks before admission to the study, a life table analysis of absolute endpoints revealed a statistical significance in favor of aspirin within the group of patients with multiple attacks. When the occurrence of carotid transient ischemic attacks during the first 6 months of follow-up was also taken into consideration, analysis of patients who had single or multiple transient ischemic attacks revealed a statistically significant differential in favor of aspirin.

The study conducted by the Canadian Cooperative Study Group was a randomized, four-treatment, double-blind trial to determine whether aspirin or sulfinpyrazone, singly or in combination, was superior to placebo in preventing transient ischemic attacks, stroke, or death in patients afflicted with transient ischemic attacks or partial nonprogressing stroke in either carotid or vertebral territory (Ref. 3). Approximately 65 percent of the 585 subjects had symptoms suggesting brain ischemia in the area supplied by the carotid artery; 25 percent of the subjects were affected in the area supplied by the vertebrobasilar artery; and 10 percent of the subjects had both the vertebrobasilar and carotid arteries affected. Patients with hemodynamic (pertaining to the movements involved in the circulation of the blood) or cardiac causes were excluded from the study. The average period of followup was 26 months. The compliance rate was 92 percent.

Three endpoints were assessed in the study: Transient ischemic attack, stroke, and death. If any of these endpoints occurred by the end of the trial, or within 6 months of withdrawal where treatment had been terminated, they were counted against their randomly assigned treatment regimen. None of the 3 drug treatment groups was significantly different from the placebo treatment group for any endpoint, but when the 2 treatment groups taking aspirin (i.e., aspirin alone and aspirin with sulfinpyrazone) were compared with the two groups that were not taking aspirin (i.e., the groups taking sulfinpyrazone alone or placebo) for the combined endpoints of stroke and death, the reduction with aspirin was 31 percent ($p<0.05$). In subset analysis, the benefit from aspirin therapy was confined to males, with a 48-percent reduction in stroke and death ($p<0.005$). There was no significant benefit in females in either treatment category.

Based upon the data described above, the agency's Peripheral and Central Nervous System (CNS) Drugs Advisory Committee concluded that there is evidence that aspirin is safe and effective for reducing the risk of recurrent transient ischemic attacks or stroke in men who have had transient ischemia of the brain due to fibrin platelet emboli (Refs. 2, 3, and 4). In concluding that aspirin is safe and effective in reducing these risks in males, the Committee recommended a dosage of 1,300 mg aspirin per day in divided doses of 650 mg twice a day or 325 mg four times a day.

Studies were submitted on the absorption characteristics of buffered aspirin and plain aspirin products (Refs. 5 and 6). Nayak et al. (Ref. 5) conducted three blinded studies (A, B, and C) on the effect of antacids on aspirin dissolution and bioavailability. The 12 normal adult subjects (8 male, 4 female) abstained from using any medication 1 week before and during the studies.

Study A was conducted to determine the absorption characteristics of four aspirin formulations with different buffering capacity and in vitro dissolution profile. Each subject abstained from solid food and liquids, except water, from midnight of each study day. The subjects were randomly divided into four equal groups assigned to the rows of a selected 4 x 4 Latin square. On each of the test days, which were 1 week apart, a single dose (2 tablets) of each of the following formulations was given: 325 mg aspirin; 325 mg aspirin with 150 mg aluminum hydroxide gel and 150 mg magnesium hydroxide; 325 mg aspirin with 75 mg aluminum hydroxide gel and 75 mg magnesium hydroxide; and 325 mg aspirin with 50 mg aluminum glycinate and 100 mg magnesium carbonate. A pretest blood sample was collected, and each subject was given a single dose of the formulations with 200 mL water.

Blood samples were collected at various intervals; the plasma was separated and frozen before being analyzed. Results were expressed as the total salicylate concentration in salicylic acid equivalents, and a pharmacokinetic analysis of data was performed. The results showed that the buffered formulations produced significantly higher peak concentrations of plasma salicylate than the unbuffered formulation. However, a comparison of the area-under-curve values showed no statistically significant difference among formulations.

Study B was conducted to assess the effect that doubling the aspirin and antacid dose would have on the absorption of aspirin. The subjects and methods were identical to study A except that each subject was given a single dose of four tablets containing 325 mg aspirin, 150 mg aluminum hydroxide gel, and 150 mg magnesium hydroxide per tablet. A pharmacokinetic analysis of data was performed.

In study C, 2 hours after a meal of 1 cup of dry cereal, 8 oz of whole milk, 6 oz of orange juice, sugar, and 1 cup of coffee or tea, three male subjects received four tablets of the same formulation used in study B (Ref. 5). The subjects swallowed the tablets with 200 mL water. The blood sampling and analysis were the same as in study A, except that blood was collected without anticoagulant and processed for serum.

The results of studies B and C showed that the concentration-time profile and the bioavailability were similar in both studies. Thus, there was no evidence of a lower or erratic absorption of aspirin due to the antacids used as compared with unbuffered aspirin.

A study was conducted to determine whether the aspirin in a commercial buffered aspirin product containing 325 mg aspirin and 150 mg magnesium-aluminum hydroxide was as effective as 325 mg plain aspirin in inhibiting platelet aggregation in vitro (Ref. 6). The methodology was collagen-induced aggregation of guinea pig or human platelets (in vitro). Separate solutions of aspirin and the buffered aspirin product were prepared using sterile saline solution. Each solution contained 3.25 mg aspirin per mL, equivalent to a molar aspirin concentration of 1.8×10^{-2}. Subsequent dilutions were used at a log concentration ratio of 1.5. Nonfasted male guinea pigs weighing 300 to 500 g were used throughout the study. When human platelets were used, they were separated and handled in the same way as those collected from guinea pigs.

Platelet aggregation assays were conducted, and the data were quantified by calculating area-under-curve values for each dilution. Aspirin and the buffered aspirin product were first compared in an experiment to find a dose range.

The results showed that both the plain aspirin and the buffered aspirin product would produce dose-related inhibitory effects on the aggregation of guinea pig platelets in the range of 1.8×10^{-4} to 1.8×10^{-5} molar concentration. The concentration for 50 percent inhibition (IC_{50}) was found to be 1.3×10^{-4} molar for the aspirin in the plain aspirin product. In the buffered aspirin product the IC_{50} was found to be 1.4×10^{-4} molar. The investigators concluded that the similarity of the IC_{50} values indicates there is no difference between the effect of plain aspirin and the effect of the buffered aspirin product on platelet aggregation. The IC_{50} values for aspirin and the buffered aspirin product on human platelets (1.4×10^{-4} and 1.3×10^{-4}, respectively) were close to those found for guinea pig platelets. The slopes of the respective regression lines were similar, indicating no specific differences.

The investigators concluded that plain aspirin and the buffered aspirin product are equally effective in inhibiting collagen-induced aggregation of both guinea pig and human platelets in vitro and that the buffered aspirin product would be as useful as plain aspirin in the prevention of transient ischemic attacks.

Based upon the Peripheral and CNS Drugs Advisory Committee's recommendation on aspirin and transient ischemic attacks and the agency's review of the data submitted to show that buffered aspirin would be expected to have similar effects, the agency concludes that both aspirin and buffered aspirin can be used for reducing the risk of recurrent transient ischemic attacks or stroke in males. This use of aspirin and buffered aspirin is being proposed for incorporation into the professional labeling section of the tentative final monograph, with the recommended dosage of 1,300 mg aspirin per day in divided doses of 650 mg twice a day or 325 mg four times a day. The agency believes that sodium-containing buffered aspirin should not be used for this purpose because the chronic ingestion of sodium is ill-advised in this patient population.

The agency also points out that aspirin or buffered aspirin without sodium is not indicated in all forms of sudden onset of focal neurologic dysfunction simulating transient ischemic attacks. Also, the effects of concurrent administration of therapeutic amounts of antacids on the absorption and the elimination of aspirin must be considered, but the current literature contains minimal information on these effects.

Levy et al. (Ref. 7) conducted a study on three children with rheumatic fever to determine whether serum salicylate concentrations are affected by an antacid containing aluminum and magnesium hydroxide. Aspirin bioavailability (completeness of absorption) was estimated from the amount of total salicylate excreted in the children's urine over a 2-hour period, with urine specimens collected during the antacid and control periods. The investigators found that the estimated daily excretion was in reasonably good agreement with the daily dose and did not decrease during antacid administration.

Levy et al. (Ref. 7) also investigated the effect of an antacid containing aluminum and magnesium hydroxide on the bioavailability of aspirin in five healthy adult males. Each subject received two 325-mg tablets of aspirin 1 hour after a breakfast of 28 g corn flakes and 500 mL milk. The tablets were swallowed whole with 50 mL water. Two of the subjects first received only aspirin; the other three were given 20 mL aluminum and magnesium hydroxide suspension with 50 mL water immediately after the aspirin was ingested. No food or coffee was permitted for 4 hours, and each subject's urine was collected periodically for 48 hours.

About 1 week later, crossover experiments compared the percentage of salicylate recovered in each subject's urine with aspirin given alone to the percentage recovered when the aspirin-antacid was given. Results (expressed as total salicylate recovered) showed that the antacid product containing aluminum and magnesium hydroxide had no apparent effect on aspirin absorption.

In addition, while reviewing data on the use of aspirin for myocardial infarction, the agency identified certain information that it considers pertinent to the use of aspirin for the prevention of transient ischemic attacks (see comment 50 below). In the Aspirin Myocardial Infarction Study (AMIS) (Ref. 8), the dosage of 1,000 mg per day of aspirin was associated with small increases in blood pressure, blood urea nitrogen, and serum uric acid levels. This dosage was also associated with increased incidences of gastrointestinal symptoms including stomach pain, heartburn, nausea and/or vomiting, as well as gross gastrointestinal bleeding. Because the dosage of aspirin proposed for the prevention of transient ischemic attacks is 1,300 mg, the agency believes that this information should be included in the proposed professional labeling for aspirin for transient ischemic attacks.

References

(1) Comment Nos. SUP005, SUP011, and CP, Docket No. 77N-0094, Dockets Management Branch.

(2) Fields, W.S., et al., "Controlled Trial of Aspirin in Cerebral Ischemia," *Stroke* 8:301-316, 1977.

(3) The Canadian Cooperative Study Group, "A Randomized Trial of Aspirin and Sulfinpyrazone in Threatened Stroke," *New England Journal of Medicine*, 299:53-59, 1978.

(4) Minutes of the FDA Peripheral and CNS Drugs Advisory Committee, August 28, 1979, included in OTC Volume 03BTFM.

(5) Nayak, R.K., et al., "Effect of Antacids on Aspirin Dissolution and Bioavailability," *Journal of Pharmacokinetics and Biopharmaceutics*, 5:597-613, 1977.

(6) W.H. Rorer, Inc., Research Division, "The Inhibition by Ascriptine of Collagen-Induced Aggregation of Guinea Pig and Human Platelets in Vitro," unpublished report in Vol. 2 of Citizen's Petition (CP), Docket No. 77N-0094, Dockets Management Branch.

(7) Levy, G., et al., "Decreased Serum Salicylate Concentrations in Children with Rheumatic Fever Treated with Antacid," *New England Journal of Medicine*, 293:323-325, 1975.

(8) Aspirin Myocardial Infarction Study Research Group, "A Randomized, Controlled Trial of Aspirin in Persons Recovered from Myocardial Infarction," *Journal of the American Medical Association*, 243:661-699, 1980.

Based upon the above discussion, the agency is proposing in § 343.80(b) the following indications, precautions, and dosage in the professional labeling:

For products containing aspirin identified in § 343.10(b) or permitted combinations identified in § 343.20(b)(4) except those containing sodium. The labeling states, under the heading "ASPIRIN FOR TRANSIENT ISCHEMIC ATTACKS," the following:

Indication:

For reducing the risk of recurrent transient ischemic attacks (TIA's) or stroke in men who have had transient ischemia of the brain due to fibrin platelet emboli. There is inadequate evidence that aspirin or buffered aspirin is effective in reducing TIA's in women at the recommended dosage. There is no evidence that aspirin or buffered aspirin is of benefit in the treatment of completed strokes in men or women.

Clinical Trials:

The indication is supported by the results of a Canadian study [1] in which 585 patients with threatened stroke were followed in a randomized clinical trial for an average of 26 months to determine whether aspirin or sulfinpyrazone, singly or in combination, was superior to placebo in preventing transient ischemic attacks, stroke, or death. The study showed that, although sulfinpyrazone had no statistically significant effect, aspirin reduced the risk of continuing transient ischemic attacks, stroke, or death by 19 percent and reduced the risk of stroke or death by 31 percent. Another aspirin study carried out in the United States with 178 patients, showed a statistically significant number of "favorable outcomes," including reduced transient ischemic attacks, stroke, and death.

Precautions:

Patients presenting with signs and symptoms of TIA's should have a complete medical and neurologic evaluation. Consideration should be given to other disorders that resemble TIA's. Attention should be given to risk factors: It is important to evaluate and treat, if appropriate, other diseases associated with TIA's and stroke, such as hypertension and diabetes.

Concurrent administration of absorbable antacids at therapeutic doses may increase the clearance of salicylates in some individuals. The concurrent administration of nonabsorbable antacids may alter the rate of absorption of aspirin, thereby resulting in a decreased acetylsalicylic acid/salicylate ratio in plasma. The clinical significance of these decreases in available aspirin is unknown.

Aspirin at dosages of 1,000 milligrams per day has been associated with small increases in blood pressure, blood urea nitrogen, and serum uric acid levels. It is recommended that patients placed on long-term aspirin treatment be seen at regular intervals to assess changes in these measurements.

Adverse Reactions:

At dosages of 1,000 milligrams or higher of aspirin per day, gastrointestinal side effects include stomach pain, heartburn, nausea and/or vomiting, as well as increased rates of gross gastrointestinal bleeding. (Other applicable warnings related to the use of aspirin as described in § 343.50(c) may also be included here.)

Dosage and Administration:

Adult oral dosage for men is 1,300 milligrams a day, in divided doses of 650 milligrams twice a day or 325 milligrams four times a day.

References

(1) The Canadian Cooperative Study Group, "A Randomized Trial of Aspirin and Sulfinpyrazone in Threatened Stroke," *New England Journal of Medicine*, 299:53-59, 1978.

(2) Fields, W.S., et al., "Controlled Trial of Aspirin in Cerebral Ischemia," *Stroke*, 8:301-316, 1977.

50. One comment submitted data (Ref. 1) and requested that the professional labeling recommended in § 343.80 be

expanded to include an indication for the use of aspirin in the prophylaxis of secondary myocardial infarction. Another comment submitted data (Ref. 2) and requested the agency to issue professional labeling guidelines that provide for the use of highly buffered aspirin in solution to prevent myocardial infarction in men with unstable angina.

The agency has reviewed the submitted data and determined that aspirin is effective in reducing the risk of death and/or non-fatal myocardial infarction in patients with a previous infarction or unstable angina pectoris. The agency evaluated six secondary prevention trials (Refs. 3 through 8) and one controlled clinical trial of unstable angina (Ref. 9). Although none of the six secondary prevention trials individually showed a significant aspirin effect on mortality, the pooled results did show a moderately impressive statistically significant reduction in the occurrence of death and/or non-fatal myocardial infarction. Five of the six secondary prevention trials showed a favorable trend. Two of the individual studies showed a significant effect, and two others showed a near significant effect ($p=0.06$, $p=0.08$) on the combined endpoint of non-fatal infarction and/or death, as well as on non-fatal infarction alone. The pooled results showed a highly significant aspirin treatment effect on the combined or non-fatal infarction endpoint. The post-infarction and unstable angina trials, while studies of different diseases, mutually support each other by showing effects on the same endpoint. The trials also provide pertinent dosing information.

Five of the six secondary prevention trials used doses of 1,000 mg per day or more; one of these trials and the unstable angina trial used about 300 mg per day. The latter two trials, along with considerable pharmacologic evidence that platelet-induced thrombogenesis can be reduced by doses near 300 mg and the expectation that gastrointestinal bleeding would likely be less prominent at lower dosages, have led the agency to conclude that 300 mg (or a conventional 325 mg dose) of aspirin per day is effective for the prevention of myocardial infarction in patients with a previous myocardial infarction or unstable angina.

In the secondary prevention trials, aspirin treatment was started at intervals after the onset of acute myocardial infarction varying from less than three days to more than five years and continued for periods of from less than one year to four years. Treatment within a week of onset of myocardial infarction was not shown to be beneficial in the cases presenting with acute infarction in the unstable angina trial. The data did show beneficial trends for stronger effects in the first six months after acute infarction and for the first two years after starting treatment. However, these trends were not well enough established to justify limiting treatment to these intervals. Due to this uncertainty, the labeling that the agency is proposing does not include any specific recommendation regarding when to start or stop aspirin treatment.

Most of the subjects in the secondary prevention trials and all of those in the unstable angina trials were male. Due to the small numbers of females in the studies, the use of aspirin for this indication in women cannot be supported by available data. However, the agency does not believe that use in women is necessarily unreasonable and the professional labeling that the agency is proposing does not discourage such use, but simply notes the limitation on the number of females in the clinical trials.

In the Aspirin Myocardial Infarction Study (AMIS) (Ref. 3), the aspirin-treated group showed a small increase in blood pressure after adjustment for baseline pressure. Similar findings for other United States aspirin trials of secondary prevention were also found. While these blood pressure elevations were clinically small, the agency believes that this finding should be included in the labeling. The agency also believes that it should be kept in mind that only about 10 percent of the subjects were hypertensive at baseline and that the blood pressure eligibility restrictions in these trials were such that severely hypertensive subjects were not entered (Refs. 4 and 5). Aspirin treated groups in both the AMIS trial and the United States aspirin studies showed small but definite increases in blood urea nitrogen and uric acid; thus, the agency concludes that during the course of long-term aspirin therapy users of this drug should be monitored regularly to assess changes in these measurements.

Based on the data from the unstable angina trial of Lewis et al. (Ref. 9), which used one 325 mg dose of aspirin in a highly buffered solution, the agency has concluded that highly buffered aspirin for solution (aspirin/antacid combination (see comment 76 below)) as well as buffered aspirin in a solid dosage form is safe and effective to reduce the risk of death and/or non-fatal myocardial infarction in patients with a previous myocardial infarction or unstable angina. However, the agency believes that sodium intake should be considered in this patient population and has included a statement concerning the amount of sodium in the aspirin/antacid combination in the Lewis trial (Ref. 9) and how much this amount of sodium adds to the intake suggested as appropriate for the dietary treatment of essential hypertension in the "1984 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure" (Ref. 10).

In conclusion, the agency is proposing that the professional labeling section of the tentative final monograph (i.e., information provided to health professionals only, and not to the general public) should include aspirin for the indication, "to reduce the risk of death and/or non-fatal myocardial infarction in patients with a previous myocardial infarction or unstable angina pectoris." The agency is proposing in § 343.80(c) the following professional labeling:

For products containing aspirin identified in § 343.10(a) or permitted combinations identified in § 343.20(b),(3) and (4). The labeling states, under the heading "ASPIRIN FOR MYOCARDIAL INFARCTION," the following: *Indication:*

Aspirin is indicated to reduce the risk of death and/or non-fatal myocardial infarction in patients with a previous infarction or unstable angina pectoris. *Clinical Trials:*

The indication is supported by the results of six large, randomized multicenter, placebo-controlled studies involving 10,816, predominantly male, post-myocardial infarction (MI) patients and one randomized placebo-controlled study of 1,266 men with unstable angina [1-7]. Therapy with aspirin was begun at intervals after the onset of acute MI varying from less than 3 days to more than 5 years and continued for periods of from less than 1 year to 4 years. In the unstable angina study, treatment was started within 1 month after the onset of unstable angina and continued for 12 weeks, and patients with complicating conditions such as congestive heart failure were not included in the study.

Aspirin therapy in MI patients was associated with about a 20-percent reduction in the risk of subsequent death and/or non-fatal reinfarction, a median absolute decrease of 3 percent from the 12- to 22-percent event rates in the placebo groups. In aspirin-treated unstable angina patients the reduction in risk was about 50 percent, a reduction in the event rate of 5 percent from the 10-percent rate in the placebo group over the 12-weeks of the study.

Daily dosage of aspirin in the post-myocardial infarction studies was 300 milligrams in one study and 900 to 1,500 milligrams in 5 studies. A dose of 325 milligrams was used in the study of unstable angina.

Adverse Reactions:

Gastrointestinal Reactions:

Doses of 1,000 milligrams per day of aspirin caused gastrointestinal symptoms and bleeding that in some cases were clinically

significant. In the largest post-infarction study (the Aspirin Myocardial Infarction Study (AMIS) with 4,500 people), the percentage incidences of gastrointestinal symptoms for the aspirin (1,000 milligrams of a standard, solid-tablet formulation) and placebo-treated subjects, respectively, were: stomach pain (14.5 percent; 4.4 percent); heartburn (11.9 percent; 4.8 percent); nausea and/or vomiting (7.6 percent; 2.1 percent); hospitalization for gastrointestinal disorder (4.8 percent; 3.5 percent). In the AMIS and other trials, aspirin-treated patients had increased rates of gross gastrointestinal bleeding. Symptoms and signs of gastrointestinal irritation were not significantly increased in subjects treated for unstable angina with buffered aspirin in solution.

(Other applicable warnings related to the use of aspirin as described in § 343.50(c) may also be included here.)

Cardiovascular and Biochemical:

In the AMIS trial, the dosage of 1,000 milligrams per day of aspirin was associated with small increases in systolic blood pressure (BP) (average 1.5 to 2.1 millimeters) and diastolic BP (0.5 to 0.6 millimeters), depending upon whether maximal or last available readings were used. Blood urea nitrogen and uric acid levels were also increased, but by less than 1.0 milligram percent.

Subjects with marked hypertension or renal insufficiency had been excluded from the trial so that the clinical importance of these observations for such subjects or for any subjects treated over more prolonged periods is not known. It is recommended that patients placed on long-term aspirin treatment, even at doses of 300 milligrams per day, be seen at regular intervals to assess changes in these measurements.

Sodium in Buffered Aspirin for Solution Formulations:

One tablet daily of buffered aspirin in solution adds 553 milligrams of sodium to that in the diet and may not be tolerated by patients with active sodium-retaining states such as congestive heart or renal failure. This amount of sodium adds about 30 percent to the 70- to 90-millequivalents intake suggested as appropriate for dietary treatment of essential hypertension in the "1984 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure".[8]

Dosage and Administration:

Although most of the studies used dosages exceeding 300 milligrams, 2 trials used only 300 milligrams and pharmacologic data indicate that this dose inhibits platelet function fully. Therefore, 300 milligrams or a conventional 325 milligram aspirin dose is a reasonable, routine dose that would minimize gastrointestinal adverse reactions. This use of aspirin applies to both solid, oral dosage forms (buffered and plain aspirin) and buffered aspirin in solution.

References

(1) Elwood, P.C., et al., "A Randomized Controlled Trial of Acetylsalicylic Acid in the Secondary Prevention of Mortality from Myocardial Infarction," *British Medical Journal*, 1:436-440, 1974.

(2) The Coronary Drug Project Research Group, "Aspirin in Coronary Heart Disease," *Journal of Chronic Diseases*, 29:625-642, 1976.

(3) Breddin K., et al., "Secondary Prevention of Myocardial Infarction: A Comparison of Acetylsalicylic Acid, Phenprocoumon or Placebo," *Homeostasis*, 470:263-268, 1979.

(4) Aspirin Myocardial Infarction Study Research Group, "A Randomized, Controlled Trial of Aspirin in Persons Recovered from Myocardial Infarction," *Journal of the American Medical Association*, 243:661-669, 1980.

(5) Elwood, P.C., and P.M. Sweetnam, "Aspirin and Secondary Mortality after Myocardial Infarction," *Lancet*, II:1313-1315, December 22-29, 1979.

(6) The Persantine-Aspirin Reinfarction Study Research Group, "Persantine and Aspirin in Coronary Heart Disease," *Circulation*, 62:449-461, 1980.

(7) Lewis, H.D., et al., "Protective Effects of Aspirin Against Acute Myocardial Infarction and Death in Men with Unstable Angina, Results of a Veterans Administration Cooperative Study," *New England Journal of Medicine*, 309:396-403, 1983.

(8) "1984 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure," United States Department of Health and Human Services and United States Public Health Service, National Institutes of Health, Publication No. NIH 84-1088, 1984.

The agency's detailed comments and evaluations of the data are on file in the Dockets Management Branch (Refs. 11 and 12).

References

(1) Comments Nos. C00108, SUP015, SUP020, and SUP026, Docket No. 77N-0094, Dockets Management Branch.

(2) Comment No. CP0005, Docket No. 77N-0094, Dockets Management Branch.

(3) Aspirin Myocardial Infarction Study Research Group, "A Randomized Controlled Trial of Aspirin in Persons Recovered From Myocardial Infarction," *Journal of the American Medical Association*, 245:661-669, 1980.

(4) The Coronary Drug Project Research Group, "Aspirin in Coronary Heart Disease," *Journal of Chronic Diseases*, 29:625-642, 1976.

(5) The Persantine-Aspirin Reinfarction Study Research Group, "Persantine and Aspirin in Coronary Heart Disease," *Circulation*, 62:449-461, 1980.

(6) Elwood, P.C., et al., "A Randomized Controlled Trial of Acetylsalicylic Acid in the Secondary Prevention of Mortality From Myocardial Infarction," *British Medical Journal*, 1:436-440, 1974.

(7) Breddin, K., et al., "Secondary Prevention of Myocardial Infarction: A Comparison of Acetylsalicylic Acid, Phenprocoumon or Placebo," *Homeostasis*, 470:263-268, 1979.

(8) Elwood, P.C., and P.M. Sweetnam, "Aspirin and Secondary Mortality After Myocardial Infarction," *Lancet*, II:1313-1315, December 22-29, 1979.

(9) Lewis, H.D., et al., "Protective Effects of Aspirin Against Acute Myocardial Infarction and Death in Men With Unstable Angina, Results of a Veterans Administration Cooperative Study," *New England Journal of Medicine*, 309:396-403, 1983.

(10) "1984 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure," United States Department of Health and Human Services and United States Public Health Service, National Institutes of Health, Publication No. NIH 84-1088, 1984.

(11) Letter from W.E. Gilbertson, FDA, to G.R. Pflug, Miles Laboratories, Inc., coded LET049, Docket No. 77N-0094, Dockets Management Branch.

(12) Letter from W.E. Gilbertson, FDA, to E.J. Hiross, Sterling Drug, Inc., coded LET048, Docket No. 77N-0094, Dockets Management Branch.

C. Comments on Advertising of Internal Analgesic Drug Products

51. Several comments suggested that changes be made in the quality and quantity of advertisements for OTC internal analgesic drug products to eliminate "excessive claims for minor differences in drug properties" and to reduce the likelihood of consumers being unduly persuaded or misled by such inappropriate statements. Another comment contended that consumers often do not realize from current OTC analgesic drug advertising that many of these products contain aspirin. An example of such advertising is as follows: "Contains more of the pain killer which doctors prescribe most." The comment urged that FDA require manufacturers to state in their advertising that their products contain aspirin.

The Federal Trade Commission (FTC) has the primary responsibility for regulating OTC drug advertising, and FDA has forwarded copies of the comments concerning internal analgesic advertising to the FTC for its consideration (Ref. 1). FDA does, however, have the authority to regulate OTC drug advertising that constitutes labeling under the Federal Food, Drug, and Cosmetic Act. See, e.g., *United States* v. *Article of Drug * * * B-Complex Cholinos Capsules*, 362 F.2d 923 (3d Cir. 1966); *V.E. Irons, Inc.* v. *United States*, 244 F.2d 34 (10th Cir.), *cert. denied*, 354 U.S. 923 (1957). In addition, for an OTC drug to be generally recognized as safe and effective and not misbranded, the advertising for the drug must satisfy the FDA regulations in § 330.1(d) (21 CFR 330.1(d)), which state that the advertising may prescribe, recommend, or suggest the drug's use only under the conditions stated in the labeling. If advertising for an OTC internal analgesic drug product offers the drug product for conditions not included in

the final monograph labeling, the drug product may be subject to regulatory action by FDA.

Reference

(1) Letter from L. Geismar, FDA, to W.B. Fisherow, FTC, June 18, 1981, included in OTC Volume 03BTFM.

52. Several comments asserted that the Panel extended its review beyond its charter by making statements concerning the advertising of the products under its review. The comments stated that FDA did not grant such authority in the procedures established for OTC drug advisory review panels. The comments further argued that the Panel's statements on OTC drug advertising were not only inappropriate for inclusion in the report, but also were based on inadequate information because, according to FDA procedures, data and information pertaining to advertising were not submitted to the Panel.

The OTC drug review procedures do not preclude a panel from expressing its concern about OTC drug advertising. The statements of opinion on advertising and the media were included by the Panel in its report upon the recommendation of the Panel's consumer liaison representative (Ref. 1). These statements were partly based on a transcript of the proceedings of a conference sponsored by the Federal Communications Commission and the FTC and attended by representatives of consumer advocate groups, pharmaceutical associations and manufacturers, the broadcast media, and the academic community.

The Panel discussed OTC drug advertising in its report in order to make its concerns known to the FTC, as well as to FDA.

Reference

(1) Summary Minutes of the 20th Meeting of the Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Drug Products, June 25, 26, and 27, 1975, incorporated in OTC Volume 030173.

D. Comments on Standard Dosage Unit and Analgesic Equivalence Value

53. Some comments supported the Panel's recommendation for standard dosage units and standard dosage schedules for all marketed OTC internal analgesic drug products containing aspirin, acetaminophen, and sodium salicylate as single ingredients. The comments stated that adopting this recommendation would benefit consumers by reducing the confusion and misuse that result from the current availability of various dosage strengths and dosage schedules of these ingredients. The comments argued that consumers are used to taking "two (325-mg) aspirin tablets" for pain relief and could ingest toxic amounts of aspirin from using dosage units larger than 325 mg. The comments maintained that dosages greater than 650 mg (two 325-mg tablets) do not provide "substantial benefit to a sufficient portion of the public" to justify making dosage unit strengths greater than 325 mg generally available.

Several comments opposed the standard and nonstandard labeling recommended by the Panel in § 343.50(d), arguing that such labeling implies differences in quality or therapeutic effect, would confuse consumers, and crowd information on the label. Several comments also opposed the concept of standard dosage units and standard dosage schedules, arguing that adopting them would deprive consumers of products with which they have been satisfied and would result in dosage changes in the labeling that may be overlooked by consumers. Some comments also argued that the concept of standard dosage unit is unsupported because various dosage levels of aspirin, acetaminophen, and sodium salicylate are safe and effective and show increasing effectiveness with increased dosages. To resolve "inconsistencies" in the dosage units and schedules, one comment recommended that the adult dosage unit for aspirin, acetaminophen, and sodium salicylate be 325 mg (standard) and 500 mg or 650 mg (nonstandard). The comment also recommended a maximum single dose of 1,000 mg for each of these ingredients with a 4-hour dosage interval and a maximum daily dose of 4,000 mg.

The agency agrees with the comments in opposition to the Panel's recommendation on standard and nonstandard labeling. The agency does not believe that use of the terms "standard" and "nonstandard" would simplify the comparison of various products containing different quantities of active ingredients or would aid consumers in selecting an OTC analgesic-antipyretic drug product. In addition, the agency is not aware that the existing manner of labeling these products has caused consumer confusion or resulted in misuse of these products. Therefore, the Panel's recommendation on standard and nonstandard labeling is not being included in this tentative final monograph.

The Panel was aware that degrees of pain and analgesic responses vary and thus provided for safe and effective OTC adult analgesic dosage ranges for aspirin and sodium salicylate of 325 to 650 mg every 4 hours, more than 325 to 500 mg every 3 hours, or 842 to 1,000 mg every 6 hours. (See the Panel's recommended § 343.10 (a) and (f).) For acetaminophen, the Panel's recommended dosage ranges were 325 to 650 mg every 4 hours, 500 mg every 3 hours, or 1,000 mg every 6 hours. (See the Panel's recommended § 343.10(b).) As stated in comment 63 below, the agency believes that it is reasonable for acetaminophen to have the same dosage and frequency of administration as aspirin. The agency is revising the dosage schedule for acetaminophen to conform to that of aspirin. In addition, the dosage of "more than" 325 mg to 500 mg every 3 hours is being restated as 325 mg to 500 mg every 3 hours to include the 325-mg minimal effective dose. Likewise, in consideration of the various analgesic dosage unit strengths currently being marketed, the agency is proposing that the dosage of 842 to 1,000 mg every 6 hours be revised to 650 to 1,000 mg every 6 hours to include the maximum recommended dose to be taken every 4 hours (i.e., 650 mg) as a minimum dose taken every 6 hours. The agency invites specific comment on this proposal.

Based upon the above conclusions and dosage recommendations, the dosage schedules for aspirin, acetaminophen, and sodium salicylate recommended by the Panel in § 343.10 (a), (b), and (f) are being revised to eliminate the concepts of "standard" and "nonstandard" schedules and are being combined under § 343.50(d)(2). The Panel's definitions of standard dosage units for these ingredients in § 343.3 (c), (m), and (p) are not being proposed in this tentative final monograph.

The agency notes that the Panel discussed a maximum initial single dose of 975 mg (15 grains (gr)) (three dosage units of 325 mg each) in a 4-hour dosing regimen (43 FR 35361) and recommended this loading dose for aspirin, acetaminophen, and sodium salicylate (§ 343.12 (a)(ii), (b)(ii), and (f)(ii)). The agency is not proposing a loading dose for these ingredients because it believes that such a provision may confuse consumers and lead to repeated dosing of 975 mg every 4 hours instead of 325 mg to 650 mg every 4 hours. For reasons stated in comments 62 and 63 below, the agency is not proposing an OTC dose of 975 mg (15 gr) or 1,000 mg every 4 hours.

54. Two comments objected to the standard dosage unit concept because it is not applicable to liquid products or a product containing aspirin in a gum base. One comment argued that it is inappropriate to use the standard

dosage unit concept for certain liquids that contain combinations of analgesic ingredients and cough/cold ingredients. The other comment, noting that the advance notice of proposed rulemaking did not provide for a nonstandard dosage unit of 227.5 mg (3.5 gr) aspirin, requested that §§ 343.10(a) and 343.12(a) be expanded to include this nonstandard dosage unit, which is identical to that of the gum base product.

As stated in comment 53 above, the agency is not adopting the Panel's recommendation for a standard dosage unit of 325 mg for OTC analgesic drug products. However, the dosage schedules of all OTC internal analgesic drug products, including liquid and gum base dosage forms, will have to comply with the final monograph when it is published. (See comments 53 above and 58 below.)

55. One comment stated that in establishing standard and usual doses the agency should not limit manufacturers to the exact metric equivalent of 10 gr, or its approximation, 650 mg. The comment pointed out that because the "United States Pharmacopeia" (U.S.P) (Ref. 1) recognizes 600 mg as the approximate metric equivalent of 10 gr, products containing either 600 or 650 mg (or the exact equivalent of 648 mg) should be allowed to use the term "usual dose."

Although the U.S.P recognizes 600 mg as an approximate equivalent to 10 gr (Ref. 2), the agency is not including the comment's suggestion that quantities other than 650 mg be equivalent to 10 gr because it agrees with the Panel's recommendation that the system of weight measurement for OTC internal analgesic drug products should be based on 1 gr being equivalent to 65 mg (42 FR 35357.)

The "usual dose" of OTC analgesic-antipyretic drugs is any of the doses that conform with the dosages specified in this tentative final monograph in the section on directions. However, the agency is not allowing use of the term "usual dose" as a descriptive term for the same reasons that it did not adopt the use of the terms "standard" and "nonstandard." (See comment 53 above.)

References

(1) "United States Pharmacopeia XX—National Formulary XV." United States Pharmacopeial Convention, Inc., Rockville, MD (inside back cover), 1980.

(2) "United States Pharmacopeia XXI—National Formulary XVI, United States Pharmacopeial Convention, Inc., Rockville, MD (inside back cover), 1985.

56. Several comments opposed the adoption of the Panel's recommended labeling statement in § 343.50(e) on analgesic equivalence value for calcium carbaspirin, choline salicylate, and magnesium salicylate. The comments contended that such labeling would crowd the required information on the label, confuse consumers, and imply that one product is more, or less, effective than another when in fact all products included in the monograph are safe and effective. Other comments, although not opposed to analgesic equivalence labeling, stated that such labeling is confusing and suggested alrernative labeling statements.

The agency agrees with the comments that such statements could be misleading to consumers. All products that meet the specifications of the monograph are safe and effective. Therefore, the agency is not adopting the analgesic equivalence value labeling statements recommended by the Panel, and § 343.50(e), statement on analgesic equivalence value, and § 343.3 (a), (i), and (o), definitions of acetaminophen, aspirin, and sodium salicylate equivalence values, are not being included in this tentative final monograph.

57. One comment argued that the 325-mg (5 gr) unit dose restriction recommended by the Panel was not appropriate for analgesic powders. The comment contended that analgesic powders represent a dosage form in which the dosage and dosage unit are equivalent. For example, one powder envelope usually contains the equivalent of two tablets of "standard" aspirin. Because the Panel allowed an initial maximum dosage of 1,000 mg and also a 1,000-mg dosage every 6 hours, the comment requested that the agency permit a dosage of 1,000 mg or less in one powder envelope, provided the Panel's dosage schedule is followed and the total daily dose does not exceed 4,000 mg.

As discussed in comment 53 above, the agency is proposing not to adopt the Panel's recommendation for a specific adult dosage unit strength. Thus, OTC analgesic-antipyretic powders may be formulated with a 1,000-mg dosage unit strength per powder envelope. However, the dosage schedules of analgesic-antipyretic powders must be in conformance with the final monograph.

E. Comments on Recommended Dosage Schedules

58. One comment urged that the Panel's recommendation in §§ 343.10(a)(2) and 343.12(a)(2) be revised by increasing the children's dosage unit for aspirin products from 80 mg (1.23 gr) to 81 mg (1.25 gr) and revising the children's dosage schedule accordingly. The comment contended that the 80-mg dosage unit is unavailable in aspirin products and that conversion to an 80-mg dosage unit would invalidate all currently available stability data for children's aspirin products. The comment argued that the availability of the 81-mg (1¼ gr) dosage unit is recognized in §§ 201.314(c) (1) and (2) (21 CFR 201.314(c) (1) and (2)) and in the USP (Ref. 1). The comment concluded that a dosage schedule based on the 81-mg dosage unit is consistent with the dosage schedules for aspirin in §§ 343.10(a)(1)(i) and 343.12(a)(1)(i) because 325 mg is a more accurate multiple of 81 mg than of 80 mg.

The agency acknowledges that there has been longstanding acceptance of the 81-mg (1¼ gr) children's dosage unit for aspirin and agrees with the comment that it should be retained. Children's acetaminophen products are marketed in an 80-mg dosage unit strength, but the difference between 80-mg and 81-mg dosage unit strengths is of no therapeutic consequence. Thus, the agency believes that the children's dosage unit for aspirin, acetaminophen, and sodium salicylate should be either 80 mg or 81 mg, and the dosage schedule for children's products is being revised accordingly.

In addition, the agency notes that the recommended dose of aspirin, acetaminophen, and sodium salicylate for children 6 to 9 years of age is 325 mg (or 320 mg when four 80-mg dosage units are used and 324 mg when four 81-mg dosage units are used). Because this dose (i.e., 325 mg) is also the minimal effective dose for adults, the agency sees no reason to exclude it from the children's dosage schedule as the minimal effective dose for children over 9 years of age. The agency has no data to show that a minimal effective dose for children over 9 years of age poses a danger of therapeutic failure and subsequent overdose with resultant toxicity, as is the case with younger age groups.

In view of the above discussion, the children's dosage schedule for aspirin, acetaminophen, and sodium salicylate that is based upon the children's dosage unit of 80 mg or 81 mg is as follows:

Age (years)	Number of 80-mg or 81-mg dosage units	Dosage (mg) [1]
Under 2	Consult a doctor.	
2 to under 4	2	160 or 162
4 to under 6	3	240 or 243
6 to under 9	4	320 or 324

Age (years)	Number of 80-mg or 81-mg dosage units	Dosage (mg) [1]
9 to under 11	4 to 5	320 to 405
11 to under 12	4 to 6	320 to 486

[1] Dose may be repeated every 4 hours while symptoms persist, up to five times a day or as directed by a doctor.

The children's dosage schedule for aspirin, aceaminophen, and sodium salicylate that is based upon the adult dosage unit of 325 mg is as follows:

Age (Years)	Number of 325-mg dosage units	Dosage (mg) [1]
Under 2	Consult a doctor.	
2 to under 4	1/2	162.5
4 to under 6	3/4	243.8
6 to under 9	1	325
9 to under 11	1 to 1¼	325 to 406.3
11 to under 12	1 to 1½	325 to 487.5

[1] Dose may be repeated every 4 hours while symptoms persist, up to five times a day or as directed by a doctor.

In § 343.50(d)(1) in the tentative final monograph, the agency is converting the dosage information in the schedules above to directions that provide concise instructions for the consumer. The agency proposes that adult dosage unit strengths exceeding 325 mg, particularly in solid dosage forms, are not suitable for use in children, because of the difficulty in dividing such dosage units to obtain an accurate children's dose.

Children's dosage units comparable to the 80-mg and 81-mg units discussed above are being proposed for carbaspirin calcium, choline salicylate, and magnesium salicylate in § 343.50(d)(4), (5), and (6) in this tentative final monograph.

Reference

(1) "United States Pharmacopeia XIX," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 39, 1975.

59. Two comments objected to the Panel's recommendation that dosage schedules for children should be based on age, asserting that they should be based on weight instead. The comments argued that dosages based on age are inaccurate because any group of children of the same age will vary in size and weight, and that the dosage schedules of virtually all other drugs are based on weight rather than age. A comment also stated that the recommended children's dosages, with relatively slight differences between adjacent age groups, are unduly complex and unwarranted.

The Panel, in reaching its recommendation on a children's dosage schedule, considered extensive data and information on pediatric dosage regimens, including toxicity potential, dosage calculation based on weight versus body surface area, and adequacy of product labeling (42 FR 35366). The agency agrees with the Panel that a children's dosage schedule based on age is acceptable because it correlates closely with dosages calculated on the basis of surface area, and because the average consumer will more readily understand such a schedule, as people usually know the child's age but do not always know the child's weight.

In addition, the agency has published a notice of intent requesting comments concerning pediatric dosing information for all OTC drug products. (See the **Federal Register** of June 20, 1988; 53 FR 23180.) This notice invites public comment on how pediatric dosing information can best be presented in OTC drug product labeling. This notice mentions that comments made in response to several OTC cough-cold tentative final monographs requested that pediatric dosages for cough-cold drug products provide a greater subdivision of age ranges that more closely approximate weight-based dosages and that are similar to the age ranges recommended by the Internal Analgesic Panel for OTC internal analgesic-antipyretic drug products for children. The notice also discusses requests that the use of weight ranges be allowed, on an optional basis, in OTC drug pediatric labeling in addition to age range labeling (53 FR 23183). The agency has not proposed any regulatory changes in this notice, but will consider all aspects for pediatric dosing information, including the use of weight ranges, for all OTC drug products in a future **Federal Register** publication.

60. One comment suggested that children aged 2 to 3 years be excluded from the children's dosage schedule for OTC aspirin drug products because they cannot communicate symptoms of disease, and these symptoms are often difficult for parents to recognize. The comment suggested that the directions for children aged 2 to 3 years should be "as directed by a physician" because illness can develop rapidly within this age group.

The agency agrees with the Panel's recommendation that the minimum age for OTC use of analgesic-antipyretic drugs is 2 years. Aspirin is used in children 2 to 3 years of age primarily to reduce fever and relieve the aches and pains that often accompany it—symptoms that children can communicate to parents or that parents can readily recognize. Based upon pharmacokinetic considerations and clinical data, the Panel recommended a safe and effective dosage schedule that could be followed by parents in treating children over 2 years of age. The agency concurs with this dosage schedule. However, the agency emphasizes that if the fever persists, the underlying cause of the fever should be determined and treated by a physician. The warnings in § 343.50(c) (2)(i) and (3) for analgesic-antipyretic drug products, limiting use for fever in children to 3 days unless directed by a doctor and advising physician consultation for persistent or worsening fever or new symptoms, are guides to parents in the safe and effective use of these products in children, as are the directions for use in § 343.50(d).

61. One comment suggested that the children's dosage schedule be more clearly displayed and that duplicate words and phrases be eliminated. Another comment stated that the dosage schedule recommended by the Panel is confusing and complex because dosage regimens are provided for ingredients as analgesics and as antipyretics, with doses listed in exact figures (such as 7.38 gr and 59.68 gr) rather than rounded figures.

The children's dosage schedule is intended to indicate clearly to drug manufacturers the specific dose of particular ingredients for specific age groups. However, these dosage schedules are not intended to appear on the label in the format they appear in the monograph. Rather, the label directions should use dosage form units (tablets, capsules, measure of liquid) and should specify, based on the monograph, the quantity of drug in each children's dosage unit and the dosage intervals.

In addition, information contained in the monograph labeling directions may be condensed on the label to provide concise dosage instructions for the consumer. Duplicated words and phrases may be eliminated. The children's dosage schedules for 80-mg, 81-mg, and 325-mg dosage units have been converted to directions that provide concise instructions for the consumer. (See § 343.50(d)(1).)

62. One comment requested that the agency allow a dosage schedule of 15 gr (975 mg) aspirin every 4 hours up to four doses (4 g) per day. The comment provided data to support its view that such a dosage regimen does not present a serious threat of toxicity (Ref. 1). The comment also maintained that this dosage schedule, rather than a 6-hour schedule, would offer consumers the convenience of undisrupted sleep.

A reply comment stated that the dosage schedule recommended by the

Panel should be followed and that no deviations from this schedule should be allowed. The reply comment expressed concern that the 975-mg dose of aspirin might be used beyond the daily maximum of four doses and present a toxicity problem.

The agency disagrees with the comment's request for an aspirin dosage regimen of 15 gr (975 mg) aspirin every 4 hours, not to exceed four doses per day. The agency concurs with the Panel's statement that this dosage regimen would not provide any significant improvement in analgesic or antipyretic effectiveness (42 FR 35361). Furthermore, although the total daily dosage of this regimen does not exceed the maximum aspirin daily dosage of 4 g (60 gr), the agency is concerned that a four-hour dosage interval for a 975 mg dose may result in consumers ignoring the daily maximum limit of four doses with continued use possibly leading to salicylate toxicity. (See also comment 63 below.)

Reference

(1) Comment No. C00060, Docket No. 77N-0094, Dockets Management Branch.

63. Two comments objected to the Panel's recommendation that following an initial dose of 1,000 mg acetaminophen (two dosage units of 500 mg each), subsequent doses should be restricted to 500 mg every 3 hours or 1,000 mg every 6 hours. Stating that this recommendation was based upon the dosage recommended for aspirin, the comments contended that, given the linear pharmacokinetics of acetaminophen, it is irrational to base acetaminophen's dosage and frequency of administration on the nonlinear pharmacokinetics of aspirin. One comment urged that the dosage for acetaminophen be 1,000 mg every 4 to 6 hours, not to exceed 4 g in 24 hours.

The agency is not adopting the comment's recommendation of an acetaminophen dosage regimen of 1,000 mg every 4 hours for the same reason it is not adopting the regimen of 975 mg aspirin every 4 hours. (See comment 62 above.)

The agency believes at this time that it is reasonable for acetaminophen and aspirin to have the same dosage and frequency of administration because, based upon the data submitted to the Panel, the safe and effective OTC dosage ranges for acetaminophen and aspirin are the same—325 mg to 650 mg every 4 hours, not to exceed 4 g in 24 hours. Also, aspirin and acetaminophen are indicated for the same OTC uses, have been extensively promoted as comparable OTC analgesics (with different side effects), and are widely and interchangeably used by consumers.

The agency concurs with the Panel's recommended acetaminophen dosage regimens of 500 mg every 3 hours and 1,000 mg every 6 hours because these dosages are in accord with the safe and effective dosage range for acetaminophen, i.e., 325 mg to 650 mg every four hours (not to exceed 4 g in 24 hours). Based on computer simulations (Ref. 1), pharmacokinetic parameters obtained from the literature (Refs. 2 through 5), and bioavailability data comparing a 650-mg dose with a 1,000-mg dose of acetaminophen (Ref. 6), the agency has determined that a 1,000-mg dose of acetaminophen every 6 hours yields a pharmacokinetic profile equivalent to that of a 650-mg dose of acetaminophen every 4 hours. A 500-mg dose of acetaminophen every 3 hours yields a blood level profile that also is similar to that of a 650-mg dose of acetaminophen every 4 hours. Therefore, the agency is proposing alternative dosage regimens for acetaminophen of 500 mg every 3 hours and 1,000 mg every 6 hours as part of the dosage schedule in § 343.50(d)(2) of the tentative final monograph. As discussed in comment 53 above, the agency is proposing the following dosages for acetaminophen, aspirin, and sodium salicylate: 325 to 650 mg every 4 hours, 325 to 500 mg every 3 hours, or 650 to 1,000 mg every 6 hours.

References

(1) OTC Volume 03BTFM.

(2) Albert, K.S., A.J. Sedman, and J.G. Wagner, "Pharmacokinetics of Orally Administered Acetaminophen in Man," *Journal of Pharmacokinetics and Biopharmaceutics*, 2:381–393, 1974.

(3) Cummings A.J., B.K. Martin, and G.S. Park, "Kinetic Considerations Relating to the Accrual and Elimination of Drug Metabolites," *British Journal of Pharmacology and Chemotherapy*, 29:136–149, 1967.

(4) Slattery, J.T., and G. Levy, "Acetaminophen Kinetics in Acutely Poisoned Patients," *Clinical Pharmacology and Therapeutics*, 25:184–195, 1979.

(5) Prescott, L. F., and N. Wright, "The Effects of Hepatic and Renal Damage on Paracetamol Metabolism and Excretion Following Overdosage: A Pharmacokinetic Study," *British Journal of Pharmacology*, 49:602–613, 1973.

(6) Research Division, McNeil Laboratories, Inc., "Acetaminophen Plasma Level Profile Following Tylenol Acetaminophen Extra Strength Capsules and APAP/R.S. Acetaminophen Tablets, Metabolic Study No. 54," Biochemical Research Report No. 199 (780306), unpublished report, included in OTC Volume 03BTFM.

64. One comment requested that the Panel's recommended monograph be revised to state that 377 mg magnesium salicylate is equivalent to 325 mg sodium salicylate rather than the 325-mg quantity of magnesium salicylate specified by the Panel (42 FR 35420). The comment explained that commercial sodium salicylate is substantially anhydrous (Refs. 1 and 2), but that magnesium salicylate is commercially available as the tetrahydrate, which contains the equivalent of about 74.5 percent salicylic acid. Assuming that the salicylic acid content is the active moiety of analgesic salicylates and because sodium salicylate contains 86.3 percent salicylic acid, the comment calculated that about 1.16 times more magnesium salicylate tetrahydrate, or 377 mg (325 mg x 1.16), is needed to be equivalent to 325 mg sodium salicylate.

The comment also pointed out that the Panel's recommended monograph does not state the molecular composition of magnesium salicylate and requested that it be clarified to state that 377 mg magnesium salicylate tetrahydrate is equivalent to 325 mg sodium salicylate. The comment concluded that, as stated in the Panel's monograph, one could assume that the difference in the salicylic acid content between 325-mg doses of magnesium salicylate and sodium salicylate could affect the therapeutic response, especially in a multidose regimen.

The agency agrees that 377 mg magnesium salicylate tetrahydrate is equivalent to 325 mg sodium salicylate. The Panel's recommendation of 325 to 650 mg magnesium salicylate every 4 hours for analgesic effect was based on data submitted on a product containing 325 mg of the tetrahydrate form of magnesium salicylate (Ref. 3). However, for adult dosage schedules for aspirin, acetaminophen, and sodium salicylate, the Panel recommended a minimum effective dosage of 325 mg for each of these ingredients (42 FR 35358), with which the agency concurs. Based upon a minimum effective dosage of 325 mg sodium salicylate, the minimum effective dosage of magnesium salicylate tetrahydrate that would contain an equivalent amount of salicylic acid is 377 mg. Therefore, the maximum dosage for magnesium salicylate should be 754 mg instead of 650 mg, and the dosages for magnesium salicylate are being revised accordingly in this tentative final monograph, which now also specifies that the dosages are based on the tetrahydrate form of magnesium salicylate (§ 343.50(d)(6)).

References

(1) Windholz, M., editor, "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 1120, 1976.

(2) "National Formulary XIV," American Pharmaceutical Association, Washington, p. 656, 1975.

(3) OTC Volume 030042.

F. Comments on Combination Drug Products and Inactive Ingredients

65. One comment objected to the Panel's recommendation in § 343.20 for combining 325 mg each of aspirin and acetaminophen in a single dosage unit for OTC use. The comment contended that because of the complex pharmacokinetics of aspirin, any combination of aspirin and acetaminophen should be subject to the requirements of a new drug application (NDA). Referring to a study by Cotty et al. (Ref. 1), the comment stated that using acetaminophen and aspirin together results in higher blood levels of aspirin than when the same quantity of aspirin is administered alone.

Other comments supported the recommended provision for combining aspirin and acetaminophen. These comments stated that such a combination should not be precluded and may be useful by sparing the side effects of each ingredient. One comment also referred to the srudy by Cotty et al. (Ref. 1) and argued that concomitant use of aspirin and acetaminophen resulted in higher blood levels of unhydrolyzed aspirin, and not total salicylate, and that except for "very specific side effects" this should not be associated with an increase in overall toxicity.

The study by Cotty et al. (Ref. 1) indicates that acetaminophen administered with aspirin appeared to increase blood concentrations of unhydrolyzed aspirin. These investigators expected no increase in toxicity because the toxicities of salicylic acid and aspirin are similar. They concluded that the increase in aspirin blood concentration and duration would be expected "to produce a net increase in pharmacologic activity over the sum of the activities of the individual drugs administered alone" because aspirin is a more potent analgesic than salicylic acid. However, this conclusion is not supported by the results of a study by Wallenstein (Ref. 2). This study demonstrated that a subtherapeutic combination of 210 mg aspirin and 150 mg acetaminophen (a 360-mg total) was essentially equivalent in analgesic effect to 360 mg of either ingredient alone and that 420 mg aspirin combined with 300 mg acetaminophen was essentially equivalent in analgesic effect to 720 mg of either ingredient alone.

After evaluating the studies discussed above, the agency concludes that the combination containing 325 mg each of aspirin and acetaminophen does not increase the overall toxicity of either ingredient in adults. (For a discussion of the use of OTC internal analgesic-antipyretic combination drug products in children, see comment 66 below.) The data provided do not support the comment's contention that because of the "complex pharmacokinetics of aspirin," combinations of aspirin and acetaminophen should be subject to the requirements of an NDA. Therefore the Panel's provision for a combination containing a 325-mg minimal effective dose each of aspirin and acetaminophen is being proposed in this monograph. However, unlike the Panel's recommendation in § 343.20(a) (1) and (2), the tentative final monograph does not require that 325 mg of each ingredient be contained in a single dosage unit. (See comment 72 below.)

References

(1) Cotty, V.O.F., et al., "Augmentation of Human Blood Acetylsalicylate Concentrations by the Simultaneous Administration of Acetaminophen with Aspirin," *Toxicology and Applied Pharmacology*, 41:7–13, 1977.

(2) Wallenstein, S.L., "Analgesic Studies of Aspirin in Cancer Patients," *Proceedings of the Aspirin Symposium*, The Aspirin Foundation, London, pp. 5–10, 1975.

66. Two comments urged that dosage schedules for children under 12 years of age be provided in § 343.20 (b) and (c) for the permitted OTC internal analgesic combination drug products recommended by the Panel in § 343.20(a). The comments asserted that the Panel's recommendations unnecessarily restrict product use by specifying only adult dosages for analgesic or antipyretic combinations and that this position contradicts other sections of the recommended monograph in which children's dosages are specified by age groups for single ingredient products, e.g., § 343.10(a) (1)(i) and (2).

The agency is concerned about the risks that may be associated with the use of analgesic-antipyretic combinations in children. For example, Bickers and Roberts observed a case of intoxication in a 5½-year-old child after a combined regimen of 300 mg aspirin and 300 mg acetaminophen, alternating every 2 hours for fever (Ref. 1). (Each drug was given individually every 4 hours.) The authors pointed out that, although many of the findings in the patient were characteristic of "simple" poisoning with either drug alone, this particular case presented difficulties in diagnosis, prognosis, and treatment strategy.

Although this patient's medication history involved more than the combined regimen of aspirin and acetaminophen, the agency shares the authors' concerns about intoxication from a combined regimen of aspirin and acetaminophen in children and notes their contention that the basis for prescribing such a regimen is wholly inadequate. In addition, the only combinations provided for in this tentative final monograph contain acetaminophen with aspirin or other salicylates. Because the agency is not aware of any data supporting the safe use of such analgesic combinations in children or any such combinations marketed for children, combinations of analgesic-antipyretic ingredients in § 343.20(a) are not being proposed for use by children under 12 years of age in the tentative final monograph.

Internal analgesic combinations containing nonanalgesic ingredients in § 343.20(b) in this tentative final monograph and the pediatric (or children's) dosages of such products will have to comply with the children's analgesic dosages included in the final monograph for OTC internal analgesic drug products. (See comment 67 below for further discussion of combination drug products containing analgesic and cough/cold ingredients.)

Reference

(1) Bickers, R.G., and R.J. Roberts, "Combined Aspirin/Acetaminophen Intoxication," *Journal of Pediatrics*, 94:1001–1003, 1979.

67. One comment objected to the Panel's recommendation that combination products be labeled to reflect all of the approved pharmacological activities of the active ingredients (42 FR 35370). The comment maintained that such labeling on a combination product containing active ingredients intended to relieve different symptoms, such as those of the common cold, would be confusing and misleading to consumers because they might think the product should be used only when all the symptoms are present. The comment stated that a combination product containing an analgesic-antipyretic ingredient should not be avoided because a single symptom of only pain or fever is present rather than both symptoms. The comment recommended that the phrase in § 343.20(d)(1), (2), (3), and (4) that states "* * * the product is labeled for the concurrent symptoms involved, * * *"

be replaced by the following statement: "The product must be labeled to reflect all of the proven pharmacological activities of the active ingredient(s) consistent with the recommended use of the product."

The agency agrees that a combination product containing an analgesic-antipyretic ingredient should not be avoided just because an individual has a single symptom of pain or fever, rather than both symptoms. As discussed in comment 16 above, the indications statement for analgesic-antipyretic ingredients in § 343.50(a)(1) is being revised to allow manufacturers flexibility in stating the uses for these ingredients.

The agency recognizes that combination products may be intended for use by a specific target population, such as consumers who are suffering from the common cold with minor pain or fever. The agency believes that the labeling for such combinations should reflect the principal intended use(s) of the product (e.g., pain reliever-fever reducer and nasal decongestant). Such labeling should be consistent with the approved indications for the active ingredients, but would not be required to contain all of the indications.

The agency believes that labeling specific to analgesic/cough-cold combinations need only appear in one monograph, which should be the one most pertinent to the intended target population of the combination product. Therefore, the agency has determined that the labeling for analgesic/cough-cold combination products should be included in the combinations segment of the cough-cold tentative final monograph, which was published in the **Federal Register** of August 12, 1988 (53 FR 30522). Accordingly, the Panel's specific recommendations in § 343.20(d)(1), (2), (3), and (4) of its monograph are not being addressed in this tentative final monograph. However, the agency has included a statement in the combinations section (§ 343.60(b)) of this tentative final monograph stating basically what the comment requested, i.e., that the labeling of the product states the indications for each ingredient in the combination, as established in the indications section of the applicable OTC drug monographs. Further, the agency has stated in § 343.60(b)(3) that for analgesic-antipyretic/cough-cold combinations, the indications stated in the cough-cold monograph should be used.

68. One comment objected to the word "essential" in the following statement in the Panel's report (42 FR 35370): "* * * that marketed products contain only those ingredients essential to the product." The comment argued that the word "essential" is too restrictive for OTC drug products. The comment maintained that some consumers might consider inactive ingredients nonessential, but other consumers consider these ingredients, such as a color or a flavor, essential to their acceptance of the product and their compliance with the directions for use. The comment recommended that excipients that contribute to patient acceptance of a product be permitted, along with those excipients necessary to prepare the final dosage form and provide stability and availability.

The phrase regarding essential ingredients was actually part of a recommendation by the Cough-Cold Panel, with which the Internal Analgesic Panel concurred (43 FR 35370). The Internal Analgesic Panel stated that it was aware of the inclusion of inactive ingredients in marketed drug products as "fillers, coatings, colorants, vehicles, aromatics, binders, sweeteners, flavoring agents, etc." and that "Such inactive ingredients are acceptable for marketing purposes provided they are pharmacologically inert and do not adversely affect the bioavailability of the active ingredients * * *." (See 43 FR 35370.)

The OTC drug review is an active, not an inactive, ingredient review. The OTC panels occasionally made recommendations with respect to inactive ingredients; however, these recommendations were made for public awareness and comment and were not intended to be included in the OTC drug monographs. Although not included in OTC drug monographs, inactive ingredients must meet the requirements of § 330.1(e) that they be ingredients that are safe and do not interfere with the effectiveness of the product or with tests to be performed on the product.

69. One comment stated that §§ 343.10(a)(2) and 343.12(a)(2) of the Panel's recommended monograph are inconsistent with § 341.20(e) of the Cough-Cold Panel's recommended monograph. The comment requested that § 341.20(e) be revised to allow children's dosages for combination products containing phenylpropanolamine, a nasal decongestant, and analgesic-antipyretic active ingredients. The comment suggested a revision in the phenylpropanolamine dosage to be consistent with the children's dosage of analgesic-antipyretic active ingredients.

This comment was submitted to both the OTC internal analgesic and the OTC cough-cold rulemakings. Adjustment of the dosage of phenylpropanolamine will be addressed in a future issue of the **Federal Register** in an amendment to the nasal decongestant portion of the cough-cold tentative final monograph. The comment was also addressed in the cough-cold combination drug products tentative final monograph (see comment 60 at 53 FR 30550).

70. Citing sections 201(p), 502(f), and 505(b) of the act (21 U.S.C. 321(p), 352(f), and 355(b)), one comment contended that the safety and effectiveness of a combination drug product as a whole should be the criteria by which it is judged, rather than the safety and effectiveness of its individual active ingredients. The comment stated that clinical testing of the contribution of each ingredient in a combination drug product would cause unnecessary expense for the manufacturer of the product. The comment suggested an alternative combination policy that would allow any number of ingredients to be included in a combination drug product in any quantity up to their maximum OTC dosage level as single ingredients, provided that the ingredients would not add a significant risk of harm from use or neutralize the effectiveness of other ingredients in the product. Based upon this suggestion, the comment requested Category I status for a combination drug product containing aspirin, acetaminophen, salicylamide, and caffeine, noting that the Panel classified as Category III both salicylamide and caffeine as analgesic adjuvants (42 FR 35483 and 35486).

The OTC drug review regulation for OTC combination drug products in § 330.10(a)(4)(iv) (21 CFR 330.10(a)(4)(iv)), which implements provisions of the act, states that:

> An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population.

The requirements for OTC combination drug products have been further delineated in the agency's "General Guidelines for OTC Drug Combination Products" (Ref. 1). Item 4 under these guidelines states:

> An ingredient claimed to be a pharmacological adjuvant (i.e., to enhance or otherwise alter the effect of another active ingredient) will be considered an active ingredient. Such an ingredient may be included in addition to one or more principal

active ingredients only if it meets the combination policy in all respects.

Item 5 under the OTC combination drug product guidelines states:

In some cases an ingredient may be appropriate for use only in a specific combination or data may be available only to support the use of the ingredient in combination but not as a single ingredient. In such cases the ingredient will be placed in Category I for use only in permissible combinations and not as a single ingredient.

Both salicylamide and caffeine are being classified as Category III ingredients in this tentative final monograph (see comments 91 and 93 below). However, if data were submitted to show that either or both of these ingredients contributed to the claimed effect of the combination, the ingredient(s) could be included in the combination in accordance with the guidelines.

Reference

(1) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products," September 1978, Docket No. 78D-0322, Dockets Management Branch.

71. One comment argued that although the Panel placed aspirin, acetaminophen, and several other analgesics in Category I, none of the combinations that are commonly used for headache has been classified as Category I. The comment urged that such combinations be kept on the OTC market because they have been commonly used and have met individual needs where single-ingredient products did not. (The comment did not name any specific products.)

Because the comment did not name any specific combination drug products or provide data on them, the agency is unable to consider the comment's arguments at this time. As previously mentioned, the regulations for OTC combination drug products have been supplemented by "General Guidelines for OTC Drug Combination Products" (see comment 70 above). The status of OTC analgesic combinations will be determined according to the regulations and these supplementary guidelines.

72. Several comments disagreed with the Panel's recommendations in §§ 343.20 (a), (b), and (c) that would permit combinations of two Category I internal analgesic-antipyretic ingredients only at the dosage limits specified and in a single large dosage unit. One comment contended that each analgesic ingredient in a combination should be permitted in lower than effective doses when such a combination can achieve a therapeutic effect similar to the higher quantity of a single ingredient. Other comments objected to combining the ingredients into a single large dosage unit. These comments requested that pharmaceutical manufacturers be allowed to divide the dosage between two smaller dosage units, with labeling directing consumers to take two dosage units per dose. The comments contended that one large dosage unit would be difficult to swallow and may lead to overdosage by consumers who are used to taking two tablets per dose. The comments also argued that such a requirement would burden pharmaceutical manufacturers and consumers with increased costs associated with retooling machinery used to make the larger dosage unit, redesigning packaging, etc.

The Panel recommended that only combinations containing the minimal effective adult dose of each analgesic-antipyretic ingredient be permitted. In the absence of data demonstrating that amounts less than the minimum effective dose contribute to effectiveness, the agency concurs with this recommendation as it applies to dosage level. However, the agency does not believe it is necessary to place specific restrictions on the amounts of active ingredients to be contained in a single dosage unit, provided the product's recommended dosage meets monograph conditions. The agency agrees with the comment that pharmaceutical manufacturers should be allowed to divide the dose of a combination product into more than one dosage unit with compensating directions for use. For example, the dosage for a tablet containing 162.5 mg of aspirin and 162.5 mg of acetaminophen would be two tablets per dose, thus meeting the minimum effective dosage requirements for each ingredient. Thus, the Panel's recommendation for a single dosage unit to contain the minimal effective dosage of each analgesic ingredient in § 343.20(a) is not being included in the tentative final monograph.

In addition, the agency has expanded the allowable combinations recommended by the Panel by proposing in § 343.20(a) to permit a range of acceptable amounts of active ingredients beyond the minimum effective dose to be contained in combination products. Based on the quantities of active ingredients in the products, the dosage schedules for analgesic-antipyretic combinations must comply with the dosages provided in § 343.60(d)(1) (i) or (ii) under the directions for use. (See also comment 65 above.)

With regard to the combinations of analgesic-antipyretic ingredients, the Panel based its recommendations on the review of single Category I ingredients as well as on data submitted on combination products. After the Panel's report was published in July 1977, the agency published "General Guideline for for OTC Drug Combination Products" (Ref. 1). The guidelines include a description of the criteria for the combination of Category I active ingredients from the same therapeutic category having the same or different mechanisms of action.

The agency believes that the Panel's recommendations for Category I classification of combining acetaminophen with aspirin or other Category I salicylates is in accordance with Item 2 of the OTC combination drug product guidelines, which states:

Category I active ingredients from the same therapeutic category that have different mechanisms of action may be combined to treat the same symptoms or condition if the combination meets the OTC combination policy in all respects and the combination is on a benefit-risk basis, equal to or better than each of the active ingredients used alone at its therapeutic dose. Such combinations may utilize each active ingredient in full therapeutic dosage or sub-therapeutic dosage, as appropriate.

Therefore, the agency proposes to include combinations of acetaminophen with aspirin or other Category I salicylates in this monograph under § 343.20(a).

With regard to the Panel's recommendations of combining aspirin and other Category I salicylates with each other, the agency finds no data referred to in the Panel's report to support such combinations and further finds that such combinations are not in accordance with the guidelines as described in Item 3, which states:

Category I active ingredient from the same therapeutic category that have the same mechanism of action should not ordinarily be combined unless there is some advantage over the single ingredients in terms of enhanced effectiveness, safety, patient acceptance, or quality of formulation. They may be combined in selected circumstances to treat the same symptoms or conditions if the combination meets the OTC combination policy in all respects, the combination offers some advantage over the active ingredients used alone, and the combination is, on the benefit-risk basis, equal to or better than each of the active ingredients used alone at this therapeutic dose.

In addition, following publication of the Panel's report the agency has received no data or information on such combinations, nor is aware of any such OTC drug products on the market.

Therefore, the agency is proposing not to include analgesic-antipyretic combinations that contain only salicylates in this monograph. The agency invites comment on this position.

Reference

(1) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products," September 1978, Docket No. 78D-0322, Dockets Management Branch.

73. One comment noted that the Panel's recommendation in § 343.20 does not provide for combinations of analgesic-antipyretic ingredients with both nasal decongestants and antihistamines, although provision was made for combination drug products containing an analgesic-antipyretic ingredient with either a nasal decongestant or an antihistamine. The comment asserted that information regarding a combination drug product containing analgesic-antipyretic ingredients, a nasal decongestant, and an antihistamine was submitted to the Panel and that such a product is consistent with the Category I combination drug products allowed in § 341.40(c) of the advance notice of proposed rulemaking on OTC cough-cold drug products. The comment requested that such a combination be incorporated into § 343.20 of the recommended OTC internal analgesic monograph.

The agency has determined that the categorization of combinations containing antihistamine and nasal decongestant ingredients properly falls within the scope of the OTC cough-cold drug product rulemaking. As mentioned in comment 67 above, the agency addressed combination drug products containing antihistamine, nasal decongestant, and analgesic-antipyretic active ingredients in the tentative final monograph for cough-cold combination drug products. (See comment 47 at 53 FR 30540.)

74. One comment opposed the 3-hour to 6-hour dosage interval recommended by the Panel for acetaminophen in § 343.10(b)(3) because it is incompatible with the 4-hour dosage interval for nasal decongestants and precludes the manufacture of a combination drug product containing acetaminophen and a nasal decongestant. The comment also argued that a 3-hour or a 6-hour dosage interval would be "foreign" to the habits of consumers, physicians, and pharmacists and would undesirably affect patient compliance.

The tentative final monograph on OTC internal analgesic drug products contains dosage schedules of acetaminophen based on 4-hour as well as 3-hour and 6-hour intervals. Thus, dosage schedules for this ingredient that are compatible with those specified for Category I oral nasal decongestants can be achieved. The agency does not believe that a dosage interval of every 6 hours would be foreign to the habits of consumers or would have an undesirable effect on patient compliance because many drugs are taken at 6-hour intervals.

G. Comments on Definitions.

75. One comment proposed that the following definition be included in § 343.3: "*Powdered aspirin analgesic.* A powdered form of aspirin packaged in individual unit doses."

The agency notes that the definitions recommended by the Panel in § 343.3 are general in nature and applicable to all dosage forms, and thus there would have been no reason for the Panel to include a definition of powdered aspirin. The agency sees no need to include this definition, and, in order to conform with format and style of recently published monographs, the definition section is being revised in the tentative final monograph to contain only one definition: analgesic-antipyretic drug.

76. One comment requested that the definition of highly buffered aspirin for solution in recommended § 343.3(k) be amended from "* * * contains at least 20 mEq of acid neutralizing capacity per 325 mg of aspirin and results in a pH of 3.5 or greater at the level of the initial 10 minute period as measured by the method established in § 331.25 of this chapter * * *." to "* * * provides at least 15 mEq of acid neutralizing capacity as measured by the method established in § 331.26 of this chapter * * *." The comment also requested that recommended § 343.20(d)(6), which refers to the combination of aspirin with an antacid, be revised accordingly. The comment presented data to show that a currently marketed highly buffered aspirin for solution product has less than 20 mEq of acid-neutralizing capacity per 325 mg aspirin and cited a submission to the Panel showing that the acid-neutralizing capacity of this product is 16.5 mEq when tested by the method in § 331.26 (Ref. 1).

After reviewing the submission to the Panel and testing the marketed product mentioned by the comment, the agency agrees that the product has less than 20 mEq of acid-neutralizing capacity per 325 mg aspirin. The agency points out that an average of 5 mEq is the minimal acid-neutralizing capacity required for an antacid to combine with the residual gastric acid and to maintain an elevated pH for 15 minutes in a normal subject. (See the advance notice of proposed rulemaking on OTC antacid drug products published in the **Federal Register** of April 5, 1973 (38 FR 8717).) Thus, a finished product must have an acid-neutralizing capacity of at least 5 mEq (§ 331.10) (21 CFR 331.10) to be labeled as an antacid. Highly buffered aspirin for solution exceeds this requirement. However, this is only one example of currently marketed drug products that contain aspirin with antacid ingredients (identified in § 331.11) in sufficient concentration to provide at least 5 mEq of acid-neutralizing capacity, thereby providing antacid activity in addition to analgesic activity.

The agency is not including the Panel's definition in § 343.3(k) because this information is contained in § 343.20(b)(3) of this tentative final monograph and is being revised to include all products containing aspirin with antacids that are generally recognized as safe and effective (i.e., those products providing at least 5 mEq of acid-neutralizing capacity) instead of highly buffered aspirin for solution only: "Aspirin identified in § 343.10(b)(1) may be combined with any antacid ingredient identified in § 331.11 or any combination of antacids permitted in accordance with § 331.10(a) provided that the finished product meets the requirements of § 331.10, is marketed in a form intended for ingestion as a solution, and bears labeling indications in accordance with § 343.60(b)(4)." Elsewhere in this issue of the **Federal Register** the agency is proposing to amend § 331.15 of the final monograph on OTC antacid drug products so that the combinations of antacids with nonantacid active ingredients listed therein will be consistent with the combinations being proposed in this tentative final monograph. (See also comment 47 above.)

The comment gave no reason for excluding the antacid test in § 331.25. This test should precede the test to determine the acid-neutralizing capacity of a product as specified in § 331.26. Both tests are required under § 331.10 for antacid products and have been retained here for aspirin with antacid products.

Reference

(1) OTC Volume 030104.

77. One comment recommended deleting the pH requirement from the definition of buffered aspirin in § 343.3(j), i.e., "* * * results in a pH of 3.5 or greater at the level of the initial 10-minute period as measured by the method established in § 331.25 of this chapter * * *." The comment argued that the requirement is unnecessarily

restrictive because it is not crucial to the definition. Another comment stated it is unclear whether the 1.9 mEq in the definition is meant to be measured or calculated, and whether it refers to 1.9 mEq of antacid ingredients per 325 mg aspirin or to 1.9 mEq of acid-neutralizing capacity above what is needed to neutralize the aspirin. This comment also stated that the pH requirement is an antacid requirement and is inappropriate for a buffered aspirin product because buffered aspirin products currently on the market theoretically do not contain sufficient antacid to raise the pH of 10 mL of 0.5 Normal hydrochloric acid to 3.5.

The comment suggested a revised definition of buffered aspirin to replace the one recommended in § 343.3(j) and gave details for a testing procedure to replace the one in the Panel's report at 42 FR 35488, which is the same as the procedure specified in § 331.26. The comment stated that the test it suggested would eliminate poorly formulated or unstable products that contain an ineffective or partially reactive antacid.

The agency is proposing only one definition in the tentative final monograph: Analgesic-antipyretic drug. Therefore the comment's request will not be discussed in the context of the monograph definitions. However, § 343.10(b)(2) of this tentative final monograph contains the same information as the Panel's definition and specifies for buffered aspirin that "* * * the finished product contains at least 1.9 millequivalents of acid-neutralizing capacity per 325 mg aspirin * * *." Because the finished product is to be tested, there must be sufficient antacid ingredients added to the product so that the finished product provides the specified acid-neutralizing capacity.

As to whether the acid-neutralizing capacity should be measured or calculated, it is apparent the Panel intended the acid-neutralizing capacity to be measured, i.e., experimentally determined, because it specified a test for measuring acid-neutralizing capacity (42 FR 35487 and 35488). Because the method of manufacture or other factors may affect the acid-neutralizing capacity, the theoretical acid-neutralizing capacity of a buffered aspirin product may be different from the experimentally determined capacity. Therefore, the acid-neutralizing capacity is to be experimentally determined (measured).

The requirements for initial pH determination in § 331.25 were devised for antacids, and not all buffered aspirin products contain sufficient quantities of antacid ingredients so that the finished product provides antacid activity. Consequently, buffered aspirin products should not be required to meet all of the standards of the antacid monograph.

To determine the acid-neutralizing capacity of the product, however, the procedure established in § 331.26 must be followed. The agency points out that data submitted to the Panel show that a well-formulated buffered aspirin product provides 1.9 mEq of acid-neutralizing capacity when measured by the method established in § 331.26 (Refs. 1 and 2). After testing buffered aspirin products according to § 331.26 and the comment's method, the agency has determined that the products provide 1.9 mEq of acid-neutralizing capacity when measured by either method. However, the method in § 331.26 is more discriminating. The agency concludes that the comments have not presented sufficient reasons for replacing the established procedure in § 331.26 with the suggested procedure. Accordingly, the agency will retain the procedure in § 331.26.

Based upon the above discussion and for clarity, the Panel's recommended § 343.20(d)(7) (redesignated § 343.10(b)(2) in this tentative final monograph) is being revised as follows: "Buffered aspirin. Aspirin identified in paragraph (b)(1) of this section may be buffered with any antacid ingredient(s) identified in § 331.11 provided that the finished product contains at least 1.9 millequivalents of acid-neutralizing capacity per 325 milligrams of aspirin in accordance with § 331.26."

References

(1) OTC Volume 030136.
(2) OTC Volume 030137.

H. Comments on Effects of Product Formulations on Drug Absorption and Pharmacologic Effectiveness

78. One comment argued that OTC aspirin rectal suppositories should be classified as Category I. The comment maintained that their long history of use and administration to hospital patients who are unable to use oral dosage forms of aspirin have shown that they are effective analgesic-antipyretic drug products and have produced no evidence of rectal irritation.

The comment submitted no data in support of its argument. The Panel noted that the rate of absorption of aspirin from suppositories was slow compared with its absorption from the oral tablet form (42 FR 35377). The Panel noted that because suppositories may have different melting or dissolution rates, therapeutic levels of the active ingredients contained in these dosage forms can be unpredictably high or low, ranging potentially from therapeutically ineffectual results to toxicity. Thus, the Panel placed OTC analgesic rectal suppositories in Category III, concluding that additional bioavailability data and evidence concerning possible rectal irritation are needed for each suppository formulation.

The agency specifically invites comment and submission of data on OTC analgesic rectal suppositories, particularly data on bioavailability and possible rectal irritation, in accordance with the discussion on testing guidelines in part II. paragraph A.2. below and with the feedback procedures published in the **Federal Register** of September 29, 1981 (46 FR 47740). In the absence of such data at this time, the agency is proposing that OTC analgesic rectal suppositories remain in Category III.

79. One comment stated that a certain timed-release aspirin product with an approved NDA dating from 1965 should not be included in an OTC drug monograph, but should be maintained as a new drug subject to an approved NDA.

The agency agrees with the comment. The particular product in question contains 650 mg aspirin in a timed-release dosage unit, a safe amount for a single dose. However, the recommended dose of the product is two tablets, followed by one to two tablets every 8 hours. A 2-tablet dose (1,300 mg) represents a quantity of active ingredient which, if released from the tablets at one time, is not generally recognized as safe for a single dose in OTC drug products. (The safe maximum single OTC doses for aspirin, as discussed in comment 53 above, are 650 mg every 4 hours or 1,000 mg every 6 hours.)

The agency concludes that this timed-release aspirin product is a new drug under § 200.31 (21 CFR 200.31), and will remain the subject of an approved NDA and not be included in the monograph. Each NDA must contain, among other information, bioavailability data showing that the total dose of the active ingredient is released at a safe rate—that is, not too quickly or too slowly.

I. Comments on Aspirin

80. One comment stated that the amount of aspirin in an OTC internal analgesic drug product should be listed both in grains and milligrams, with grains shown first and milligrams shown parenthetically.

Although manufacturers may voluntarily list quantities of active ingredients in either grains or metric units or both, the agency believes that it would be useful for manufacturers to list ingredients in metric units. The Metric Conversion Act of 1975 (80 Stat. 1007) was enacted to increase voluntarily the use of the metric system of weights and

measures in the United States. In support of this policy, the agency has developed a Compliance Policy Guide (Ref. 1) to establish general and specific guidance for the voluntary use of metric units of quantity on the labeling of FDA-regulated commodities. This guide states that a declaration of quantity of contents in units of weight is expressed in terms of the kilogram, gram, milligram, or microgram. While historically the amount of aspirin in an OTC internal analgesic drug product was listed in apothecary units (grains), based on the Metric Conversion Act of 1975, the agency is encouraging use of milligram units. This approach is consistent with current labeling policy for FDA-regulated commodities.

Reference

(1) "Metric Declaration of Quantity of Contents on Products Labels," reprint of Food and Drug Administration Compliance Policy Guide 7150.17, 1987.

81. One comment stated that the number of tablets in an aspirin product container should be shown on the label.

The agency points out that the declaration of net quantity of contents of an OTC drug package is already provided for in § 201.62(a) (21 CFR 201.62(a)), which states that the "* * * quantity of drugs in tablet, capsule, * * * or other unit form * * * shall be expressed in terms of numerical count * * *." Thus the number of tablets in an aspirin product container is required to be shown on the label.

82. Several comments stated that menstrual blood flow might be increased by the ingestion of aspirin products. One comment stated that many women use products containing aspirin to relieve pain from menstrual cramps and that warnings for these products should indicate that aspirin might increase menstrual blood flow. Another comment stated that aspirin, which appears to be the most commonly used analgesic for menstrual cramps, is not a cause of massive uterine bleeding.

Based on available information, aspirin does not appear to affect normal menstrual blood flow, and there are no data demonstrating that a warning to that effect is necessary. The agency is aware that the Miscellaneous Internal Panel reviewed the use of aspirin for the relief of pain of menstrual cramps and concluded that it is safe for such use. (See the **Federal Register** of December 7, 1982; 47 FR 55076.) Neither that Panel nor the Internal Analgesic Panel was aware of any evidence that aspirin increases menstrual blood flow.

The direct irritant effects of aspirin upon the gastric mucosa and its effects upon platelet aggregation have been well described in the medical literature, and the possible adverse effects of aspirin upon postoperative bleeding have been well discussed in the literature. It is recognized that doses of aspirin greater than the recommended therapeutic doses may reduce plasma prothrombin by interfering with the role of vitamin K in the production of prothrombin and decreasing platelet aggregation, thus prolonging the coagulation process (42 FR 35384). However, these effects seem to be unrelated to those involved in normal menstrual blood flow.

83. One comment stated that there was no mention in the Panel's recommended monograph of the "unique safety" of the powder dosage form of aspirin compared with other dosage forms. The comment attributed the safety of aspirin powders to their physical form and packaging and presented data to show that there have been only a few accidental ingestions of aspirin powders compared with a large number of accidental ingestions of other forms of aspirin. The comment also pointed out that the Consumer Product Safety Commission (CPSC) exempted aspirin powders from the safety packaging requirements of the Poison Prevention Packaging Act.

No attempt has been made in the tentative final monograph to compare the safety of dosage forms; such a comparison is not the intent of the OTC drug review. The comment's discussion is not related to the Panel's or the agency's conclusions on the absorption and pharmacologic effectiveness of aspirin powders and therefore provides no basis for revising the Panel's recommended monograph.

J. Comment on Acetaminophen

84. One comment disagreed with the Panel's recommendation that the standards for child-resistant safety closures for aspirin products, as set forth in regulations (16 CFR 1700.15 (a), (b), and (c)) established according to the Poison Prevention Packaging Act of 1970, should apply to acetaminophen products as well. This comment requested an exemption for liquid dosage forms of acetaminophen containing less than 1 g of acetaminophen per fluid ounce (oz). Several comments agreed with the Panel and noted that the CPSC proposed in the **Federal Register** of February 3, 1978 (43 FR 4632) to require child-resistant packaging for acetaminophen preparations containing more than 1 g of acetaminophen in a single package.

CPSC, and not FDA, regulates child-resistant packaging. CPSC issued a final rule in the **Federal Register** of August 31, 1979 (44 FR 51211), requiring child-resistant packaging for acetaminophen-containing preparations in oral dosage form containing more than 1 g of acetaminophen in a single package. This requirement became effective on February 27, 1980 for acetaminophen products packaged after that date, with the following exceptions: Effervescent acetaminophen preparations and acetaminophen preparations in powder form. The comment requesting an exemption for liquid acetaminophen products with less than 1 g of acetaminophen per fluid oz submitted the same request to CPSC, which, in turn, addressed this issue in its final rule and denied the comment's request for exemption (44 FR 51213). FDA concurs with that decision.

K. Comment on Antipyrine

85. One comment submitted data to upgrade the Category III status of antipyrine to Category I and to eliminate the Panel's recommendation of a single 975-mg dose of antipyrine per 24-hour period. The data consisted of three papers on the metabolism, including the half-life, of antipyrine in animals and humans and addressed the metabolism of antipyrine in blacks (Refs. 1, 2, and 3). The comment stated that "these studies provide assurance that a total daily dosage schedule of 3,000 mg or even 4,000 mg of antipyrine would not result in excessively high blood levels, in spite of the acknowledged extended half-life of the drug."

The agency has reviewed the data cited by the comment and concludes that the data are insufficient to justify Category I status for antipyrine. None of the studies provided any significant data to show that antipyrine is safe after repeated doses or to justify changing the Panel's recommendation of one single 975-mg dose per 24 hours.

The agency agrees with the Panel that more data are needed on the safety of antipyrine and is proposing that this ingredient remain classified as Category III. Because of its long half-life, studies on antipyrine should address the amount of this drug that can be safely given within 24 hours and determine an appropriate dosage interval to prevent a toxic amount of the drug from accumulating in the body. In addition, in order to determine sensitivity to antipyrine, epidemiological studies should be conducted that consider pharmacogenetic factors and include several racial groups.

The agency's detailed comments and evaluations on the data are on file in the Dockets Management Branch (Ref. 4).

References

(1) Fraser, H.S., et al., "Factors Affecting Antipyrine Metabolism in West African Villagers," *Clinical Pharmacology and Therapeutics*, 20:369–376, 1976.

(2) Breckenridge, A., and M. Orme, "Clinical Implications of Enzyme Induction," *Annals New York Academy of Sciences*, 179:421–431, 1971.

(3) Vesell, E.S., et al., "Relationship Between Plasma Antipyrine Half-Lives and Hepatic Microsomal Drug Metabolism in Dogs," *Pharmacology*, 10:317–328, 1973.

(4) Letter from W.E. Gilbertson, FDA, to T.E. Watson, T.E. Watson Company, coded LET015 to C00102, Docket No. 77N–0094, Dockets Management Branch.

L. Comment on Quinine

86. One comment stated that despite the side effects (such as ringing in the ears, headache, nausea, and visual disturbances) of quinine in large doses (e.g., 2 g per day), it is effective at much lower doses for nocturnal leg cramps and should remain available OTC for this use. In support of its position, the comment cited "The Pharmacological Basis of Therapeutics," edited by Goodman and Gilman (Ref. 1), which states that the dose of quinine for nocturnal leg cramps is 200 to 300 mg before retiring.

The agency is aware of the nocturnal leg cramp dosage for quinine given in the reference cited by the comment. The use of quinine for nocturnal leg cramps has been addressed by the Miscellaneous Internal Panel in the advance notice of proposed rulemaking entitled, "Quinine for the Treatment of Nocturnal Leg Muscle Cramps for Over-the-Counter Human Use," published in the **Federal Register** of October 1, 1982 (47 FR 43562). The agency concurred in the Panel's classification of quinine for this use in Category III in the tentative final monograph published in the **Federal Register** of November 8, 1985 (50 FR 46588).

The agency also agrees with the Internal Analgesic Panel's conclusions that the risk of toxic effects of quinine on the skin (e.g., rashes) and on the gastrointestinal, nervous, and cardiovascular systems outweighs its benefit in relieving pain or fever. In fact, the reference cited by the comment describes the toxicity of quinine and does not include analgesic, antipyretic, or antirheumatic actions as therapeutic uses for this drug (Ref. 1). The agency concurs with the Panel, and is proposing in this tentative final monograph that quinine is Category II when labeled for any OTC antipyretic or internal analgesic use other than the treatment and/or prevention of nocturnal leg muscle cramps.

Reference

(1) "The Pharmacological Basis of Therapeutics," 5th Ed., edited by L.S. Goodman, and A. Gilman, MacMillan Publishing Co., Inc., New York, pp. 1062–1065, 1975.

M. Comments on Salsalate

87. One comment requested clarification of the status of salsalate, stating that in the table of active ingredients (42 FR 35350) this ingredient is classified as Category III for analgesic effectiveness, but is classified in the active ingredients section as a Category III analgesic for both safety and effectiveness (42 FR 35443).

The table of active ingredients should have shown Category III status of salsalate as an antirheumatic, antipyretic, and analgesic for both safety and effectiveness. The Panel's classification of salsalate as an analgesic is correct (42 FR 35443), but it should have also been shown as Category III for both safety and effectiveness as an antipyretic and an antirheumatic (42 FR 35452 and 35468).

The Panel's position on the categorization of salsalate can be clarified by reviewing the minutes of the Panel's 28th meeting. These minutes state that "the Panel concluded that salsalate should remain in Category III on the basis of insufficient evidence of safety and effectiveness." Furthermore, the Panel's discussion on the safety of salsalate on pages 35452 and 35468 consists of reference to the safety discussion on page 35443, in which the Panel concluded that there were insufficient data to determine salsalate's safety as an OTC analgesic. Because FDA has received no further data on salsalate to warrant a change if its Category III classification, the agency concurs with the Panel that salsalate is a Category III OTC analgesic, antipyretic, and antirheumatic ingredient.

88. One comment objected to the Panel's recommendation that additional toxicology data, such as teratogenicity studies and effects on various organs, may be needed on salsalate. The comment pointed out that because salsalate is an ester of two molecules of salicylic acid, there is no reason to consider it other than "pharmacologically equivalent to salicylic acid" or to expect metabolites other than those found with sodium salicylate. The comment further argued that, as a salicylate analgesic, salsalate should be considered a "salt or similar variant" of a Category I analgesic and that the crossover bioavailability studies for evaluating analgesic effectiveness (42 FR 35445) should be adequate to establish its effectiveness. Because of the acknowledged difference in absorption rates between salsalate and other salicylates, the comment suggested that a crossover bioavailability study should measure the rates of hydrolysis or dissociation of aspirin, sodium salicylate, and salsalate, and determine the peak plasma levels, the times of peak levels, the fractions of doses absorbed, and the half-life during the recommended dosage period of 10 days for an OTC analgesic.

As the Panel pointed out, data on the pharmacokinetics of salsalate are conflicting and incomplete. The study proposed in the comment should be conducted using analytical procedures that differentiate between parent drug (intact salsalate), salicylic acid, and other metabolites that may be formed. If the study shows that any amount of salsalate is absorbed intact and is present in the blood, then salsalate cannot be considered equivalent to salicylic acid, or a "salt or similar variant" of salicylic acid, and a general toxicological profile will be needed.

89. One comment from a manufacturer inquired whether pharmacokinetic data alone can be used to establish the effectiveness of a Category III antirheumatic active ingredient (salsalate). The firm proposed to use a method that differentiates and quantitates levels of salsalate and salicylic acid in serum. The proposed study would compare the pharmacokinetics of salicylate derived from aspirin with the pharmacokinetics of salicylate derived from salsalate after administration of a single dose each of aspirin and salsalate.

The Panel recommended that effectiveness data on salsalate be required according to its guidelines for antirheumatic drugs, which state that antirheumatic studies should be designed to test the anti-inflammatory activity of an ingredient separate from any other action the ingredient may have and that the studies should be double-blind crossover in design, with aspirin as the standard drug (42 FR 35468). The agency concludes that pharmacokinetic data alone are inadequate to establish the effectiveness status of salsalate as an antirheumatic agent and that controlled clinical studies are needed (Ref. 1).

Reference

(1) Letter from W.E. Gilbertson, FDA, to J. Schaefer, Jr., Fisons Corporation, July 18, 1978, included in OTC Volume 03BTFM.

N. Comment on General Discussion of Antirheumatic Agents

90. One comment stated that, although there is extensive literature on fibrositis, the Panel devoted only one paragraph to this subject in its report and cited no references relating to fibrositis. The comment stated that it appeared that the Panel had deliberately ignored this subject because it would drastically weaken its argument that all inflammatory arthritis is malignant rheumatoid arthritis. The comment pointed out that fibrositis is self-limited and treatable by self-medication, and that much of what is initially diagnosed as probable rheumatoid arthritis is later found to be fibrositis.

The agency notes that the Panel did not suggest that all inflammatory conditions are malignant (progressively degenerating) rheumatoid arthritis. Many of the rheumatic conditions listed in the Panel's report are not malignant conditions. Fibrositis was not discussed in the report because the Panel chose to discuss in detail only the more commonly occurring rheumatic diseases. The agency believes that including a discussion of fibrositis would not have affected the Panel's conclusions on OTC arthritis labeling. Fibrositis is not amenable to self-diagnosis because the presenting symptoms are similar to those of the more serious rheumatic diseases. An indication for fibrositis is being included in the professional labeling section of this tentative final monograph (§ 343.80(a)). The agency's proposals on consumer labeling claims concerning arthritis are discussed in comments 17, 18, and 19 above.

O. Comments on Adjuvants and Corrective Agents

91. Several comments urged that caffeine as an OTC analgesic adjuvant be reclassified from Category III to Category I. The comments cited several studies to support their contention that caffeine is an effective analgesic adjuvant, and also to dispute the Panel's concern that in humans caffeine may interfere with the effectiveness of the antipyretic component in combination drug products containing caffeine and an antipyretic ingredient.

After reviewing the studies cited by the comments, the agency agrees with the Panel that there are insufficient data to reclassify caffeine as an analgesic adjuvant from Category III to Category I or to show that it does nor interfere with the antipyretic activity of analgesic-antipyretic ingredients. Of the studies cited, three presented new data and information (Refs. 1, 2, and 3). In a study by Cass and Frederik (Ref. 1), the investigators concluded that it could not be determined whether the addition of caffeine was a positive or negative factor in assessing analgesic effect. The agency concurs with the authors and concludes that the study fails to demonstrate the contribution of caffeine as an analgesic adjuvant.

Thomas et al. (Ref. 2) studied the metabolism of phenacetin and acetaminophen as single ingredients as well as when each ingredient was combined with aspirin, caffeine, and codeine. This study did not address the effectiveness of caffeine as an analgesic or antipyretic adjuvant and cannot be used as evidence of effectiveness.

Wojcicki et al. (Ref. 3) reported on a double-blind, crossover trial that compared the clinical relief of headache and postoperative pain in patients using three analgesic preparations. The authors concluded that the analgesic effectiveness demonstrated by the preparation containing 500 mg acetaminophen and 50 mg caffeine "suggests that this medication is superior to the preparations that did not contain caffeine. This study is not a true crossover study because only patients who felt that they needed additional analgesics crossed over to the second treatment.

The agency proposes that, in order to establish Category I status for caffeine's effectiveness as an analgesic adjuvant, it must be demonstrated that caffeine makes a positive contribution to the effectiveness of the combination product as an analgesic. If the product also makes antipyretic claims, it must be shown that caffeine does not decrease its antipyretic effectiveness.

The agency's detailed comments and evaluations on the data are on file in the Dockets Management Branch (address above) (Refs. 4 to 7).[1]

References

(1) Cass, L.J., and W.S. Frederik, "The Augmentation of Analgesic Effect of Aspirin with Phenacetin and Caffeine," *Current Therapeutic Research*, 4:583–588, 1962.

(2) Thomas, B.H., et al., "Effect of Aspirin, Caffeine, and Codeine on the Metabolism of Phenacetin and Acetaminophen," *Clinical Pharmacology and Therapeutics*, 13:906–910, 1972.

(3) Wojcicki, J., et al., "A Double-Blind Comparative Evaluation of Aspirin, Paracetamol and Paracetamol+Caffeine (Finimal) for their Analgesic Effectiveness," *Archivum Immunologiae et Therapiae Experimentalis*, 25:175–179, 1977.

(4) Letter from W.E. Gilbertson, FDA, to T.H. Chambers, Goody's Mfg. Corp., coded LET011 to C00033, Docket No. 77N–0094, Dockets Management Branch.

(5) Letter from W.E. Gilbertson, FDA, to M.A. Bass, the National Association of Pharmaceutical Manufacturers, coded LET012 to C00046, Docket No. 77N–0094, Dockets Management Branch.

(6) Letter from W.E. Gilbertson, FDA, to C.F. Baker, Burroughs Wellcome Co., coded LET013 to C00048, Docket No. 77N–0094, Dockets Management Branch.

(7) Letter from W.E. Gilbertson, FDA, to R.M. Palmes, Bristol-Myers Products, coded LET014 to C00060 and LET010, Docket No. 77N–0094, Dockets Management Branch.

(8) Comment Nos. LET00021, LET00024, LET00029, RPT, SUP00025, SUP00027, SUP00028, SUP00030, and CR00002, Docket No. 77N–0094, Dockets Management Branch.

[1] Industry has responded to FDA's concern and provided additional data (Ref. 8) which are currently undergoing review by the agency.

92. One comment requested that the agency permit the use of caffeine as an adjuvant at dosage levels up to 150 mg per single adult dose, or 75 mg per dosage unit, instead of the Panel's recommended 65 mg per single dose. The comment stated that the Panel's single dose of caffeine (65 mg) in combination with analgesics was inconsistent with the Panel's allowable maximum daily dose of 600 mg caffeine. The comment also pointed out that a 65-mg single dose of caffeine seems inconsistent with the dosage of 100 mg to 200 mg recommended by the Advisory Review Panel on OTC Sedative, Tranquilizer, and Sleep-Aid Drug Products.

The Sleep-Aid Panel recommended dosages for caffeine's use as a stimulant, not as an analgesic-antipyretic adjuvant. The Internal Analgesic Panel, however, reviewed caffeine both as an analgesic-antipyretic active ingredient and as an analgesic-antipyretic adjuvant. Caffeine used alone as an OTC analgesic-antipyretic active ingredient was classified by the Panel as Category II. As an analgesic-antipyretic adjuvant, it was classified by the Panel as Category III.

The agency agrees with the comment that the Panel's report is inconsistent with respect to caffeine dosages. The agency has no objection to a dosage level of 150 mg per single adult dose, which is within the dosage range recommended for restoring alertness or wakefulness by the Sleep-Aid Panel and included by the agency in the final monograph for OTC stimulant drug products which was published in the **Federal Register** of February 29, 1988 (53 FR 6100). However, because data are still needed to demonstrate effectiveness of caffeine as an adjuvant in combination with analgesic, antipyretic, and antirheumatic ingredients, the agency proposes to

classify it as Category III for this use. (See comment 91 above.)

Reference

(1) OTC Volume 030049.

93. One comment disagreed with the Panel's recommendation that salicylamide be placed in Category III for safety and effectiveness as an OTC analgesic adjuvant. The comment argued that the harmful effects of salicylamide cited by the Panel occur only at doses of 1,000 mg or more and not at the lower doses (650 mg or less) used as an OTC analgesic adjuvant. The comment also stated that the Panel failed to consider 35 submitted references substantiating the safety of salicylamide and that nothing in the Panel's report presents reasons for suspecting that the addition of salicylamide would either detract from the effectiveness of the combination or present any safety risk.

The agency agrees with the Panel that there is insufficient information to determine the safety and effectiveness of salicylamide as an adjuvant or as a single ingredient in internal analgesic drug products. The comment submitted no new data or information to alter this decision.

The Panel did consider the 35 submitted references along with all the other data available on salicylamide in concluding that salicylamide was Category III for safety and effectiveness as an adjuvant and as a single-ingredient internal analgesic (Refs. 1 and 2). Deficiencies in the data on salicylamide available to the Panel are discussed in the Panel's report (42 FR 35439 and 35486).

To justify the inclusion of an adjuvant, such as salicylamide, in a combination drug product, the adjuvant must make a positive contribution to the safety and effectiveness of the combination. (See comment 70 above for further discussion of this subject.) Salicylamide in high doses (600 mg or more) has been shown to inhibit salicylate and acetaminophen metabolism by competing for the glucuronidation pathway (Refs. 2, 3, and 4). This inhibition of the metabolism may result in a prolonged therapeutic effect, which is why salicylamide is claimed to be an adjuvant. Whether salicylamide in low doses (less than 600 mg) in combination with salicylate salts or acetaminophen also delays the metabolism of these analgesics and, if so, to what degree, is not known. Therefore, more data are needed on the pharmacokinetics of salicylamide to establish the safety and effectiveness of this ingredient as an internal analgesic adjuvant in such a formulation.

References

(1) OTC Volume 030069.

(2) OTC Volume 030072.

(3) Levy, G., and J.A. Procknal, "Drug Biotransformation Interactions in Man. I. Mutual Inhibition in Glucuronide Formation of Salicylic Acid and Salicylamide in Man," *Journal of Pharmaceutical Sciences*, 57:1330–1335, 1968.

(4) Levy, G., and H. Yamada, "Drug Biotransformation Interactions in Man. III. Acetaminophen and Salicylamide," *Journal of Pharmaceutical Sciences*, 60:215–221, 1971.

P. Comments on Antacid or Buffering Ingredients

94. One comment questioned which antacid or buffering agents may be used as corrective agents with aspirin. The comment noted that the Panel gave a specific list of ingredients of buffering systems (42 FR 35469), but that the Panel's recommendations in § 343.3 (j) and (k) state that antacid active ingredients identified in § 331.11 may be added to aspirin. The comment urged that any of the antacid active ingredients listed in § 331.11 be permitted in combination with aspirin and that these ingredients not be restricted to those listed at 42 FR 35469.

The agency wishes to clarify that the list of ingredients in the Panel's report (42 FR 35469) was not meant to exclude other ingredients identified in § 331.11 of the antacid final monograph as ingredients of buffering systems for use with aspirin as antacids or correctives. As recommended by the Panel in § 343.20(d) (6) and (7) and § 343.3 (j) and (k) and proposed by the agency in the tentative final monograph, the antacid or buffering agents permitted in buffered aspirin or highly buffered aspirin drug products include all of the ingredients identified in § 331.11 of the final monograph for OTC antacid drug products (21 CFR 331.11).

95. Comments expressed opposing views on whether the agency should reconsider the use of highly buffered aspirin for solution products for the concurrent symptoms of headache and acid indigestion as part of the internal analgesic rulemaking, in view of the agency's final decision to allow such a combination in the final monograph for OTC antacid drug products. The antacid final monograph states in § 331.15(b), "An antacid may contain any generally recognized as safe and effective analgesic ingredient(s), if it is indicated for use solely for the concurrent symptoms involved, e.g., headache and acid indigestion, and is marketed in a form intended for ingestion as a solution."

The agency stated in the preamble to the final rule for OTC antacid drug products (39 FR 19862) that the Internal Analgesic Panel was reviewing OTC internal analgesics for their safety, effectiveness, and appropriate labeling, and that the analgesic component of an antacid-analgesic combination drug product would remain under consideration and would be the subject of a further review and determination by the agency according to the procedures specified in § 330.10. Because a panel may also find it necessary to review the safety, effectiveness, and rationality of combination drug products within which the individual ingredients are contained, it is possible that a particular drug combination may be reviewed by more than one panel. In such instances, the agency subsequently considers each panel's recommendations in determining whether the combination is appropriate for the relief of specific concurrent symptoms, is subject to the labeling requirements of more than one monograph, or whether special labeling is needed for the combination.

The data submitted to the Internal Analgesic Panel for its evaluation of the analgesic component of highly buffered aspirin for solution, an analgesic-antacid combination drug product, included the same information that had been submitted to the Antacid Panel. The agency concludes that it was appropriate for the Internal Analgesic Panel to reconsider some of the issues that the Antacid Panel had considered. Furthermore, it is appropriate for the agency to consider recommendations from both Panels, as well as the comments and reply comments received in response to the Internal Analgesic Panel's recommended monograph.

96. Two comments stated that because most consumers do not know that a popular OTC highly buffered aspirin for solution product contains aspirin, they are unaware of the potential risks in using this product.

The comments provided no evidence to support the statement that "most consumers" are unaware of the presence of aspirin in the product to which they referred. Section 502(e) (1) of the act (21 U.S.C. 352(e)) requires that the labeling of all OTC drugs contain the established name of each active ingredient in the product. In addition, consumers are alerted to the potential side effects of aspirin-containing products by the label warnings proposed for such products in this tentative final monograph.

Section 502(c) of the act (21 U.S.C. 352(c)) also provides that information required to appear on the labeling be placed thereon prominently and with such conspicuousness as to render it likely to be read and understood by the ordinary individual under customary

conditions of purchase and use. The requirements for labeling ingredient information are spelled out more fully in the regulations at 21 CFR 201.10.

The agency believes that products labeled in accord with existing regulations and the requirements being established by this monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products will not present consumers with the potential problem described by the comments.

Q. Comment on Antihistamine-Analgesic Combinations

97. One comment argued that a currently marketed OTC drug product containing acetaminophen and phenyltoloxamine dihydrogen citrate is effective in treating tension headache and relieving musculoskeletal pain associated with anxiety and is more effective than acetaminophen alone in relieving pain. The comment mentioned studies by de Sola Pool (Ref. 1) and Gilbert (Ref. 2) that were submitted to the Panel. In response to the Panel's criticism of de Sola Pool's study, the comment submitted Drummond's reanalysis of this study (Ref. 3) and an independent analysis of Wallenstein (Ref. 4). The comment also submitted the results of a new study conducted by Scheiner (Ref. 5). The comment concluded that these studies show that phenyltoloxamine dihydrogen citrate in combination with acetaminophen should be classified as a Category I adjuvant.

The agency has reviewed the new data submitted and concludes that the data remain insufficient to support the effectiveness of phenyltoloxamine dihydrogen citrate as an analgesic adjuvant. The statistical reanalyses of the de Sola Pool study performed by Drummond (Ref. 3) and Wallenstein (Ref. 4) conclude that acetaminophen with phenyltoloxamine dihydrogen citrate is more effective than acetaminophen alone for the relief of headache. However, the study did not use a standardized scoring system to rate symptoms and the symptom complex being treated was not clearly defined. Therefore, the study is not acceptable as proof of the effectiveness of the ingredient as an analgesic adjuvant.

Gilbert's study (Ref. 2) did not show that the combination of acetaminophen and phenyltoloxamine dihydrogen citrate enhanced pain relief over acetaminophen alone. Drug differences were not detected until 48 hours after treatment started, an unacceptably long delay in a pain study. In addition, many pain states will spontaneously resolve over this period of time, and this effect may bias the study. There were a number of technical problems with the study, e.g., the patient population was too heterogeneous, and only 1 of 19 measures used for rating drug effects was concerned with pain. The agency's detailed comments and evaluations on the data are on file in the Dockets Management Branch (address above) (Ref. 6).

The agency did not review the new study by Scheiner (Ref. 5) because the investigator was disqualified by FDA. The accuracy and reliability of the data from this study would need to be validated before the agency could accept this study in support of claims for the effectiveness of phenyltoloxamine dihydrogen citrate as an analgesic adjuvant.

Therefore, the agency proposes to classify phenyltoloxamine dihydrogen citrate as a Category III internal analgesic adjuvant in this tentative final monograph.

Regarding labeling, the agency proposes to classify as Category II any claims that represent or suggest relief of or treatment for tension or anxiety, including "for the treatment of tension headache." The agency proposes to classify such labeling claims as Category II because these claims imply the treatment of tension and anxiety rather than the amelioration of the pain that may be associated with such symptoms. In the final monograph for OTC daytime sedative drug products, the agency concluded that based on the available data any products labeled, represented, or promoted for indications such as "calmative," "soothes away the tension," and "calming down" are regarded as new drugs for which approved new drug applications would be required for marketing (44 FR 36380).

The Internal Analgesic Panel classified the term "nervous tension headache" in Category II (42 FR 35435). In its discussion of headache, the Panel identified the psychogenic headache as a major type of headache and stated that these "muscle contraction" or "tension headaches" may account for up to 90 percent of the chronic headaches seen by the physician. The Panel further recommended that the cause of chronic and recurrent headaches requires diagnosis by a physician. However, the Panel also stated that the occasional headache may be due to a variety of causes, including tension, and concluded that analgesics are safe and effective for the symptomatic relief of the occasional headache (42 FR 35352).

The agency concurs with the Panel that chronic and recurrent headaches require diagnosis by a physician. However, the agency also believes that consumers are familiar with headaches perceived to be due to tension. Because the warnings proposed in § 343.50(c) (1) and (2) of this tentative final monograph will adequately warn consumers against self-use of analgesics for pain that continues to persist, the agency has no objection to the use of the phrase "pain of tension headache" as acceptable additional information for the labeling of analgesic-containing products provided that additional words are not used that imply any treatment for tension or anxiety. Because the agency believes that the proposed indication "For the temporary relief of minor aches and pains associated with * * * 'headache '* * *'." is sufficiently broad to encompass headache from a variety of causes, the agency is not proposing to include the phrase "pain of tension headache" in its proposed indication for OTC internal analgesic drug products. This information may be included elsewhere in the labeling provided the phrase is not intermixed with labeling established by the monograph.

In addition, the Panel placed the claim "for the relief of musculoskeletal pain associated with anxiety" in Category II (42 FR 35486). The agency agrees with the Panel's classification because it believes that the term "musculoskeletal pain" is not readily understood by consumers. Furthermore, the agency is not aware of any OTC analgesic product labeled with such an indication. Therefore, the agency does not propose to include the claim "for the relief of musculoskeletal pain" in the monograph.

References

(1) De Sola Pool, N., "Analgesic/Calmative Effects of Acetaminophen and Phenyltoloxamine in the Treatment of Simple Nervous Tension Accompanied by Headache," draft of unpublished paper, in OTC Volume 030155.

(2) Gilbert, M.M., "The Efficacy of Percogesic in Relief of Musculoskeletal Pain Associated with Anxiety," draft of unpublished paper, in OTC Volume 030154.

(3) Drummond, C., "Re-analysis of the Study, " 'Analgesic/Calmative Effects of Acetaminophen and Phenyltoloxamine in the Treatment of Simple Nervous Tension Accompanied by Headache'," draft of unpublished paper, Comment No. SUP-3, Docket No. 77N-0094, Dockets Management Branch.

(4) Wallenstein, S.L., "Statistical Evaluation of Clinical Protocol Associates Study," draft of unpublished paper, Comment No. SUP-3, Docket No. 77N-0094, Dockets Management Branch.

(5) Scheiner, J.J., "The Efficacy of Percogesic in Treating Anxiety Caused by Musculoskeletal Trauma," draft of unpublished paper, Comment No. SUP03, Docket No. 77N-0094, Dockets Management Branch.

(6) Letter from W.E. Gilbertson, FDA, to E.B. Adams, Endo Laboratories, Inc., coded ANS 80/11/17 to C00045 and SUP003, Docket No. 77N-0094, Dockets Management Branch.

R. Comments on Data Required for Evaluation

98. Several comments objected to the Panel's recommended aspirin tablet dissolution-testing procedure (42 FR 35488). One comment questioned the applicability of the procedure for any use other than quality control because of the variable results that can be obtained. A few comments criticized the methodology, such as the dissolution medium and the apparatus, and noted the disparity between the Panel's recommended dissolution-testing procedure and that of the United States Pharmacopeial Convention (USPC). Other comments stated that the procedure did not provide for combination drug products containing aspirin.

The Panel concluded that "significant variation in dissolution rate and absorption rate between aspirin products demonstrates the need for a standard dissolution test which can be used to detect preparations which will be so slowly absorbed as to potentially increase local adverse effects on the gastric mucosa or decrease therapeutic effects due to decreased bioavailability" (42 FR 35374). Therefore, the Panel recommended its testing procedure to elicit public comments for the development of a dissolution standard for aspirin tablets that would assure that these drug products are properly formulated. Since the Panel's report was published, the agency and the USPC have worked to develop a dissolution standard for aspirin tablets and capsules. Dissolution tests for aspirin capsules, aspirin tablets, and buffered aspirin tablets have become official in the U.S.P. (Refs. 1, 2, and 3). The agency is proposing to require this dissolution testing in new § 343.90.

Dissolution tests have also become official in the U.S.P. for acetaminophen and aspirin tablets (Ref. 4) and for combination drug products containing aspirin, alumina, and magnesia (Ref. 5). The agency is also proposing to require this testing in new § 343.90. Dissolution tests for other OTC aspirin combination drug products have not yet been formulated, and FDA is deferring to the USPC to develop compendial dissolution standards for such combinations. As appropriate tests are developed, FDA intends to propose to require them as part of this monograph or related monographs. Until appropriate dissolution standards are in place, other OTC aspirin combination products are classified as Category III. Interested persons are invited to submit data in support of appropriate dissolution tests for any such combination products for potential inclusion in the final monograph.

References

(1) "United States Pharmacopeia XXI—National Formulary XVI," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 77, 1985.

(2) "United States Pharmacopeia XXI—National Formulary XVI," Supplement 4, United States Pharmacopeial Convention, Inc., Rockville, MD, 2130, 1986.

(3) "United States Pharmacopeia XXI—National Formulary XVI," Supplement 4, United States Pharmacopeial Convention, Inc., Rockville, MD, 2131, 1986.

(4) "United States Pharmacopeia XXI—National Formulary XVI," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 14, 1985.

(5) "United States Pharmacopeia XXI—National Formulary XVI," Supplement 2, United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 1812 and 1813, 1985.

99. Noting that the Panel's recommended monograph contains no guidelines for studies needed to reclassify enteric-coated aspirin from Category III to Category I, one comment submitted proposed guidelines for studies to demonstrate the bioavailability of aspirin in an enteric-coated dosage form. The guidelines referred to an in vitro dissolution methodology for enteric-coated tablets, which the comment stated will be published in the U.S.P., and included a general proposal for designing a clinical protocol to test the bioavailability of enteric-coated aspirin. Two comments also submitted clinical protocols for bioavailability studies for enteric-coated aspirin products and requested that the protocols be approved by FDA for reclassifying enteric-coated aspirin from Category III to Category I.

The agency is aware that in vitro dissolution methodology for enteric-coated aspirin tablets and capsules has now been included in the U.S.P. (Ref. 1). However, the "enteric-coated" designation has been deleted in the U.S.P., and the products are now referred to as "Aspirin Delayed-Release Tablets" and "Aspirin Delayed-Release Capsules." FDA believes that the newly adopted U.S.P. test is an appropriate standard to support the reclassification of enteric-coated aspirin products from Category III to I. Therefore, the agency is proposing to include this dissolution test in the internal analgesic tentative final monograph in new § 343.90(c).

The agency had previously responded to the comments' clinical protocols for bioavailability studies (Refs. 2 and 3). Copies of these responses are on file in the Dockets Management Branch (address above). The need for bioavailability studies is superseded by the methodology recently included in the U.S.P.

The agency proposes that any other enteric-coated analgesics, e.g., sodium salicylate, remain in Category III until adequate specifications are established for these products.

References

(1) "United States Pharmacopeia XXI—National Formulary XVI," Supplement 3, United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 1972 and 1973, 1985.

(2) Letter from W.E. Gilbertson, FDA, to D. Marcus, Norcliff Thayer Inc., coded LET009 to C00109, Docket No. 77N-0094, Dockets Management Branch.

(3) Letter from W.E. Gilbertson, FDA, to E.J. Hiross, Sterling Drug Inc., coded ANS to C00110, Docket No. 77N-0094, Dockets Management Branch.

100. One comment, noting that the Panel recommended a dissolution test for plain as well as buffered aspirin tablets (42 FR 35488), expressed concern that there is no provision for a comparable test method for aspirin powder dosage forms.

The agency points out that the statement to which the comment referred is in the Panel's discussion of tablet dosage forms (42 FR 35374), in which the Panel expressed concern about significant variations in dissolution rate and absorption rate in buffered and unbuffered aspirin tablets. This concern prompted the Panel to recommend a dissolution test for aspirin tablets (buffered and unbuffered). The Panel did not recommend a dissolution test for powders because it concluded that they are rapidly absorbed and often reach peak blood levels more rapidly than the tablet dosage form (42 FR 35376).

As stated in comment 98 above, the agency is proposing to include in new § 343.90 of the internal analgesic tentative final monograph all of the dissolution tests for aspirin products that are in the U.S.P. There are no official dissolution tests for aspirin powders. Based on the Panel's discussion of powders and the fact that the agency is unaware of any problems of absorption with aspirin powders, the agency concludes that dissolution testing is not needed for either buffered or unbuffered aspirin powders.

101. One comment observed that the Panel's recommended buffered aspirin acid-neutralizing testing procedure (42 FR 35487) did not provide for the removal of aspirin. The comment stated that because aspirin interferes with the

assay, it should be removed before determining the buffering capacity.

The agency disagrees with the comment's suggestion that aspirin be removed from buffered aspirin drug products before testing their acid-neutralizing capacity. As stated in § 343.10(b)(2) of this tentative final monograph, the finished product must provide 1.9 mEq of acid-neutralizing capacity, which exceeds the amount needed to neutralize the aspirin. Therefore, no provision for the removal of aspirin is needed in the testing procedure.

102. One comment pointed out that measurement of the acid-neutralizing capacity of combination drug products containing buffered aspirin and other active ingredients may require modifications in the standard method used for testing buffered aspirin products in § 331.25.

The comment did not provide any specific examples of needed modifications. However, the agency has revised § 331.29 to establish a mechanism for requesting specific modifications in the test procedure. This revision was published as a final rule in the **Federal Register** of August 31, 1982 (47 FR 38480) and states that any proposed modification and the data to support it should be submitted as a petition according to § 10.30. The revision further provides for a redelegation of authority to grant or deny such petitions in order to facilitate prompt action.

S. Comments on Additional Ingredients for Monograph

103. One comment requested that the lysine salt of aspirin, which has been marketed in a number of countries for several years, be included in the tentative final monograph with an indication for the temporary relief from occasional minor aches, pains, and headaches. The comment provided information on the chemical and physical properties, toxicity, bioavailability, pharmacokinetics, and gastrointestinal tolerance of a lysine aspirin product. The comment stated that lysine aspirin is a readily soluble salt of aspirin that dissociates in water into lysine and acetylsalicylic acid, that the product is intended for solution in water prior to administration, and that acetylsalicylic acid is the active moiety that exists in the gastrointestinal tract and is absorbed.

The agency has determined that the lysine salt of aspirin is a "new drug" as defined in section 201(p)(2) of the act (21 U.S.C. 321(p)(2)) as follows:

Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

FDA interprets the terms "material extent" and "material time" to mean availability in the United States marketplace. The agency is unaware that lysine aspirin has ever been marketed as a drug in the United States. The comment provided no evidence to show otherwise. Thus, the agency regards this ingredient to be a new drug, requiring an approved application prior to OTC marketing.

104. One comment submitted information on calcium salicylate and requested that it be included as an analgesic ingredient in the tentative final monograph.

The Panel did not review calcium salicylate because no data were submitted on this ingredient. The comment provided information on the historical use, physical properties, and chemical preparation of calcium salicylate, but supplied no evidence that it has been marketed in the United States and provided no substantive data to demonstrate the safety and effectiveness of this ingredient as an OTC analgesic-antipyretic. FDA is not aware that calcium salicylate has ever been marketed as an OTC analgesic-antipyretic in the United States. Thus, calcium salicylate falls within the definition of a new drug within the meaning of section 201(p) of the act, as discussed in comment 103 above, and requires an approved application prior to marketing as an OTC analgesic-antipyretic drug.

The agency's detailed comments and evaluations on the data are on file in the Dockets Management Branch (Ref. 1).

Reference

(1) Letter from W.E. Gilbertson, FDA, to C. Schreur, Schreur Investments Inc., coded LET026 Docket No. 77N-0094, Dockets Management Branch.

105. One comment to the Miscellaneous Internal Panel requested that potassium salicylate be included as a Category I ingredient for use in OTC menstrual drug products. The comment argued that potassium salicylate is a naturally occurring substance and is equivalent to sodium salicylate and salicylic acid in terms of salicylate activity.

The comment did not include any data on this ingredient nor were any submitted to the Miscellaneous Internal Panel or to the Internal Analgesic Panel. The agency is aware that potassium salicylate has been marketed in the United States as an ingredient in OTC and prescription analgesic drug products (Refs. 1 through 6). Until data on potassium salicylate are submitted for review, however, the agency has an insufficient basis to consider further the request to include this ingredient in an OTC drug monograph. Based on its marketing history, potassium salicylate is classified as Category III in this tentative final monograph.

References

(1) Van Tyle, W.K., "Chapter 10—Internal Analgesic Products," *in* "Handbook of Nonprescription Drugs," 5th Ed., American Pharmaceutical Assoc., Washington, pp. 132–133, 1977.

(2) Van Tyle, W.K., "Chapter 10—Internal Analgesic Products," *in* "Handbook of Nonprescription Drugs," 7th Ed., American Pharmaceutical Assoc., Washington, p. 204 and p. 367, 1982.

(3) Korbethy, S.H., C.A. Sohn, and R.P. Tannenbaum, "Chapter 17—Menstrual Products," *in* "Handbook of Nonprescription Drugs," 7th Ed., American Pharmaceutical Assoc., Washington, p. 367, 1982.

(4) Sohn, C.A., B.H. Korbethy, and R.P. Tannenbaum, "Chapter 17—Menstrual Products," *in* "Handbook of Nonprescription Drugs," 7th Ed., American Pharmaceutical Assoc., Washington, p. 382, 1986

(5) Billings, N.F., and S.M. Billings, editors, "American Drug Index," 31st Ed., J.B. Lippincott Co., Philadelphia, p. 495, 1987.

(6) Huff, B.B., editor, "Physicians' Desk Reference," 41st Ed., Medical Economics Co., Inc., Oradell, NJ, p. 1631, 1987.

II. The Agency's Tentative Adoption of the Panel's Report

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. *Summary of ingredient categories.* The agency has reviewed all the claimed active ingredients submitted to the Internal Analgesic and Miscellaneous Internal Panels, as well as other data and information available at this time, and concurs with the Panels' categorization of ingredients. In addition, the agency has reviewed three ingredients not reviewed by the Panels. For the convenience of the reader, the following table is included as a summary of the categorization of analgesic-antipyretic active ingredients by the Panels and the proposed classification by the agency.

Analgesic-antipyretic active ingredients	Panels	Agency
Acetaminophen	I	I
Acetanilide [1]	II	II

Analgesic-antipyretic active ingredients	Panels	Agency
Aluminum aspirin	III	III
Antipyrine	III	III
Aspirin	I	I
Calcium salicylate	(2)	(3)
Carbaspirin calcium	I	I
Choline salicylate	I	I
Codeine	II	II
Iodoantipyrine [4]	II	II
Lysine aspirin	(2)	(3)
Magnesium salicylate	I	I
Potassium salicylate	(2)	III
Phenacetin	II	II
Quinine	II	II
Salicylamide	III	III
Salsalate	III	III
Sodium salicylate	I	I

[1] Formerly acetanilid.
[2] Not reviewed by the Internal Analgesic or Miscellaneous Internal Panels.
[3] Determined by the agency to be a "new drug."
[4] Identified by the Panel as iodopyrine.

After reviewing the available data and information, the agency has concluded that the Internal Analgesic Panel's categorization of ingredients for safety and effectiveness as analgesic-antipyretic adjuvants will remain unchanged, except for methapyrilene fumarate. The agency's reasons for recategorizing methapyrilene salts are presented in paragraph B. 32 below.

The following table is included as a summary of the categorization of analgesic-antipyretic adjuvant ingredients.

Analgesic-antipyretic adjuvants	Panel	Agency
Aminobenzoic acid	II	II
Caffeine	III	III
Methapyrilene fumarate	III	II
Pheniramine maleate	III	III
Phenyltoloxamine dihydrogen citrate.	III	III
Pyrilamine maleate	III	III
Salicylamide	III	III
Sodium para-aminobenzoate	II	II

The tables above do not address antirheumatic use, which appears only in professional labeling. The tables also do not address dosage forms, such as timed-release products, rectal suppositories, and enteric-coated aspirin. These dosage forms are discussed in comments 78, 79, and 99 above.

2. *Testing of Category II and Category III conditions.* The Panel recommended testing guidelines for analgesic, antipyretic, and antirheumatic drug products (42 FR 35444, 35453, 35468, and 35487). The agency is offering these guidelines as the Panel's recommendations without adopting them or making any formal comment on them unless otherwise noted in this document. (See comments 85, 88, 89, 91, 93, 97, 98, and 101 above.)

Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any internal analgesic, antipyretic, or antirheumatic ingredient or condition included in the review by following the procedures outlined in the agency's policy statement published in the **Federal Register** of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). This policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Changes in the Panel's Recommendations

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the Panel's report and recommended monograph with the changes described in FDA's responses to the comments above and with other changes described in the summary below. A summary of the changes made by the agency follows.

1. The Panel recommended as a statement of indications for OTC analgesic drug products: "For the temporary relief of occasional minor aches, pains and headache," and as a statement of indications for OTC antipyretic drug products: "For the reduction of fever." The agency is expanding and combining these statements to allow the inclusion of representative types of pain and causes of fever that are amenable to OTC treatment. (See comments 15, 16, and 17 above.) Accordingly, the statements in §§ 343.50(a) (2) and (3) are being deleted, and the labeling statement recommended in § 343.50(a)(1) is being changed to the following statement in this tentative final monograph (§ 343.50(b)(1)): "For the temporary relief of minor aches and pains" [which may be followed by one or more of the following: ("associated with" (select one or more of the following: "a cold," "the common cold," "sore throat," "headache," "toothache," "muscular aches," "backache," "the premenstrual and menstrual periods" (which may be followed by: "(dysmenorrhea)"), or "premenstrual and menstrual cramps" (which may be followed by: "(dysmenorrhea)"))), ("and for the minor pain from arthritis"), and ("and to reduce fever.")] The agency is also proposing to include "flu" as an indication for analgesic-antipyretic products containing acetaminophen. In addition, the agency is proposing that an OTC analgesic-antipyretic drug product may be identified as a "pain reliever," "analgesic (pain reliever)," "pain reliever-fever reducer," or "analgesic (pain reliever)-antipyretic (fever reducer)" (§ 343.50(a)).

2. The agency is proposing combined analgesic-antipyretic labeling for analgesic-antipyretic drug products labeled only for use in children, e.g., children's acetaminophen. Based upon representative types of pain and causes of fever that are amenable to OTC treatment in children over 2 years of age, the indications statement for OTC children's analgesic-antipyretic drug products is being proposed as follows (§ 343.50(b)(2)): "For the temporary relief of minor aches and pains" [which may be followed by: ("associated with" (select one or more of the following: "a cold," "the common cold," "sore throat," "headache," or "toothache")) and/or ("and to reduce fever.")] The agency is also proposing to include "flu" as an indication in the labeling of products that contain acetaminophen. (See comments 15 and 16 above.)

3. The agency is proposing in §§ 343.50 (c)(1)(ii) and (c)(2)(ii) of this tentative final monograph that internal analgesic drug products labeled for the relief of sore throat pain bear a modified version of the warning statement currently recommended in 21 CFR 369.20 for "throat preparations for temporary relief of minor sore throat: Lozenges, troches, washes, gargles, etc." (See comment 15 above.) In the tentative final monograph for OTC oral health care drug products, the agency has proposed to remove the existing recommended warning statement in § 369.20 as well as the suggested warning for OTC drugs for minor sore throats in § 201.315. (See 53 FR 2456.)

4. The warnings recommended by the Panel in §§ 343.50(c)(1) (i) and (ii) are being revised and proposed as three warnings as follows in § 343.50(c):

(1) *For products labeled for adults*—(i) *For products containing any ingredient in § 343.10.* "Do not take this product for pain for more than 10 days or for fever for more than 3 days unless directed by a doctor. If pain or fever persists or gets worse, if new symptoms occur, or if redness or swelling is present, consult a doctor because these could be signs of a serious condition."

(2) *For products labeled for children 2 years to under 12 years of age*—(i) *For products containing any ingredient in § 343.10.* "Do not give this product for pain for more than 5 days or for fever for more than 3 days unless directed by a doctor. If pain or fever persists or gets worse, if new symptoms occur, or if redness or swelling is present, consult a

doctor because these could be signs of a serious condition."

(3) *For products labeled both for adults and for children 2 years to under 12 years of age.* * * * "Do not take this product for pain for more than 10 days (for adults) or 5 days (for children), and do not take for fever for more than 3 days unless directed by a doctor. If pain or fever persists or gets worse, if new symptoms occur, or if redness or swelling is present, consult a doctor because these could be signs of a serious condition. Do not give this product to children for the pain of arthritis unless directed by a doctor."

These warnings are being revised for clarity, to distinguish between products used by adults and/or children, and to alert consumers to appropriate time limitations on self-treatment with OTC analgesic-antipyretic drug products as well as to symptoms that require professional treatment. (See comments 13, 14, 18, and 30 above.)

5. Because the agency is combining the indications for pain and fever into a single statement and because dosage schedules are the same for analgesic and antipyretic ingredients, the agency is proposing a single dosage schedule in § 343.50(d) for each analgesic-antipyretic ingredient. (See comments 16 and 53 above.) Section § 343.10 is being revised to list all active ingredients, and §§ 343.12 and 343.14 are being deleted.

6. The agency is proposing deletion of the warning recommended in § 343.50(c)(5)(ii) because consumers might interpret it to mean that acetaminophen can be used to treat arthritis. The agency is also proposing deletion of the warning recommended for aspirin in § 343.50(c)(3)(i) because the agency is concerned that different labeling statements on acetaminophen and aspirin products concerning arthritis might encourage consumers to self-diagnose and self-treat arthritis. (See comment 19 above.)

7. The agency is proposing the following in § 343.50(b)(4)(i) to provide for children's labeling: *For products labeled only for children 2 to under 12 years of age containing any ingredient identified in § 343.10.* (A) The labeling of the product contains, on the principal display panel, either of the following:

(*1*) "Children's (*trade name of product or generic name of ingredient(s)*)."

(*2*) "(*Trade name of product or generic name of ingredient(s)*) for Children."

(B) The labeling for adults in § 343.50(d) and the statement "Children 2 to under 12 years of age" in § 343.50(d)(3)(ii) are not required. (See comment 30 above.)

8. The following are agency-initiated changes in the Panel's recommended monograph based on the format and style of recently published monographs:

(a) The signal word "warning" has been used routinely in all labeling in OTC drug monographs instead of the signal word "caution." Accordingly, the word "caution" is not being included in § 343.50(c)(1)(v) (B) and (C) in this proposed monograph. (See comment 32 above.)

(b) The definition section contains only one definition: analgesic-antipyretic drug. Other definitions appearing in the advance notice of proposed rulemaking are not considered necessary for this tentative final monograph.

(c) The agency is redesignating proposed Subpart D of the monograph as Subpart C, placing the labeling sections under Subpart C.

(d) In an effort to simplify OTC drug labeling, the agency proposed in a number of tentative final monographs to substitute the word "doctor" for "physician" in OTC drug monographs on the basis that the word "doctor" is more commonly used and better understood by consumers. Based on comments received to these proposals, the agency has determined that final monographs and other applicable OTC drug regulations will give manufacturers the option of using either the word "physician" or the word "doctor." This tentative final monograph proposes that option.

9. The agency is proposing to delete the first sentence of the aspirin hypersensitivity warning recommended in § 343.50(c)(4)(i) (redesignated § 343.50(c) (1)(iv)(A) and (2)(iv)(A)), "This product contains aspirin." (See comment 33 above.) This sentence is unnecessary because section 502(e)(1) of the act (21 U.S.C. 352(e)(1)) requires all drug products to bear on the label the established name of the active ingredient or ingredients contained in the product.

10. The agency is proposing that the warning recommended in § 343.50(c)(3)(v) (redesignated § 343.50(c)(1)(v)(C)) be identified as a drug interaction precaution (see comment 36 above) as follows: "*Drug Interaction Precaution.* Do not take this product if you are taking a prescription drug for anticoagulation (thinning the blood), diabetes, gout, or arthritis unless directed by a doctor." This precaution is being modified in § 343.50(c)(2)(v)(C) for products labeled for children 2 years to under 12 years of age. For products labeled both for adults and children, the precaution for adults will apply. (See § 343.50(c)(3).)

11. The agency is revising the warning recommended in § 343.50(c)(3)(ii) (redesignated § 343.50(c) (1)(v)(A) and (2)(v)(A)) to read: "If ringing in the ears or a loss of hearing occurs, consult a doctor before taking any more of this product." The agency believes this wording more clearly conveys the appropriate course of action to the consumer. (See comment 39 above.)

12. The statements recommended by the Panel in § 343.50(c)(3)(iii) (*a*) and (*b*) are being moved to § 343.50(d)(3) (i) and (ii) in the tentative final monograph because they are directions for use, not warnings. (See comment 41 above.)

13. The agency is proposing deletion of the term "stomach distress" from § 343.50(c)(3)(iv) (redesignated § 343.50(c)(1)(v)(B)) and is revising the warning as follows: "Do not take this product if you have stomach problems (such as heartburn, upset stomach, or stomach pain) that persist or recur, or if you have ulcers or bleeding problems, unless directed by a doctor." This warning is being further revised in § 343.50(c)(2)(*vi*)(B) for products labeled for children 2 years to under 12 years of age. For products labeled for both adults and children, the warning for adults will apply. (See § 343.50(c)(3). See also comment 31 above.)

14. The Panel classified the claims "acts five times faster than aspirin" and "reaches peak action twelve times faster than aspirin" in Category II for choline salicylate. However, the agency finds a reasonable basis to classify such claims in Category III. (See comment 45 above.) This classification is consistent with the Panel's treatment of similar claims for buffered aspirin, i.e., the data are not sufficient to support such claims as "faster to the bloodstream than plain aspirin."

15. The agency finds that labeling claims such as "extra-strength," "extra pain relief," "maximum strength," and "arthritis strength" are outside the scope of the OTC drug review. (See comment 48 above.)

16. The Panel recommended a children's dosage unit of 80 mg for aspirin and acetaminophen. The agency is proposing that the children's dosage unit for aspirin, acetaminophen, and sodium salicylate be 80 mg or 81 mg because both strengths are marketed, and the difference between these strengths is of no therapeutic consequence. In addition, a minimal effective dose for children over 9 years of age (i.e., 320 mg for the 80-mg dosage unit, 324 mg for the 81-mg dosage unit, or 325 mg for the 325-mg dosage unit) is being added to the children's dosage schedule. (See comment 58 above.)

17. Quantities of active ingredients are expressed in the tentative final

monograph in metric units only. Manufacturers may voluntarily list quantities of active ingredients in both apothecary and metric units. (See comment 80 above.)

18. The agency is not adopting the analgesic equivalence value labeling statements recommended by the Panel in § 343.50(e) because they do not appear to serve their intended purpose and could be confusing to consumers. (See comment 56 above.)

19. The statements on dosage units recommended in § 343.50(d) are also being deleted in this tentative final monograph. The agency believes that the terms "standard" and "nonstandard" would not serve their intended purpose of simplifying comparisons among various products and may confuse consumers. (See comment 53 above.)

20. The dosage schedules for aspirin, acetaminophen, and sodium salicylate recommended by the Panel in § 343.10 (a), (b), and (f) are being revised to eliminate the concepts of "standard" and "nonstandard" schedules and are being combined under § 343.50(d)(2). (See comment 53 above.) In accordance with the agency's changes discussed in this paragraph and in paragraph number 18 above, the Panel's recommended definitions in § 343.3 (c), (m), and (p) are not being included in this tentative final monograph.

21. The agency concurs with the Panel's recommendation on dosages of aspirin, acetaminophen, and sodium salicylate for adults and has incorporated this information in the directions section of the tentative final monograph (§ 343.50(d)), except that the agency is not including in the tentative final monograph a maximum initial dose of 975 mg for these ingredients when given in a 4-hour dosage regimen. (See comments 53 and 63 above.)

22. The Panel recommended a dosage of 325 to 650 mg magnesium salicylate every 4 hours, based upon data submitted on a product containing 325 mg of the tetrahydrate form of magnesium salicylate. This is the same as the dosage range established for sodium salicylate. However, the agency has determined that 377 mg magnesium salicylate tetrahydrate, and not 325 mg, is equivalent to 325 mg sodium salicylate. Given a minimum effective dosage of 325 mg sodium salicylate, the dosage of magnesium salicylate tetrahydrate that would contain an equivalent amount of salicylic acid is 377 mg. Therefore, the agency concludes that the minimum effective dosage of magnesium salicylate should be 377 mg, and the maximum dosage for this ingredient should be 754 mg. The dosages for magnesium salicylate are being revised accordingly, and this tentative final monograph specifies in § 343.50(d)(6) that the dosages are based on the tetrahydrate form of magnesium salicylate. (See comment 64 above.)

23. The agency is not including analgesic-antipyretic combinations that contain only salicylates in this monograph because such combinations are not in accordance with general OTC combination drug product guidelines. (See comment 72 above.) However, the agency has expanded the allowable combinations recommended by the Panel by providing a range of acceptable amounts of active ingredients that may be contained in a combination product. The agency discussed combination products containing analgesic and cough-cold ingredients in § 341.40 of the cough-cold combinations tentative final monograph (53 FR 30522). Accordingly, the Panel's recommendations in § 343.20(d) (1), (2), (3), and (4) of its monograph are not being addressed in this tentative final monograph, and appropriate cross-references to Part 341 are being included. (See comment 67 above.)

24. Based on the recommendations of the Miscellaneous Internal Panel, the agency has expanded the combination section of the monograph to provide for allowable combinations of analgesic ingredients or combinations of analgesic ingredients with a diuretic when the product is labeled for "menstrual" claims. (See the tentative final monograph for OTC menstrual drug products published elsewhere in this issue of the **Federal Register**.)

25. The agency notes that the Panel concluded that OTC acetaminophen products for children should be packaged in containers containing no more than 36 tablets (42 FR 35415). This recommendation was based on an existing regulation recommending a 36-tablet limitation of 1¼ gr children's aspirin tablets in § 201.314(c)(2) (21 CFR 201.314(c)(2)) and not on data pertaining to the toxicity of acetaminophen in children. No comments were submitted in response to the Panel's recommendation. The agency has evaluated currently marketed pediatric acetaminophen products (Ref. 1) and does not believe it necessary to include this packaging limitation in the tentative final monograph. The agency specifcally invites comments on the need for a regulation to limit the number of dosage units per container for pediatric dosage forms of acetaminophen in light of child proof closures and the degree of voluntary compliance in effect at this time among the manufacturers of these products. The agency also invites comments on the need for a regulation requiring the 36-tablet limitation for pediatric aspirin products which is recommended in 21 CFR 201.314(c)(2).

Reference

(1) Cardinale, V.A., Editor, "1987 Redbook," Medical Economics Company Inc., Oradell, NJ, pp. 100–103, 130, 253, 452, 563, 600, 1987.

26. The agency is changing the Panel's recommended single dose of 65 mg caffeine to 75 mg caffeine as an analgesic adjuvant, not to exceed a single adult dose of 150 mg or a maximum daily dose of 600 mg. Caffeine remains in Category III as an analgesic adjuvant. However, industry has responded to FDA's concern and provided additional data which are currently under review by the agency. (See comment 92 above.)

27. The agency is proposing to include by reference the dissolution testing procedures for aspirin capsules, as contained in U.S.P. XXI at page 77, for aspirin tablets as contained in U.S.P. XXI Supplement 4 at page 2130, and for buffered aspirin tablets, as contained in U.S.P. XXI Supplement 4 at page 2131, as part of this tentative final monograph. (See comment 98 above.) Furthermore, the agency is also including by reference the dissolution standard for acetaminophen and aspirin tablets as contained in U.S.P. XXI at page 14, the dissolution standard for one aspirin combination product as contained in U.S.P. XXI Supplement 2 at pages 1812 and 1813, and the dissolution standard for enteric coated aspirin tablets (delayed-release tablets) as contained in U.S.P. XXI Supplement 3 at pages 1972 and 1973. (See comments 98 and 99 above.)

28. The agency is deleting the Panel's recommended definition for buffered aspirin in § 343.3(j) and is including the definition in the active ingredients section (§ 343.10(b)(2)) of this tentative final monograph as a result of the establishment of a U.S.P. monograph for buffered aspirin tablets in U.S.P. XXI Supplement 4 at page 2131. The definition of buffered aspirin in § 343.10(b)(2) of this tentative final monograph is being proposed as follows: Buffered Aspirin "Aspirin identified in paragraph (b)(1) of this section may be buffered with any antacid ingredient(s) identified in § 331.11 provided that the finished product contains at least 1.9 milliequivalents of acid-neutralizing capacity per 325 milligrams in accordance with § 331.26." (See comments 42 and 77 above.)

29. The agency is deleting the Panel's recommended definition in § 343.3(k) because the same information is

contained in § 343.20(d)(6) (see comment 76 above) which is being redesignated § 343.20(b)(3) in this tentative final monograph and is being revised to include all products containing aspirin with antacid as follows: "Aspirin identified in § 343.10(b)(1) may be combined with any antacid ingredient identified in § 331.11 or any combination of antacids permitted in accordance with § 331.10(a) provided that the finished product meets the requirements of § 331.10, is marketed in a form intended for ingestion as a solution, and bears labeling indications in accordance with § 343.60(b)(4)."

In addition, the agency is proposing that such products be identified as follows: "pain reliever/fever reducer" (or the variation permitted in § 343.50(a)) and "antacid." (See comments 42 and 76 above.)

30. The agency is proposing indications for products containing aspirin with antacid that are based upon the aspirin indications for pain and fever in § 343.50(b)(1) and the antacid indications in § 331.30(b). (See comment 47 above.)

31. The labeling for products containing acetaminophen with antacid (acetaminophen and antacid combinations), provided for in recommended § 343.20(d)(5) and redesignated § 343.20(b)(1) in this tentative final monograph, is being modified to include a statement of identity and the revised indications labeling in § 343.60. (See comment 47 above.)

32. The agency is including in § 343.80 proposed professional labeling on the use of aspirin, buffered aspirin, or aspirin in combination with an antacid in the prevention of myocardial infarction in patients with a previous infarction or unstable angina pectoris. The agency is also proposing to incorporate labeling on the use of aspirin and buffered aspirin without sodium for transient ischemic attacks. (See comments 49 and 50 above.)

A number of other professional labeling indications also are being proposed in § 343.80(a) of the tentative final monograph. The agency is aware that some manufacturers have included statements in the labeling of their internal analgesic-antipyretic drug products that advise consumers to see their doctor for other (or new) uses of aspirin (or name of product). Such information may be beneficial to consumers, and the agency has no objection to a general statement of this type being included in the labeling of OTC internal analgesic-antipyretic drug products. The agency is also aware that information about these other uses of these products has appeared in newspapers and magazines and on television and radio. The agency is concerned that consumers may read or hear this information and self-medicate with an OTC drug product for one of these conditions without consulting with their doctor. Consumers should not self-medicate with an OTC analgesic-antipyretic drug product for any of these professional indications, and use for any of these conditions should be only under a doctor's supervision because serious side effects may occur. The agency believes that it is important that any information provided to consumers about other (professional) uses of these products be accompanied by a counterbalancing statement that the consumer should not use the product for more than 10 days (consistent with the allowable OTC labeling being proposed in this tentative final monograph) without consulting their doctor because serious adverse effects may occur. Examples include possible bleeding and stroke.

Based upon these new uses of aspirin and recognizing the evolving nature of this issue, the agency is proposing the following optional statement in this tentative final monograph: "See your doctor for other uses of [insert name of ingredient or trade name of product], but do not use for more than 10 days without consulting your doctor because serious side effects may occur." The agency believes that such information should be provided to consumers in the most effective manner and should be prominently displayed in labeling so that it may readily be seen and understood. At this time, the agency is proposing this as optional (allowable) labeling. The agency invites comment on this statement or other alternative labeling, appropriate placement in labeling, and whether the 10 day limitation on use should be an integral part of any such statement. The agency also invites comment on whether this information should be part of the required labeling for these products.

33. The agency is not adopting the liver warning in § 343.50(c)(5)(i), but is proposing that one of the following overdose warnings appear on all acetaminophen products to follow those general overdose warnings required in § 330.1(g) (21 CFR 330.1(g)): for products labeled for adults (§ 343.50(c)(1)(iii)), "Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms" or for products labeled for children (§ 343.50(c)(2)(iii)), "Prompt medical attention is critical even if you do not notice any signs or symptoms." For products labeled for both adults and children, the warning for adults will apply, as described in § 343.50(c)(3). (See comment 25 above.)

34. The agency has reclassified methapyrilene fumarate from Category III to Category II as an OTC analgesic, antipyretic, and antirheumatic adjuvant ingredient. A tentative final rule for nighttime sleep-aids, published in the **Federal Register** of June 13, 1978 (43 FR 25544), proposed to place methapyrilene in Category II because of preliminary studies implicating this drug as a carcinogen, or a carcinogen synergist with nitrates, in rats. However, at that time, the studies were too preliminary to support a definitive finding of carcinogenicity for methapyrilene that would necessitate its immediate removal from all products in the OTC drug market.

On May 1, 1979, the agency received an interim report from the National Cancer Institute (NCI) regarding carcinogenicity studies performed with methapyrilene at the Frederick Cancer Research Center. The results of these studies have been published by Lijinsky, Reuber, and Blackwell (Ref. 1). The NCI interim report stated that methapyrilene is a potent carcinogen in rats and must be considered a potential carcinogen in man. FDA reviewed this report and concurred with its conclusions. In June 1979, the agency initiated a recall letter to all manufacturers holding an approved new drug application (NDA) for products containing methapyrilene. This voluntary recall has eliminated drug products containing methapyrilene from the marketplace. Products containing methapyrilene are now considered to be misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) and "new drugs" under section 201(p) of the act (21 U.S.C. 321(p)).

The agency received no comments on methapyrilene fumarate, which was classified as Category III by the Panel as an analgesic adjuvant. Based on the studies discussed above, the agency has reclassified methapyrilene fumarate from Category III to Category II.

Reference

(1) Lijinsky, W., M.D. Reuber, and B.N. Blackwell, "Liver Tumors Induced in Rats by Chronic Oral Administration of the Common Antihistamine Methapyrilene Hydrochloride," *Science*, 209:817–819, 1980.

35. The agency is expanding the Panel's recommended warning on salicylate allergy in § 343.50(c)(6) (redesignated § 343.50(c) (1)(v) and (2)(v)) to include aspirin in an effort to assure that consumers, most of whom are apt to be familiar with aspirin, will

understand that aspirin is also a salicylate and that the allergic reaction that they may associate with aspirin is a salicylate allergy and can be caused by any of the ingredients in this drug group.

36. The Panel was concerned with the effects of aspirin or carbaspirin calcium on increasing duration of labor, changing hemostatic mechanisms in the newborn and increasing maternal blood loss (42 FR 35404). The latter may be a hazard particularly in premature labor and thus at any time during the last 3 months of pregnancy. For these reasons, the Panel concluded that there is a potential hazard to the use of aspirin during pregnancy and recommended the following warning on all aspirin-containing products: "Do not take this product during the last 3 months of pregnancy except under the advice and supervision of a physician." The agency received no comments on this issue, but is expanding the Panel's labeling recommendation to inform consumers of the reason for the warning. In addition, in the **Federal Register** of December 3, 1982 (47 FR 54750), the agency published a final rule to amend the general drug labeling provisions in Part 201 by adding new § 201.63, which includes the following warning to pregnant and nursing women concerning the use of OTC drugs that are intended for systemic absorption: "As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product." Because of this more recent general warning, the agency is proposing that the following revised warning follow the warning required in § 201.63(a): "IMPORTANT: Do not take this product during the last 3 months of pregnancy unless directed by a doctor. Aspirin taken near time of delivery may cause bleeding problems in both mother and child."

37. After reviewing the conclusions stated in three Panel reports (Oral Cavity at 42 FR 22796, Internal Analgesic at 42 FR 35376, and Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment at 44 FR 69845) concerning aspirin's ability to exert a topical effect as well as the available data, the agency concluded that there are not sufficient data available to permit final classification of aspirin as a topical analgesic/anesthetic in the tentative final monograph for OTC oral health care drug products, published in the **Federal Register** of January 27, 1988 (53 FR 2436). In that tentative final monograph, the agency deferred the systemic effectiveness of aspirin in a chewing gum dosage form for the relief of many kinds of pain including sore throat to this rulemaking (53 FR 2442). Although the topical analgesic effect of aspirin is not being specifically addressed in this rulemaking, the agency tentatively accepts the conclusion of the majority of the Oral Cavity Panel and the Internal Analgesic Panel that aspirin in a chewing gum base is safe for the relief of sore throat pain when labeled with adequate directions and warnings against misuse.

Although the Internal Analgesic Panel concluded that the topical effect of aspirin or any analgesic in a chewing gum dosage form has not been adequately tested for the treatment of sore throat pain, it found the marketing of an OTC analgesic in a chewing gum formulation acceptable for its systemic analgesic effect if the product provides the minimum effective dose (325 to 650 mg aspirin/dose) and is labeled according to the Panel's proposed monograph. The Panel also stated its concern about the possibility of oral mucosal damage and the effect of aspirin on blood clotting after oral surgery or tonsillectomy and recommended that the labeling of such product formulations include the warning, "Do not take this product for at least 7 days after tonsillectomy or oral surgery except under the advice and supervision of a physician." The Panel further recommended that aspirin for a local topical effect be deferred to the Oral Cavity Panel for evaluation (42 FR 35376).

The Oral Cavity Panel concluded that OTC anesthetic/analgesic ingredients are useful for the treatment of the symptoms of occasional minor sore throat and mouth but was divided in its conclusions about the safety and effectiveness of aspirin as an anesthetic/analgesic ingredient for topical use on the mucous membranes of the mouth and throat (47 FR 22769 and 22796). The majority of the Panel concluded that aspirin incorporated in a chewing gum base is safe and effective as an OTC anesthetic/analgesic ingredient for topical use on the mucuous membranes of the mouth and throat. However, the minority of the Panel concluded that there were insufficient data available to permit final classification of the safety and effectiveness of aspirin as an OTC anesthetic/analgesic ingredient. The minority of the Panel had reservations about the safety of topically applied aspirin used in the oral cavity and believed that aspirin has no known topical anesthetic or analgesic activity. It also believed that any analgesic effect from aspirin applied topically in the oral cavity is ultimately due to systemic absorption and not to topical application. Both the majority and minority of the Panel concluded that aspirin should not be used following operative procedures of the mouth or throat.

Because the agency is aware that aspirin increases bleeding time and inhibits platelet aggregation (42 FR 35384 and 47 FR 22797) and because aspirin-related hemorrhage after oral surgery and tonsillectomy is a well documented occurrence (Refs. 1, 2, and 3), the agency agrees with both the Internal Analgesic and Oral Cavity Panels that aspirin in a chewing gum form or chewable tablet form should not be used for at least 7 days after oral surgery or tonsillectomy (42 FR 35377 and 47 FR 22798 and 22801). The agency is therefore proposing the following warning for these dosage forms of aspirin: "Do not take this product for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor."

References

(1) Hersh, R.A., "A Clinical Study Comparing the Incidence of Postoperative Bleeding in Patients Using Salicylate Containing Analgesics Versus Acetaminophen Analgesics," *The Bulletin of the Bergen County Dental Society*, 40:6–8 and 16, 1974.

(2) Reuter, S.H., and W.W. Montogomery, "Aspirin vs Acetaminophen After Tonsillectomy," *Archives of Otolaryngology*, 42:214–217, 1964.

(3) Singer, R., "Acetylsalicylic Acid: A Probable Cause for Secondary Tonsillectomy Hemorrhage," *Archives of Otolaryngology*, 42:19–20, 1945.

38. Section 201.314 (21 CFR 201.314) sets forth certain labeling requirements regarding warnings on OTC drug products containing salicylates and statements of policy on labeling such drugs. Several provisions of § 201.314 may be superseded by the requirements established in several OTC drug final monographs (e.g., internal analgesic, external analgesic, and overindulgence in alcohol and food). When those monographs are finalized, the agency will revise the appropriate portions of § 201.314. In addition, the agency may incorporate some of the requirements of § 201.314 into the appropriate monographs.

In addition, the agency is proposing to remove paragraph (a)(1) of § 310.201 and reserve paragraph (a)(1) for future use. The provisions of § 310.201(a)(1) will be superseded by the requirements of the internal analgesic final monograph. For the same reason, those portions of §§ 369.20 and 369.21 applicable to salicylates and acetaminophen are also proposed for removal.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC internal analgesic, antipyretic, and antirheumatic drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, Pub. L. 96–354. That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC internal analgesic, antipyretic, and antirheumatic drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any impact that this rulemaking would have on OTC internal analgesic, antipyretic, and antirheumatic drug products. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on OTC internal analgesic, antipyretic, and antirheumatic drug products should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on internal analgesic, antipyretic, and antirheumatic drug products, a period of 180 days from the date of publication of this proposed rulemaking in the **Federal Register** will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined that under 21 CFR 25.24(c)(6) 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.

Sections 343.50(c)(1)(viii)(A) and 343.50(c)(2)(viii)(A) of this proposed rule contain collection of information requirements. As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA has submitted a copy of this proposed rule to the Office of Management and Budget (OMB) or its review of these collection of information requirements. Other organizations and individuals desiring to submit comments on the collection of information requirements should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, Rm. 3208, New Executive Office Bldg., Washington, DC 20503, Attn: Shannah Koss.

Interested persons may, on or before May 16, 1989, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before May 16, 1989. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register**.

Interested persons, on or before November 16, 1989, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before January 16, 1990. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the **Federal Register** of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (HFA–305) (address above). Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on January 16, 1990. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the **Federal Register** unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects

21 CFR Part 310

Administrative practice and procedure, Drugs, Prescription exemption.

21 CFR Part 343

Internal analgesics, Labeling, Over-the-counter drugs.

21 CFR Part 369

Labeling, Over-the-counter drugs, Warning and caution statements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR Part 310 is revised to read as follows:

Authority: Secs. 501, 502, 503, 505, 701, 704, 705, 52 Stat. 1049–1053 as amended, 1055–1056 as amended, 67 Stat. 477 as amended, 52 Stat. 1057–1058 (21 U.S.C. 351, 352, 353, 355, 371, 374, 375); 5 U.S.C. 553; 21 CFR 5.10 and 5.11.

§ 310.201 [Amended]

2. In Subpart C, § 310.201 *Exemption for certain drugs limited by new-drug applications to prescription sale* is amended by removing paragraph (a)(1) and reserving it.

3. Part 343 is added to read as follows:

PART 343—INTERNAL ANALGESIC, ANTIPYRETIC, AND ANTIRHEUMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.
343.1 Scope.
343.3 Definitions.

Subpart B—Active Ingredients

343.10 Analgesic-antipyretic active ingredients.
343.20 Permitted combinations of active ingredients.

Subpart C—Labeling

343.50 Labeling of analgesic-antipyretic drug products.
343.60 Labeling of permitted combinations of active ingredients.
343.80 Professional labeling.

Subpart D—Testing Procedures

343.90 Dissolution Testing.

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.10 and 5.11.

Subpart A—General Provisions

§ 343.1 Scope.

(a) An over-the-counter analgesic-antipyretic drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this part in addition to each of the general conditions established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 343.3 Definitions.

As used in this part:

Analgesic-antipyretic drug. An agent used to alleviate pain and to reduce fever.

Subpart B—Active Ingredients

§ 343.10 Analgesic-antipyretic active ingredients.

The active ingredients of the product consist of any of the following when used within the dosage limits established for each ingredient in § 343.50(d):

(a) Acetaminophen.

(b) *Aspirin ingredients.* (1) Aspirin.

(2) Buffered aspirin. Aspirin identified in paragraph (b)(1) of this section may be buffered with any antacid ingredient(s) identified in § 331.11 of this chapter provided that the finished product contains at least 1.9 milliequivalents of acid-neutralizing capacity per 325 milligrams of aspirin in accordance with § 331.26 of this chapter.

(c) Carbaspirin calcium.

(d) Choline salicylate.

(e) Magnesium salicylate.

(f) Sodium salicylate.

§ 343.20 Permitted combinations of active ingredients.

The following combinations are permitted provided each active ingredient is present within the established dosage limits and the product is labeled in accordance with § 343.60. Combinations containing aspirin must also meet the standards of an acceptable dissolution test, as set forth in § 343.90.

(a) *Combinations of acetaminophen with other analgesic-antipyretic active ingredients.* Acetaminophen identified in § 343.10(a) may be combined with any one ingredient listed below provided that each dose of the product contains 325 to 500 milligrams acetaminophen and the amount of the other ingredient as follows and provided that the product is not labeled for use by children under 12 years of age:

(1) Aspirin 325 to 500 milligrams.

(2) Carbaspirin calcium 414 to 637 milligrams.

(3) Choline salicylate 435 to 669 milligrams.

(4) Magnesium salicylate 377 to 580 milligrams.

(5) Sodium salicylate 325 to 500 milligrams.

(b) *Combinations of analgesic-antipyretic active ingredients with nonanalgesic-nonantipyretic active ingredients*—(1) *Acetaminophen and antacid combinations.* Acetaminophen identified in § 343.10(a) may be combined with any antacid ingredient identified in § 331.11 of this chapter or any combination of antacids permitted in accordance with § 331.10(a) of this chapter provided that the finished product meets all the requirements of § 331.10 of this chapter and bears labeling indications in accordance with § 343.60(b)(2).

(2) *Analgesic-antipyretic and cough-cold combinations.* See § 341.40 of this chapter.

(3) *Aspirin and antacid combinations.* Aspirin identified in § 343.10(b)(1) may be combined with any antacid ingredient identified in § 331.11 of this chapter or any combination of antacids permitted in accordance with § 331.10(a) of this chapter provided that the finished product meets the requirements of § 331.10 of this chapter, is marketed in a form intended for ingestion as a solution, and bears labeling indications in accordance with § 343.60(b)(4).

(4) *Analgesic and diuretic combinations.* Any analgesic identified in § 343.10 or any combination of analgesics identified in § 343.20(a) may be combined with any diuretic identified in § 357.1012 of this chapter provided the product bears labeling indications in accordance with § 357.1060(b) of this chapter.

Subpart C—Labeling

§ 343.50 Labeling of analgesic-antipyretic drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "pain reliever" or "analgesic (pain reliever)." If the product is also labeled to include the indication "to reduce fever," then the statement of identity of the product consists of the established name of the drug, if any, and identifies the product as a "pain reliever-fever reducer" or "analgesic (pain reliever)-antipyretic (fever reducer)."

(b) *Indications.* The labeling of the product states, under the heading "Indications," any of the phrases listed in this paragraph, as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established in this paragraph (b), may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For products containing any ingredient identified in § 343.10.* "For the temporary relief of minor aches and pains" [which may be followed by one or more of the following: ("associated with" (select one or more of the following: "a cold," "the common cold," "sore throat," "headache," "toothache," "muscular aches," "backache," "the premenstrual and menstrual periods" (which may be followed by: "(dysmenorrhea),") or "premenstrual and menstrual cramps" (which may be followed by: "(dysmenorrhea)))", ("and for the minor pain from arthritis"), and ("and to reduce fever.")]

(2) *For products labeled only for children 2 years to under 12 years of age.* "For the temporary relief of minor aches and pains" [which may be followed by: ("associated with" (select one or more of the following: "a cold," "the common cold," "sore throat," "headache," or "toothache")) and/or ("and to reduce fever.")]

(3) *For products containing acetaminophen as identified in § 343.10(a).* The term "flu" may be added to the indications identified in paragraphs (b) (1) and (2) above.

(4) *Other required statements—(i) For products labeled only for children 2 to under 12 years of age containing any ingredient identified in § 343.10.* (A) The labeling of the product contains, on the principal display panel, either of the following:

(*1*) "Children's *(trade name of product or generic name of ingredient(s))."*

(*2*) *"(Trade name of product or generic name of ingredient(s))* for Children."

(B) The labeling for adults in § 343.50(d) and the statement "Children 2 to under 12 years of age" in § 343.50(d)(3)(ii) are not required.

(ii) *For products labeled only for adults containing any ingredient identified in § 343.10 and any combination identified in § 343.20.* (A) The labeling of the product contains, on the principal display panel, either of the following:

(*1*) "Adult's *(trade name of product or generic name of ingredient(s))."*

(*2*) *"(Trade name of product or generic name of ingredient(s)) for adults."*

(B) The labeling for children in § 343.50(d) and the word "Adults" in § 343.50(d)(3)(i) are not required.

(C) The product should not contain any labeling for children under 12 years of age except the following statement under the heading "Directions," "Children under 12 years of age: consult a doctor."

(c) *Warnings.* The labeling of the product contains the following statements under the heading "Warnings." If applicable, warnings may be combined to eliminate duplicative words or phrases so the resulting warning(s) are clear and understandable.

(1) *For products labeled for adults*—(i) *For products containing any ingredient in § 343.10.* "Do not take this product for pain for more than 10 days or for fever for more than 3 days unless directed by a doctor. If pain or fever persists or gets worse, if new symptoms occur, or if redness or swelling is present, consult a doctor because these could be signs of a serious condition."

(ii) *For products containing any ingredient in § 343.10 and labeled for the relief of sore throat pain.* "If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly."

(iii) *For products containing acetaminophen identified in § 343.10(a).* The following statement must follow the general warning identified in § 330.1(g) of this chapter: "Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms."

(iv) *For products containing aspirin or carbaspirin calcium identified in §§ 343.10 (b) and (c).* (A) "Do not take this product if you are allergic to aspirin or if you have asthma unless directed by a doctor."

(B) The following warning must follow the general warning identified in § 201.63(a) of this chapter: "IMPORTANT: Do not take this product during the last 3 months of pregnancy unless directed by a doctor. Aspirin taken near the time of delivery may "cause bleeding problems in both mother and child."

(C) *For products in a chewable dosage form.* "Do not take this product for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor."

(v) *For products containing aspirin, carbaspirin calcium, choline salicylate, magnesium salicylate, or sodium salicylate identified in §§ 343.10 (b), (c), (d), (e), and (f).* (A) "If ringing in the ears or a loss of hearing occurs, consult a doctor before taking any more of this product."

(B) "Do not take this product if you have stomach problems (such as heartburn, upset stomach, or stomach pain) that persist or recur, or if you have ulcers or bleeding problems, unless directed by a doctor."

(C) *"Drug Interaction Precaution.* Do not take this product if you are taking a prescription drug for anticoagulation (thinning the blood), diabetes, gout, or arthritis unless directed by a doctor."

(vi) *For products containing choline salicylate, magnesium salicylate, or sodium salicylate identified in § 343.10 (d), (e), and (f).* "Do not take this product if you are allergic to salicylates (including aspirin) unless directed by a doctor."

(vii) *For products containing magnesium salicylate identified in § 343.10(e) in an amount more than 50 milliequivalents of magnesium in the recommended daily dosage.* "Do not take this product if you have kidney disease unless directed by a doctor."

(viii) *For products containing sodium salicylate identified in § 343.10(f)*—(A) *For products containing 0.2 milliequivalent (5 milligrams) or higher of sodium per dosage unit.* The labeling of the product contains the sodium content per dosage unit (e.g., tablet, teaspoonful) if it is 0.2 milliequivalent (5 milligrams) or higher.

(B) *For products containing more than 5 milliequivalents (125 milligrams) sodium in the maximum recommended daily dosage.* "Do not take this product if you are on a sodium restricted diet unless directed by a doctor."

(2) *For products labeled for children 2 years to under 12 years of age*—(i) *For products containing any ingredient in § 343.10.* "Do not give this product for pain for more than 5 days or for fever for more than 3 days unless directed by a doctor. If pain or fever persists or gets worse, if new symptoms occur, or if redness or swelling is present, consult a doctor because these could be signs of a serious condition."

(ii) *For products containing any ingredient in § 343.10 and labeled for the relief of sore throat pain.* "If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly."

(iii) *For products containing acetaminophen identified in § 343.10(a).* The following statement must follow the general warning identified in § 330.1(g) of this chapter: "Prompt medical attention is critical even if you do not notice any signs or symptoms."

(iv) *For products containing aspirin or carbaspirin calcium identified in § 343.10 (b) and (c).* (A) "Do not give this product to children who are allergic to aspirin or who have asthma unless directed by a doctor."

(B) *For products in a chewable dosage form.* "Do not give this product for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor."

(v) *For products containing aspirin, carbaspirin calcium, choline salicylate, magnesium salicylate, or sodium salicylate identified in § 343.10 (b), (c), (d), (e), and (f).* (A) "If ringing in the ears or a loss of hearing occurs, consult a doctor before giving any more of this product."

(B) "Do not give this product to children who have stomach problems (such as heartburn, upset stomach, or stomach pain) that persist or recur, or who have ulcers or bleeding problems, unless directed by a doctor."

(C) *"Drug Interaction Precaution.* Do not give this product to children who are taking a prescription drug for anticoagulation (thinning the blood), diabetes, gout, or arthritis unless directed by a doctor."

(vi) *For products containing choline salicylate, magnesium salicylate, or sodium salicylate identified in § 343.10 (d), (e), and (f).* "Do not give this product to children who are allergic to salicylates (including aspirin) unless directed by a doctor."

(vii) *For products containing magnesium salicylate identified in § 343.10(e) in an amount more than 50 milliequivalents of magnesium in the*

recommended daily dosage. "Do not give this product to children who have kidney disease unless directed by a doctor."

(viii) *For products containing sodium salicylate identified in § 343.10(f)*—(A) *For products containing 0.2 milliequivalent (5 milligrams) or higher of sodium per dosage unit.* The labeling of the product contains the sodium content per dosage unit (e.g., tablet, teaspoonful) if it is 0.2 milliequivalent (5 milligrams) or higher.

(B) *For products containing more than 5 milliequivalents (125 milligrams) sodium in the maximum recommended daily dosage.* "Do not give this product to children who are on a sodium restricted diet unless directed by a doctor."

(3) *For products labeled both for adults and for children 2 years to under 12 years of age.* The labeling of the product contains the warnings identified in § 343.50(c)(1) except that the warning in § 343.50(c)(1)(i) is replaced with the following: "Do not take this product for pain for more than 10 days (for adults) or 5 days (for children), and do not take for fever for more than 3 days unless directed by a doctor. If pain or fever persists or gets worse, if new symptoms occur, or if redness or swelling is present, consult a doctor because these could be signs of a serious condition. Do not give this product to children for the pain of arthritis unless directed by a doctor."

(d) *Directions.* The labeling of the product contains the following statements under the heading "Directions."

(1) *"For products labeled only for children 2 years to under 12 years of age."* The dosage information for children in paragraphs (d) (2), (4), (5), and (6) of this section should be converted to directions that are easily understood by the consumer. For example, the number of 80-milligram, or 81-milligram, or 325-milligram dosage units corresponding to the children's doses in paragraph (d)(2) of this section can be expressed in the labeling as follows:

DIRECTIONS

Age (years)	Number of 80-mg or 81-mg [1] dosage units	Number of 325-mg [1] dosage units
Under 2	Consult a doctor.	Consult a doctor.
2 to under 4	2	½.
4 to under 6	3	¾.
6 to under 9	4	1.
9 to under 11	4 to 5	1 to 1¼.

DIRECTIONS—Continued

Age (years)	Number of 80-mg or 81-mg [1] dosage units	Number of 325-mg [1] dosage units
11 to under 12	4 to 6	1 to 1½.

[1] Dose may be repeated every 4 hours while symptoms persist, up to four times a day or as directed by a doctor.

(2) *For products containing acetaminophen, aspirin, or sodium salicylate identified in § 343.10(a), (b), and (f).* Adults: Oral dosage is 325 to 650 milligrams every 4 hours or 325 to 500 milligrams every 3 hours or 650 to 1,000 milligrams every 6 hours, while symptoms persist, not to exceed 4,000 milligrams in 24 hours, or as directed by a doctor. Children 11 to under 12 years of age: Oral dosage is 320 to 487.5 milligrams every 4 hours while symptoms persist, not to exceed 5 doses or 2,437.5 milligrams in 24 hours. Children 9 to under 11 years of age: Oral dosage is 320 to 406.3 milligrams every 4 hours while symptoms persist, not to exceed 5 doses or 2,031.5 milligrams in 24 hours. Children 6 to under 9 years of age: Oral dosage is 320 to 325 milligrams every 4 hours while symptoms persist, not to exceed 5 doses or 1,625 milligrams in 24 hours. Children 4 to under 6 years of age: Oral dosage is 240 to 243.8 milligrams every 4 hours while symptoms persist, not to exceed 5 doses or 1,219 milligrams in 24 hours. Children 2 to under 4 years of age: Oral dosage is 160 to 162.5 milligrams every 4 hours while symptoms persist, not to exceed 5 doses or 812.5 milligrams in 24 hours. Children under 2 years: Consult a doctor. The dosage schedules above are followed by "or as directed by a doctor."

(3) *For products containing aspirin, carbaspirin calcium, choline salicylate, magnesium salicylate, or sodium salicylate identified in § 343.10(b), (c), (d), (e), and (f) intended for oral administration as a solid dosage form.* (i) "Adults: Drink a full glass of water with each dose."

(ii) "Children 2 to under 12 years of age: Drink water with each dose."

(4) *For products containing carbaspirin calcium identified in § 343.10(c).* Adults: Oral dosage is 414 to 828 milligrams every 4 hours or 414 to 637 milligrams every 3 hours or 828 to 1,274 milligrams every 6 hours, while symptoms persist, not to exceed 5,096 milligrams in 24 hours. Children 11 to under 12 years of age: Oral dosage is 408.8 to 621 milligrams every 4 hours while symptoms persist, not to exceed 5 doses or 3,105 milligrams in 24 hours. Children 9 to under 11 years of age: Oral dosage is 408.8 to 517.5 milligrams every 4 hours while symptoms persist, not to exceed 5 doses or 2,587.5 milligrams in 24 hours. Children 6 to under 9 years of age: Oral dosage is 408.8 milligrams every 4 hours while symptoms persist, not to exceed 5 doses or 2,070 milligrams in 24 hours. Children 4 to under 6 years of age: Oral dosage is 306.6 milligrams every 4 hours while symptoms persist, not to exceed 5 doses or 1,552.5 milligrams in 24 hours. Children 2 to under 4 years of age: Oral dosage is 204.4 milligrams every 4 hours while symptoms persist, not to exceed 5 doses or 1,035 milligrams in 24 hours. Children under 2 years: Consult a doctor. The dosage schedule above is followed by "or as directed by a doctor."

(5) *For products containing choline salicylate identified in § 343.10(d).* Adults: Oral dosage is 435 to 870 milligrams every 4 hours or 435 to 669 milligrams every 3 hours or 870 to 1,338 milligrams every 6 hours, while symptoms persist, not to exceed 5,352 milligrams in 24 hours. Children 11 to under 12 years of age: Oral dosage is 430 to 652.5 milligrams every 4 hours while symptoms persist, not to exceed 5 doses or 3,262.5 milligrams in 24 hours. Children 9 to under 11 years of age: Oral dosage is 430 to 543.8 milligrams every 4 hours while symptoms persist, not to exceed 5 doses or 2,719 milligrams in 24 hours. Children 6 to under 9 years of age: Oral dosage is 430 milligrams every 4 hours while symptoms persist, not to exceed 5 doses or 2,175 milligrams in 24 hours. Children 4 to under 6 years of age: Oral dosage is 322.5 milligrams every 4 hours while symptoms persist, not to exceed 5 doses or 1,632.5 milligrams in 24 hours. Children 2 to under 4 years of age: Oral dosage is 215 milligrams every 4 hours while symptoms persist, not to exceed 5 doses or 1,087.5 milligrams in 24 hours. Children under 2 years: Consult a doctor. The dosage schedule above is followed by "or as directed by a doctor."

(6) *For products containing magnesium salicylate. identified in § 343.10(e).* Dosages are based on the tetrahydrate form of magnesium salicylate. Adults: Oral dosage is 377 to 754 milligrams every 4 hours or 377 to 580 milligrams every 3 hours or 754 to 1,160 milligrams every 6 hours, while symptoms persist, not to exceed 4,640 milligrams in 24 hours. Children 11 to under 12 years of age: Oral dosage is 372.4 to 65.5 milligrams every 4 hours while symptoms persist, not to exceed 5 doses or 2,827.5 milligrams in 24 hours. Children 9 to under 11 years of age: Oral

dosage is 372.4 to 471.3 milligrams every 4 hours while symptoms persist, not to exceed 5 doses or 2,356.5 milligrams in 24 hours. Children 6 to under 9 years of age: Oral dosage is 372.4 milligrams every 4 hours while symptoms persist, not to exceed 5 doses or 1,885 milligrams in 24 hours. Children 4 to under 6 years of age: Oral dosage is 279.3 milligrams every 4 hours while symptoms persist, not to exceed 5 doses or 1,414 milligrams in 24 hours. Children 2 to under 4 years of age: Oral dosage is 186.2 milligrams every 4 hours while symptoms exist, not to exceed 5 doses or 942.5 milligrams in 24 hours. Children under 2 years of age: Consult a doctor. The dosage schedule above is followed by "or as directed by a doctor."

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

(f) *Optional statement. For products containing aspirin, carbaspirin calcium, choline salicylate, magnesium salicylate, or sodium salicylate identified in § 343.10 (b), (c), (d), (e), and (f).* The labeling may state in a prominent place the following statement: "See your doctor for other uses of" [insert name of ingredient or trade name of product]", but do not use for more than 10 days without consulting your doctor because serious side effects may occur."

§ 343.60 Labeling of permitted combinations of active ingredients.

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs.

(b) *Indications.* The labeling of the product states, under the heading "Indications," the indication(s) for each ingredient in the combination, as established in the indications sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (b). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For permitted combinations identified in § 343.20(a).* The indications in § 343.50(b)(1) should be used.

(2) *For permitted combinations identified in § 343.20(b)(1).* The indications are the following: "For the temporary relief of minor aches and pains with" (select one or more of the following: "heartburn," "sour stomach," or "acid indigestion") (which may be followed by: "and upset stomach associated with" (select one of the following, as appropriate: "this symptom" or "these symptoms.")]

(3) *For permitted combinations identified in § 343.20(b)(2).* The indications in § 341.85 of this chapter should be used.

(4) *For permitted combinations identified in § 343.20(b)(3).* The indications are the following: "For the temporary relief of minor aches and pains with" (select one or more of the following: "heartburn," "sour stomach," or "acid indigestion") [which may be followed by: "and upset stomach associated with" (select one of the following, as appropriate: "this symptom" or "these symptoms")] and "Also may be used for the temporary relief of minor aches and pains alone" [which may be followed by one or more of the following: ("such as associated with" (select one or more of the following: "a cold," "the common cold," "sore throat," "headache," "toothache," "muscular aches," "backache," "the premenstrual and menstrual periods" (which may be followed by: "(dysmenorrhea)") or "premenstrual and menstrual cramps" (which may be followed by: "(dysmenorrhea)")]), ("and for the minor pain from arthritis"), and ("and to reduce fever.")]

(5) *For permitted combinations identified in § 343.20(b)(4).* The indications in § 357.1050(b) of this chapter should be used.

(c) *Warnings.* The labeling of the product states, under the heading "Warnings," the warning(s) for each ingredient in the combination, as established in the warnings sections of the applicable OTC drug monographs.

(d) *Directions.* The labeling of the product states, under the heading "Directions," directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (d). When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC drug monograph.

(1) *For products containing permitted combinations identified in § 343.20(a)—*

(i) *When each ingredient is present in the minimum allowable amount.* Adults: Oral dosage is every 4 hours while symptoms persist, not to exceed 6 doses in 24 hours or as directed by a doctor. Children under 12 years of age: Consult a doctor.

(ii) *When either ingredient is present in an amount above the minimum allowable quantity.* Adults: Oral dosage is every 6 hours while symptoms persist, not to exceed 4 doses in 24 hours or as directed by a doctor. Children under 12 years of age: Consult a doctor.

(e) *Optional labeling statements for permitted combinations identified in § 343.20(b)(3).* The labeling may state "Contains buffering ingredients." The labeling may also contain the statement in § 343.50(f).

§ 343.80 Professional labeling.

The labeling of a product provided to health professionals (but not to the general public) may contain the following statements:

(a) *For products containing aspirin, carbaspirin calcium, choline salicylate, magnesium salicylate, or sodium salicylate identified in § 343.10 (b), (c), (d), (e), and (f) except those buffered with sodium.* "For rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus, osteoarthritis (degenerative joint disease), ankylosing spondylitis, psoriatic arthritis, Reiter's syndrome, and fibrositis."

(b) *For products containing aspirin identified in § 343.10(b) except those buffered with sodium.* The labeling states, under the heading "ASPIRIN FOR TRANSIENT ISCHEMIC ATTACKS," the following:

"Indication:

For reducing the risk of recurrent transient ischemic attacks (TIA's) or stroke in men who have had transient ischemia of the brain due to fibrin platelet emboli. There is inadequate evidence that aspirin or buffered aspirin is effective in reducing TIA's in women at the recommended dosage. There is

no evidence that aspirin or buffered aspirin is of benefit in the treatment of completed strokes in men or women.

Clinical Trials:

The indication is supported by the results of a Canadian study (1) in which 585 patients with threatened stroke were followed in a randomized clinical trial for an average of 26 months to determine whether aspirin or sulfinpyrazone, singly or in combination, was superior to placebo in preventing transient ischemic attacks, stroke, or death. The study showed that, although sulfinpyrazone had no statistically significant effect, aspirin reduced the risk of continuing transient ischemic attacks, stroke, or death by 19 percent and reduced the risk of stroke or death by 31 percent. Another aspirin study carried out in the United States with 178 patients, showed a statistically significant number of "favorable outcomes," including reduced transient ischemic attacks, stroke, and death (2).

Precautions:

Patients presenting with signs and symptoms of TIA's should have a complete medical and neurologic evaluation. Consideration should be given to other disorders that resemble TIA's. Attention should be given to risk factors: it is important to evaluate and treat, if appropriate, other diseases associated with TIA's and stroke, such as hypertension and diabetes.

Concurrent administration of absorbable antacids at therapeutic doses may increase the clearance of salicylates in some individuals. The concurrent administration of nonabsorbable antacids may alter the rate of absorption of aspirin, thereby resulting in a decreased acetylsalicylic acid/salicylate ratio in plasma. The clinical significance of these decreases in available aspirin is unknown.

Aspirin at dosages of 1,000 milligrams per day has been associated with small increases in blood pressure, blood urea nitrogen, and serum uric acid levels. It is recommended that patients placed on long-term aspirin treatment be seen at regular intervals to assess changes in these measurements.

Adverse Reactions:

At dosages of 1,000 milligrams or higher of aspirin per day, gastrointestinal side effects include stomach pain, heartburn, nausea and/or vomiting, as well as increased rates of gross gastrointestinal bleeding."

(Other applicable warnings related to the use of aspirin as described in § 343.50(c) may also be included here.)

Dosage and Administration:

Adult oral dosage for men is 1,300 milligrams a day, in divided doses of 650 milligrams twice a day or 325 milligrams four times a day.

References

(1) The Canadian Cooperative Study Group, "A Randomized Trial of Aspirin and Sulfinpyrazone in Threatened Stroke," *New England Journal of Medicine*, 299:53–59, 1978.

(2) Fields, W.S., et al., "Controlled Trial of Aspirin in Cerebral Ischemia," *Stroke* 8:301–316, 1977."

(c) *For products containing aspirin identified in § 343.10(b) or permitted combinations identified in § 343.20(b)(3).* The labeling states, under the heading "ASPIRIN FOR MYOCARDIAL INFARCTION," the following:

"Indication

Aspirin is indicated to reduce the risk of death and/or non-fatal myocardial infarction in patients with a previous infarction or unstable angina pectoris.

Clinical Trials

The indication is supported by the results of six large, randomized multicenter, placebo-controlled studies involving 10,816, predominantly male, post-myocardial infarction (MI) patients and one randomized placebo-controlled study of 1,266 men with unstable angina (1–7). Therapy with aspirin was begun at intervals after the onset of acute MI varying from less than 3 days to more than 5 years and continued for periods of from less than 1 year to 4 years. In the unstable angina study, treatment was started within 1 month after the onset of unstable angina and continued for 12 weeks, and patients with complicating conditions such as congestive heart failure were not included in the study.

Aspirin therapy in MI patients was associated with about a 20-percent reduction in the risk of subsequent death and/or non-fatal reinfarction, a median absolute decrease of 3 percent from the 12- to 22-percent event rates in the placebo groups. In aspirin-treated unstable angina patients the reduction in risk was about 50 percent, a reduction in the event rate of 5 percent from the 10-percent rate in the placebo group over the 12-weeks of the study.

Daily dosage of aspirin in the post-myocardial infarction studies was 300 milligrams in one study and 900 to 1,500 milligrams in 5 studies. A dose of 325 milligrams was used in the study of unstable angina.

Adverse Reactions

Gastrointestinal Reactions

Doses of 1,000 milligrams per day of aspirin caused gastrointestinal symptoms and bleeding that in some cases were clinically significant. In the largest post-infarction study (the Aspirin Myocardial Infarction Study (AMIS) with 4,500 people), the percentage incidences of gastrointestinal symptoms for the aspirin (1,000 milligrams of a standard, solid-tablet formulation) and placebo-treated subjects, respectively, were: stomach pain (14.5 percent; 4.4 percent); heartburn (11.9 percent; 4.8 percent); nausea and/or vomiting (7.6 percent; 2.1 percent); hospitalization for gastrointestinal disorder (4.8 percent; 3.5 percent). In the AMIS and other trials, aspirin-treated patients had increased rates of gross gastrointestinal bleeding. Symptoms and signs of gastrointestinal irritation were not significantly increased in subjects treated for unstable angina with buffered aspirin in solution."

(Other applicable warnings related to the use of aspirin as described in § 343.50(c) may also be included here.)

"Cardiovascular and Biochemical

In the AMIS trial, the dosage of 1,000 milligrams per day of aspirin was associated with small increases in systolic blood pressure (BP) (average 1.5 to 2.1 millimeters) and diastolic BP (0.5 to 0.6 millimeters), depending upon whether maximal or last available readings were used. Blood urea nitrogen and uric acid levels were also increased, but by less than 1.0 milligram percent.

Subjects with marked hypertension or renal insufficiency had been excluded from the trial so that the clinical importance of these observations for such subjects or for any subjects treated over more prolonged periods is not known. It is recommended that patients placed on long-term aspirin treatment, even at doses of 300 milligrams per day, be seen at regular intervals to assess changes in these measurements.

Sodium in Buffered Aspirin for Solution Formulations

One tablet daily of buffered aspirin in solution adds 553 milligrams of sodium to that in the diet and may not be tolerated by patients with active sodium-retaining states such as congestive heart or renal failure. This amount of sodium adds about 30 percent to the 70- to 90-milliequivalents intake suggested as appropriate for dietary treatment of essential hypertension in the "1984 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure" (8).

Dosage and Administration

Although most of the studies used dosages exceeding 300 milligrams, 2 trials used only 300 milligrams and pharmacologic data indicate that this dose inhibits platelet function fully. Therefore, 300 milligrams or a conventional 325 milligram aspirin dose is a reasonable, routine dose that would minimize gastrointestinal adverse reactions. This use of aspirin applies to both solid, oral dosage forms (buffered and plain aspirin) and buffered aspirin in solution.

References

(1) Elwood, P.C., et al., "A Randomized Controlled Trial of Acetylsalicylic Acid in the Secondary Prevention of Mortality from Myocardial Infarction," *British Medical Journal*, 1:436–440, 1974.

(2) The Coronary Drug Project Research Group, "Aspirin in Coronary Heart Disease," *Journal of Chronic Diseases*, 29:625–642, 1976.

(3) Breddin K., et al., "Secondary Prevention of Myocardial Infarction: A Comparison of Acetylsalicylic Acid, Phenprocoumon or Placebo," *Homeostasis*, 470:263–268, 1979.

(4) Aspirin Myocardial Infarction Study Research Group, "A Randomized, Controlled Trial of Aspirin in Persons Recovered from Myocardial Infarction," *Journal of the American Medical Association*, 243:661–669, 1980.

(5) Elwood, P.C., and P.M. Sweetnam, "Aspirin and Secondary Mortality after Myocardial Infarction," *Lancet*, II:1313–1315, December 22–29, 1979.

(6) The Persantine-Aspirin Reinfarction Study Research Group, "Persantine and Aspirin in Coronary Heart Disease," *Circulation*, 62:449–461, 1980.

(7) Lewis, H.D., et al., "Protective Effects of Aspirin Against Acute Myocardial Infarction and Death in Men with Unstable Angina, Results of a Veterans Administration Cooperative Study," *New England Journal of Medicine*, 309:396–403, 1983.

(8) "1984 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure," United States Department of Health and Human Services and United States Public Health Service, National Institutes of Health, Publication No. NIH 84–1088, 1984."

Subpart D—Testing Procedures

§ 343.90 Dissolution Testing.

(a) *Acetaminophen and aspirin tablets.* Acetaminophen and aspirin tablets must meet the dissolution standard for acetaminophen and aspirin tablets as contained in U.S.P. XXI at page 14.

(b) *Aspirin capsules.* Aspirin capsules must meet the dissolution standard for aspirin capsules as contained in U.S.P. XXI at page 77.

(c) *Aspirin delayed-release capsules and aspirin delayed-release tablets.* Aspirin delayed-release capsules and aspirin delayed-release tablets must meet the dissolution standard for aspirin delayed-release capsules and aspirin delayed-release tablets as contained in U.S.P. XXI Supplement 3 at pages 1972 and 1973, respectively.

(d) *Aspirin tablets.* Aspirin tablets must meet the dissolution standard for aspirin tablets as contained in U.S.P. XXI Supplement 4 at page 2130.

(e) *Aspirin, alumina, and magnesia tablets.* Aspirin in combination with alumina and magnesia in a tablet dosage form must meet the dissolution standard for aspirin, alumina, and magnesia tablets as contained in U.S.P. XXI Supplement 2 at pages 1812 and 1813.

(f) *Buffered aspirin tablets.* Buffered aspirin tablets must meet the dissolution standard for buffered aspirin tablets as contained in U.S.P. XXI Supplement 4 at page 2131.

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

4. The authority citation for 21 CFR Part 369 continues to read as follows:

Authority: Secs. 502, 503, 506, 507, 701, 52 Stat. 1050–1052 as amended, 1055–1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended (21 U.S.C. 352, 353, 356, 357, 371); 21 CFR 5.10 and 5.11.

§ 369.20 [Amended]

5. In Subpart B, § 369.20 *Drugs; recommended warning and caution statements* is amended by removing the entry for "SALICYLATES, INCLUDING ASPIRIN AND SALICYLAMIDE (EXCEPT METHYL SALICYLATE, EFFERVESCENT SALICYLATE PREPARATIONS, AND PREPARATIONS OF AMINOSALICYLIC ACID AND ITS SALTS)."

§ 369.21 [Amended]

6. In Subpart B, § 369.21 *Drugs; warning and caution statements required by regulations* is amended by removing the entry for "ACETAMINOPHEN (N-ACETYL-*p*-AMINOPHENOL)."

Dated: August 5, 1988.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 88–26157 Filed 11–15–88; 8:45 am]

BILLING CODE 4160–01–M

federal register

Wednesday
November 16, 1988

Part V

Environmental Protection Agency

Twenty-Third Report of the Interagency Testing Committee to the Administrator; Receipt of Report and Request for Comments

40 CFR Parts 712 and 716

Preliminary Assessment Information and Health and Safety Data Reporting; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-41030; FRL-3476-6]

Twenty-Third Report of the Interagency Testing Committee to the Administrator; Receipt of Report and Request for Comments Regarding Priority List of Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Interagency Testing Committee (ITC), established under section 4(e) of the Toxic Substances Control Act (TSCA), transmitted its Twenty-Third Report to the Administrator of EPA on November 1, 1988. This report, which revises and updates the Committee's priority list of chemicals, adds six chemicals to the list for priority consideration by EPA in promulgation of test rules under section 4(a) of the Act. The Twenty-Third Report is included with this notice. The new chemicals are tris(2-chloroethyl)-phosphate (CAS No. 115-96-8), three tris(2-chloropropyl)-phosphate, (CAS Nos. 6145-73-9, 13674-84-5, and 13674-87-8), tetrakis(2-chloroethyl)-ethylene diphosphate (CAS No. 33125-86-9) and butyraldehyde (CAS No. 123-72-8). These chemicals are not designated for response within 12 months. Crotonaldehyde (CAS No. 4170-30-3), which was recommended with intent-to-designate by the ITC in its Twenty-Second Report (53 FR 18196; May 20, 1988), now is designated for response within 12 months. In response to ITC's designation, EPA will either initiate rulemaking under section 4(a) of TSCA, or publish a **Federal Register** notice explaining the reasons for not initiating such rulemaking within 12 months. EPA invites interested persons to submit written comments on the report, and to attend Focus Meetings to help narrow and focus the issues raised by the ITC's recommendations.

Additionally, EPA is soliciting interest in public participation in the consent agreement process for tris(2-chloroethyl)-phosphate, three tris(2-chloropropyl)-phosphates, and tetrakis(2-chloroethyl)-ethylene diphosphate.

The ITC also has removed two chemicals, ethylbenzene and methyl ethyl ketoxime, from the priority list.

DATES: Written comments should be submitted by December 16, 1988. Submit written notice of interest in being designated an "interested party" to development of consent agreements for tris(2-chloroethyl)-phosphate, three tris(2-chloropropyl)-phosphates and tetrakis(2-chloroethyl)-ethylene diphosphate by December 16, 1988.

Focus Meetings will be held on December 13, 1988.

ADDRESS: Send written submissions to: TSCA Public Docket Office (TS-793), Office of Toxic Substances, Environmental Protection Agency, Rm. NE G-004, 401 M Street SW., Washington, DC 20460.

Submissions should bear the document control number (OPTS-41030).

The public record supporting this action, including comments, is available for public inspection in Rm. NE G-004 at the address noted above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Focus Meetings will be held at EPA Headquarters, Rm. 103 NE Mall, 401 M Street SW., Washington, DC. Persons planning to attend the Focus Meetings, and/or seeking to be informed of subsequent public meetings on these chemicals, should notify the TSCA Assistance Office at the address listed below. To ensure seating accommodations at the Focus Meetings, persons interested in attending are asked to notify EPA at least one week ahead of the schedule date.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: EPA has received the TSCA Interagency Testing Committee's Report to the Administrator.

I. Background

TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq*; 15 U.S.C. 2601 *et seq.*) authorizes the Administrator of EPA to promulgate regulations under section 4(a) requiring testing of chemical substances and mixtures in order to develop data relevant to determining the risks that such chemical substances and mixtures may present to health and the environment. Section 4(e) of TSCA established an Interagency Testing Committee to make recommendations to the Administrator of EPA on chemical substances and mixtures to be given priority consideration in proposing test rules under section 4(a). Section 4(e) directs the ITC to revise its list of recommendations at least every 6 months as necessary. The ITC may "designate" up to 50 substances and mixtures at any one time for priority consideration by the Agency. Crotonaldehyde is a designated chemical. For such designations, the Agency must within 12 months either intitiate rulemaking or issue in the **Federal Register** its reasons for not doing so. The ITC's Twenty-Third Report was received by the Administrator on November 1, 1988, and follows this Notice. The Report adds six substances to the TSCA section 4(e) priority list.

II. Written and Oral Comments and Public Meetings

EPA invites interested persons to submit detailed comments on the ITC's new recommendations. The Agency is interested in receiving information concerning additional or ongoing health and safety studies on the subject chemicals as well as information relating to the human and environmental exposure to these chemicals.

A notice is published elsewhere in today's **Federal Register** adding the substances recommended in the ITC's Twenty-Third Report to the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716), which requires the reporting of unpublished health and safety studies on the listed chemicals. These chemicals also will be added to the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712) published elsewhere in this issue. The section 8(a) rule requires the reporting of production volume, use, exposure, and release information on the listed chemicals.

Focus Meetings will be held to discuss relevant issues pertaining to these chemicals and to narrow the range of issues/effects which will be the focus of the Agency's subsequent activities in responding to the ITC recommendations. The Focus Meetings will be held on December 13, 1988, as follows:

9:30 a.m. Tris(2-chloroethyl)-phosphate, three tris(chloroprophyl)-phosphates, and tetrakis(2-chloroethyl)-ethylene disphosphate

1:00 p.m. Butyraldehyde

They will be held at EPA Headquarters, Rm. 103 NE Mall, 401 M St., SW., Washington, DC. These meetings are intended to supplement and expand upon written comments submitted in response to this notice.

Persons wishing to attend these meetings, or subsequent meetings on these chemicals, should call the TSCA Assistance Office at the telephone number listed above at least one week in advance.

This notice also serves to invite persons interested in participating in or monitoring negotiations for consent agreements for tris(2-chloroethyl)-

phosphate, three tris(chloropropyl)-phosphates, and tetrakis(2-chloroethyl)-ethylene diphosphate to notify EPA no later than December 16, 1988. The procedures for negotiations are described in 40 CFR 790.22. All written submissions should bear the identifying docket number (OPTS-41030).

III. Status of List

In addition to adding the six recommendations to the priority list, the ITC's Twenty-Third Report notes the removal of two chemicals from the list. Ethylbenzene has been removed from the list because the data gaps previously identified by the ITC have been satisfactorily resolved. Subsequent to ITC's preparation of its Twenty-Second Report, EPA responded to the ITC's recommendation for methyl ethyl ketoxime by publishing a Notice of Proposed Rulemaking in the **Federal Register** (53 FR 35838; September 15, 1988). The current list contains two designated substances, five chemicals recommended with intent-to-designate, and fourteen recommended substances.

Authority: 15 U.S.C. 2603.

Dated: November 4, 1988.

Joseph J. Merenda,

Director, Existing Chemical Assessment Division.

TWENTY-THIRD REPORT OF THE TSCA INTERAGENCY TESTING COMMITTEE TO THE ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY

Summary

Section 4 of the Toxic Substances Control Act of 1976 (TSCA, Pub. L. 94-469) provides for the testing of chemicals in commerce that may present an unreasonable risk of injury to health or the environment. It also provides for the establishment of a Committee (ITC), composed of representatives from eight designated Federal agencies, to recommend chemical substances and mixtures (chemicals) to which the Administrator of the U.S. Environmental Protection Agency (EPA) should give priority consideration for the promulgation of testing rules.

Section 4(e)(1)(A) of TSCA directs the Committee to recommend to the EPA Administrator chemicals to which the Administrator should give priority consideration for the promulgation of testing rules pursuant to section 4(a). The Committee is required to designate those chemicals, from among its recommendations, to which the Administrator should respond within 12 months by either initiating a rulemaking proceeding under section 4(a) or publishing the Administrator's reason for not initiating such a proceeding. At least every 6 months, the Committee makes those revisions in the TSCA section 4(e) Priority List that it determines to be necessary and transmits them to the EPA Administrator.

As a result of its deliberations, the Committee is revising the TSCA section 4(e) Priority List by the addition of 6 chemicals.

The Priority List is divided into three parts: Part A contains those recommended chemicals and groups designated for priority consideration and response by the EPA Administrator within 12 months. Part B contains chemicals and groups of chemicals recommended with intent-to-designate. This category was established by the Committee in its seventeenth report (50 FR 47603; November 19, 1985) to take advantage of rules promulgating automatic reporting requirements for non-designated ITC recommendations under the section 8(a) Preliminary Assessment rule and the TSCA section 8(d) Health and Safety Data Reporting rule. Information received following recommendation with intent-to-designate may influence the Committee to either designate or not designate the chemicals or groups of chemicals in a subsequent report to the Administrator. Part C contains chemicals and groups of chemicals that have been recommended for priority consideration by EPA without being designated for response within 12 months. The changes to the Priority List are presented, together with the types of testing recommended, in the following Table 1:

TABLE 1.—ADDITIONS TO THE SECTION 4(E) PRIORITY LIST

[November 1988]

Chemical/Group	Recommended studies
A. *Designated for response within 12 months:*	
Crotonaldehyde [1] CAS No. 4170-30-3.	Chemical Fate: Volatilization rate from water; aerobic aquatic biodegradation rate. Health Effects: None. Ecological Effects: Acute toxicity to algae, fish and aquatic invertebrates.
B. *Recommended with Intent-to-Designate:*	
Tris(2-chloroethyl)-phosphate [2] CAS No. 115-96-8.	Chemical Fate: Environmental monitoring; vapor pressure; biodegradation. Health Effects: None. Ecological Effects: Acute toxicity to aquatic and terrestrial plants; chronic toxicity to fish.
Tris(chloropropyl)-phosphates, including the following:	Chemical Fate: Environmental monitoring; water solubility; vapor pressure; octanol/water partition coefficient; biodegradation. Health Effects: Acute and subchronic effects, including cholinesterase inhibition, 90-day subchronic effects and reproductive effects. Health effects recommendations apply only to CAS Nos. 6145-73-9 and 13674-84-5.
Tris(2-chloro-1-propyl) phosphate [3] CAS No. 6145-73-9	
Tris(1-chloro-2-propyl) phosphate [4] CAS No. 13674-84-5; and	
Tris(1,3-dichloro-2-propyl) phosphate [5] CAS No. 13674-87-8.	Ecological Effects: Acute toxicity to fish, aquatic invertebrates and algae; chronic toxicity to fish.
Tetrakis(2-chloroethyl)-ethylene diphosphate [6] CAS No. 33125-86-9.	Chemical Fate: Environmental monitoring; water solubility; vapor pressure; octanol/water partition coefficient; biodegradation. Health Effects: None. Ecological Effects: Acute toxicity to fish, algae and aquatic invertebrates.
C. *Recommended Without Being Designated for Response Within 12 Months:*	
Butyraldehyde [7] CAS No. 123-72-8.	Chemical Fate: Monitoring in the vicinity of major manufacturing and use sites. Health Effects: In depth toxicology evaluation if warranted by monitoring data. Ecological Effects: Toxicity studies with representative biota if warranted by monitoring data.

CA Index Names (9 CI)

1. 2-Butenal
2. Ethanol, 2-chloro-, phosphate (3:1)
3. 1-Propanol,2-chloro-, phosphate (3:1)
4. 2-Propanol,1-chloro-, phosphate (3:1)
5. 2-Propanol,1,3-dichloro-, phosphate (3:1)
6. Phosphoric acid,1,2-ethanediyl tetrakis(2-chloroethyl) ester
7. Butanal

Note: Crotonaldehyde was recommended with intent-to-designate by the Committee in the twenty-second report (53 FR 18196; May 20, 1988).

TSCA Interagency Testing Committee

Statutory Member Agencies and Their Representatives

Council on Environmental Quality
William Mills, Member [1]
Department of Commerce
Patrick D. Cosslett, Member
Raimundo Prat, Alternate
Environmental Protection Agency
John D. Walker, Member
Laurence S. Rosenstein, Alternate
National Cancer Institute
Richard Adamson, Member
Elizabeth K. Weisburger, Alternate
National Institute of Environmental Health Sciences
James K. Selkirk, Member and Chairperson
National Institute for Occupational Safety and Health
Bryan D. Hardin, Member and Vice Chairperson
Rodger L. Tatken, Alternate
National Science Foundation
Rodger W. Baier, Member
Jarvis L. Moyers, Alternate
Occupational Safety and Health Administration
Robert Turnage, Member
Stephen Mallinger, Alternate

Liaison Agencies and Their Representatives

Consumer Product Safety Commission
Lakshmi C. Mishra
Department of Agriculture
Richard M. Parry, Jr.
Elise A. B. Brown
Department of Defense
Harry Salem [2]
Melvin E. Anderson [2]
Department of the Interior
Gregory J. Smith [3]
Martha L. Gay [4]
Food and Drug Administration
Arnold Borsetti
National Library of Medicine
Vera Hudson
National Toxicology Program
Dorothy Canter

Committee Staff

Robert H. Brink, Executive Secretary
Norma Williams, ITC Program Specialist

Support Staff

Alan Carpien—Office of the General Counsel, EPA

Notes

(1) Appointed on July 27, 1988.
(2) Appointed on September 9, 1988.
(3) Appointed on April 29, 1988.
(4) Appointed on June 3, 1988.

The Committee acknowledges and is grateful for the assistance and support given the ITC by the staff of Dynamac Corporation (technical support contractor) and personnel of the EPA Office of Toxic Substances.

Chapter 1—Introduction

1.1 *Background.* The TSCA Interagency Testing Committee (Committee) was established under section 4(e) of the Toxic Substances Control Act of 1976 (TSCA, Pub. L. 94–469). The specific mandate of the Committee is to recommend to the Administrator of the U.S. Environmental Protection Agency (EPA) chemical substances and mixtures in commerce that should be given priority consideration for the promulgation of testing rules to determine their potential hazard to human health and/or the environment. TSCA specifies that the Committee's recommendations shall be in the form of a Priority List, which is to be published in the **Federal Register.** The Committee is directed by section 4(e)(1)(A) of TSCA to designate those chemicals on the Priority List to which the EPA Administrator should respond within 12 months by either initiating a rulemaking proceeding under section 4(a) or publishing the Administrator's reason for not initiating such a proceeding. There is no statutory time limit for EPA response regarding chemicals that ITC has recommended but not designated for response within 12 months.

At least every 6 months, the Committee makes those revisions in the section 4(e) Priority List that it determines to be necessary and transmits them to the EPA Administrator.

The Committee is composed of representatives from eight statutory member agencies and seven liaison agencies. The specific representatives and their affiliations are named in the front of this report. The Committee's chemical review procedures and priority recommendations are described in previous reports (Refs. 1 through 7).

1.2 *Committee's previous reports.* Twenty-two previous reports to the EPA Administrator have been issued by the Committee and published in the **Federal Register** (Refs. 1 through 7). Ninety-six entries (seventy-six chemicals and twenty groups of chemicals) were recommended for priority consideration by the EPA Administrator and designated for response within 12 months. In addition, 24 chemicals and one group of chemicals were recommended without being so designated. Overall, in the 22 reports to the EPA Administrator, the Committee has recommended testing for 100 chemicals and 21 groups of chemicals. A complete list of recommended chemicals may be obtained by contacting the ITC Executive Secretary at the following address/telephone number: Robert Brink, U.S. Environmental Protection Agency (TS–792), 401 M St., SW., Washington, DC 20460, (202) 382–3820.

1.3 *Committee's activities during this reporting period.* Between April 22, 1988 and October 20, 1988, the Committee continued to review chemicals from its fifth and sixth scoring exercises, and from nominations by Member Agencies, Liaison Agencies and State Agencies.

The Committee contacted chemical manufacturers and trade associations to request information that would be of value in its deliberations. Most of those contacted provided unpublished information on current production, exposure, uses, and effects of chemicals under study by the Committee.

During this reporting period, the Committee reviewed available information on 54 chemicals. Six were selected for addition to the section 4(e) Priority List, and twenty-one were deferred indefinitely. The remaining chemicals are still under study.

In its twentieth report to the EPA Administrator (Ref. 5, ITC, 1987), the Committee placed ethylbenzene (CAS No. 100–41–4) on the Priority List in the "Recommended with Intent-to-Designate" category. The Committee recommeded that ethylbenzene be tested for acute toxicity to freshwater algae and invertebrates and to saltwater algae, invertebrates and fish. Subsequently, the Committee learned that acute toxicity testing of ethylbenzene with freshwater invertebrates had recently been completed at the University of Wisconsin. As noted in the twenty-first and twenty-second reports, the Committee also was informed that a consortium of ethylbenzene producers, the Styrene and Ethylbenzene Association, voluntarily sponsored studies on the other acute toxicity tests recommended by the Committee. The Committee deferred a decision on whether or not to designate ethylbenzene pending a review of the data developed during the above studies. The Committee has reviewed the data developed in those studies and has concluded that all of the data gaps identified in the twentieth report have been satisfactorily resolved. Therefore, the Committee has decided that ethylbenzene should be removed from the Priority List.

1.4 *The TSCA section 4(e) Priority List.* Section 4(e)(1)(B) of TSCA directs the Committee to: "* * * make such revisions in the [priority] list as it

determines to be necessary and * * * transmit them to the Administrator together with the Committee's reasons for the revisions." Under this authority, the Committee is revising the Priority List by adding six chemicals: tris(2-chloroethyl)phosphate (CAS No. 115-96-8), tris(2-chloro-l-propyl)-phosphate (CAS No. 6145-73-9), tris(l-choloro-2-propyl)phosphate (CAS No. 13674-84-5), tris(1,3-dichloro-2-propyl)phosphate (CAS No. 13674-87-8), tetrakis(2-chloroethyl)ethylene diphosphate (CAS No. 33125-86-9), and butyraldehyde (CAS No. 123-72-8). In addition, the Committee is designating, for repsonse within 12 months, crotonaldehyde, which was recommended with intent-to-designate in the twenty-second report. Two chemicals are being removed from the Priority List at this time. Methyl ethyl ketoxime (CAS No. 96-29-7) was the subject of a Notice of Proposed Rulemaking (53 FR 35838; September 15, 1988) and ethylbenzene (CAS No. 100-41-4) is being removed for the reasons given in section 1.3.

With the six new recommendations and two removals noted in this report, twenty-one entries now appear on the section 4(e) Priority List. The Priority List is divided in the following Table 2 into three parts; namely, A. Chemicals and Groups of Chemicals Designated for Response Within 12 Months, B. Chemicals and Groups of Chemicals Recommended with Intent-to-Designate, and C. Chemicals and Groups of Chemicals Recommended Without Being Designated for Response Within 12 Months. Table 2 follows:

TABLE 2—THE TSCA SECTION 4(E) PRIORITY LIST, NOVEMBER 1988

Entry	Date of designation
A. Chemicals and Groups of Chemicals Recommended and Designated for Response Within 12 Months:	
1. 1,6-Hexamethylene diisocyanate.	May 1988
2. Crotonaldehyde	Nov. 1988
B. Chemicals and Groups of Chemicals Recommended with Intent-to-Designate:	
1. Tris(2-chloroethyl phosphate.	Nov. 1988
2. Tris(2-chloro-l-propyl) phosphate.	Nov. 1988
3. Tris(1-choloro-2-propyl) phosphate.	Nov. 1988
4. Tris(1,3-dichloro-2-propyl) phosphate.	Nov. 1988
5. Tetrakis(2-chloroethyl) ethylene diphosphate.	Nov. 1988
C. Chemicals and Groups of Chemicals Recommended Without Being Designated for Response Within 12 Months:	
1. Diisodecyl phenyl phosphite	Nov. 1985
2. C.I. Disperse Blue 79	Nov. 1986
3. *N*-[5-[bis[2-(acetyloxy) ethyl]amino]-2-[(2-bromo-4,6-dinitrophenyl) azo]-4-methoxy phenyl]-acetamide.	May 1987
4. *N*-[5-[bis[2-(acetyloxy) ethyl]amino]-2-[2-chloro-4,6-dinitrophenyl) azo]-4-methoxy phenyl]-acetamide.	May 1987
5. *N*-[5-[bis[2-(acetyloxy) ethyl]amino]-2-[(2-chloro-4,6-dinitrophenyl) azo]-4-ethoxy phenyl]-acetamide.	May 1987
6. Imidazolium compounds, 4,5-dihydro-1-methyl-2-nortallow alkyl-1-(2-tallow amidoethyl), Me sulfates.	May 1988
7. Ethanaminium,2-amino-N-(2-aminoethyl)-N-(2-hydroxyethyl)-N-methyl-N,N'-ditallow acyl derivs., Me sulfates (salts).	May 1988
8. Poly(oxy-1,2-ethanediyl)α-[2-[bis(2-aminoethyl)-methylammonio]-ethyl]-ω-hydroxy-, N,N'-dicoco acyl derivs., Me sulfates (salts).	May 1988
9. Poly(oxy-1,2-ethanediyl),α-[2- [bis (2-aminoethyl)-methylammonio]-ethyl]-ω-, N,N'-bis(hydrogenated tallow acyl) derivs., Me sulfates (salts).	May 1988
10. Poly(oxy-1,2-ethanediyl), α-[2-[bis (2-aminoethyl)-methyl-ammonio-ethyl]-ω-hydroxy-, N,N'-ditallow acyl derivs., Me sulfates (salts).	May 1988
11. Poly[oxy(methyl-1,2-ethanediyl)],α-[2-[bis(2-aminoethyl)-methylammonio]-methyl ethyl]-ω-hydroxy-, N,N'-ditallow acyl derivs., Me sulfates (salts).	May 1988
12. Poly(oxy-1,2-ethanediyl),α-[3-[bis(2-aminoethyl)-methylammonio]-2-hydroxypropyl]-ωhydroxy-, N-coco acyl derivs., Me sulfates (salts).	May 1988
13. Poly(oxy-1,2-ethanediyl),α-[2-[bis(2-aminoethyl)-methylammonio]-ethyl]-ωhydroxy-, N,N'-di-C_{14-18} acyl derivs., Me sulfates (salts)D May 1988.	
14. Butyraldehyde	Nov. 1988.

REFERENCES

(1) Sixteenth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, May 21, 1985, 50 FR 20930-20939. Includes references to Reports 1 through 15 and an annotated list of removals.

(2) Seventeenth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, November 19, 1885, 50 FR 47603-47612.

(3) Eighteenth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, May 19, 1986, 51 FR 18368-18375.

(4) Nineteenth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, November 14, 1986, 51 FR 41417-41432.

(5) Twentieth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, May 20, 1987, 52 FR 19020-19026.

(6) Twenty-first Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, November 20, 1987, 52 FR 44830-44837.

(7) Twenty-second Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, May 20, 1988, 53 FR 18196-18210.

Chapter 2—Recommendations of the Committee

2.1 *Chemicals recommended for priority consideration by the EPA Administrator.* As provided by section 4(e)(1)(B) of TSCA, the Committee is adding the following chemical substances to the section 4(e) Priority List: tris(2-chloroethyl)phosphate (CAS No. 115-96-8), tris(2-chloro-1-propyl)phosphate (CAS No. 6145-73-9), tris(1-chloro-2-propyl)phosphate (CAS No. 13674-84-5), tris(1, 3-dichloro-2-propyl)phosphate (CAS No. 13674-87-8), tetrakis(2-chloroethyl)ethylene diphosphate (CAS No. 33125-86-9), and butyraldehyde (CAS No. 123-72-8). In addition, the Committee is designating for response within 12 months one chemical that was recommended with intent-to-designate in the twenty-second report. The designated chemical is crotonaldehyde (CAS No. 4170-30-3). The recommendation of these chemicals is made after considering the factors identified in section 4(e)(1)(A) and other relevant information, as well as the professional judgment of Committee members.

2.2 *Chemicals designated for response within 12 months*—2.2.a *Crotonaldehyde.* In the twenty-second report to the Administrator of EPA (53 FR 18196) crotonaldehyde was recommended with intent-to-designate. The rationale for that recommendation appears in the twenty-second report. Information reviewed by the Committee in response to the twenty-second report includes any public comments on the Committee's recommendations; production volume, use, exposure and release information reported by

manufacturers of crotonaldehyde under the TSCA section 8(a) Preliminary Assessment rule; health and safety studies submitted under TSCA 8(d) Health and Safety Data Report rule; and any unpublished and published data available to the Committee.

After reviewing the information, the Committee concluded that data are still lacking on certain chemical fate factors and ecological effects. For these reasons and for the reasons previously presented (53 FR 18196) the Committee is now designating crotonaldehyde for response within 12 months and recommending that it be tested for the following:

1. *Chemical fate.* Volatilization rate from water; aerobic aquatic biodegradation rate.

2. *Health effects.* None.

3. *Ecological effects.* Acute toxicity to algae, fish and aquatic invertebrates.

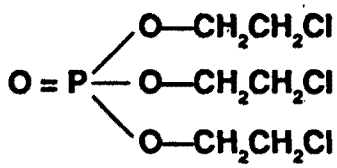
2.3 *Chemicals recommended with intent-to-designate*—2.3.a *Tris(2-chloroethyl)phosphate—Summary of recommended studies.* It is recommended that tris(2-chloroethyl)phosphate (TCEP) be tested for the following:

1. *Chemical Fate.* Environmental monitoring; vapor pressure; biodegradation.

2. *Health Effects.* None.

3. *Environmental Effects.* Acute toxicity to aquatic and terrestrial plants; chronic toxicity to fish.

PHYSICAL AND CHEMICAL INFORMATION

CAS No. 115-96-8	
Synonyms:	Ethanol, 2-chloro, phosphate (3:1) (9Cl); Tris (β-chloroethyl) phosphate; FYROL CEF; FYROL PCF; Celluflex CEF; Disflamol TCA; Niax Flame Retardant 3CF.
Acronym:	TCEP.
Structural Formula:	
Empirical Formula	$C_{612}CH_3O_4P$.
Molecular Weight	285.5.
Melting Point (°C)	−55 (Ref. 25, Sandmeyer and Kirwin, 1981).
Boiling Point (°C)	330 (Ref. 2, Aldrich, 1986).
Vapor Pressure (mmHg)	No information was found.
Solubility in Water (mg/L):	7,943 (Ref. 31, Yoshioka et al., 1986).
Specific Gravity:	1.425 @ 20/20° (Ref. 28, Sax and Lewis, 1987).
Log Octanol/Water Partition Coefficient (log P)	1.7 (Ref. 31, Yoshioka et al., 1986).
Henry's Law Constant:	1.81×10^{-7} atm m^3/mol (Ref. 21, Muir, 1984).
Adsorption Coefficient (Koc):	5.2 (Estimated; Ref. 4, CHEMEST, 1988).
Description of Chemical:	Colorless liquid with slight odor (Ref. 17, Lefaux, 1968).

Rationale for Recommendations

I. Exposure Information

A. *Production/use/release to the environment.* Tris (2-chloroethyl) phosphate (TCEP) is produced in substantial but CBI annual amounts in the U.S. Actual production volumes are considered to be confidential business information. It is used as a flame retardant additive for flexible and rigid polyurethane and polyisocyanurate foams, carpet-backing, flame-retardant paints and lacquers, various resins, coatings and adhesives (Ref. 15, Kirk-Othmer, 1980). The major use appears to be in foams such as the flexible foams used in automobiles and furniture and rigid foams for building insulation materials. It is unlikely that there is any natural production of TCEP. Most of the production eventually will be released to the environment as furniture, and landfills. Some may be released during thermal decomposition (accidental fires and waste incineration). Muir (Ref. 21, 1984) cited a report by Cho and Klaus (1980) stating that 41 percent of TCEP remains intact after thermal oxidation in air at 370°C. However, Paciorek et al. (Ref. 23, 1978) reported that 85 percent of the TCEP chlorine was accounted for in volatile products of degradation at 370°C, which indicates that no more than 15 percent of the TCEP was left undegraded.

B. *Evidence for environmental exposure.* TCEP, in common with many similar tris(haloalkyl)phosphates, has been found in numerous environmental samples throughout the world, at very low concentrations. TCEP was found in river waters in Japan at 17 to 350 ng/L at 14 of 16 sites at Kitakyushu (Ref. 12, Ishikawa et al., 1985b) and in Canadian rivers at 13 sites, with a mean concentration of 8.7 ng/L (Ref. 29, Williams and LeBel, 1981). TCEP was detected in the Netherlands in the river Waal (Ref. 19, Meijers and Van der Leer, 1976) and the Rhine (Ref. 24, Piet et al., 1987). TCEP was present in ground water from two wells at Fort Devens, MA at concentrations of 0.28 and 0.81 ug/L (Ref. 3, Bedient et al., 1983; Ref. 10, Hutchins et al., 1984). Water from the Great Lakes contained TCEP at a mean concentration of 1.7 ng/L at ten Canadian sites (Ref. 30, Williams and LeBel, 1981) and at concentrations of 3 to 9.6 ng/L at 4 of 5 sites in a later report (Ref. 16, LeBel et al., 1987). Samples from 10 coastal sites in Japan contained 14 to 60 ng/L in the seawater (Ref. 12, Ishikawa et al., 1985b). Sewage treatment facilities in Japan contained from 540 to 1,200 ng/L TCEP in the influent to the plants and 500 to 1,200

ng/L in the effluents. Similarly, at night soil treatment facilities, the influent contained 190 to 1,500 ng/L TCEP and the effluents were found to have 190 to 1,500 ng/L (Ref. 13, Ishikawa et al., 1985c). Five river and ocean sediment samples from Japan contained 13 to 28 ng TCEP/g of sediment. None was detected in a sixth sample (Ref. 12, Ishikawa et al., 1985b). TCEP was detected but not quantified in ambient air at Kitakyushu, Japan (Ref. 9, Haraguchi et al., 1985).

In a survey of infant and toddler dietary intake from October 1978 through September 1979, Gartrell et al. (Ref. 7, 1985a) reported finding TCEP in composite U.S. drinking water at an average concentration of 0.3 ug/L. Drinking water in Japan, examined over a 1-year period, contained 2 to 60.5 ng/L TCEP, with a mean concentration of 17.4 ng/L (Ref. 1, Adachi et al., 1984). Fifteen pooled U.S. drinking water samples contained an average of 2.6 ng/L TCEP (Ref. 18, Lucas, 1984) and Millington et al. (Ref. 20, 1983) reported finding TCEP on activated carbon filter beds used at 40 U.S. drinking water treatment plants. In a study of drinking water samples in England, Fielding et al. (Ref. 6, 1981) found TCEP in one of fourteen samples. LeBel et al. (Ref. 16, 1987) found TCEP at 0.3 to 9.2 ng/L in duplicate drinking water samples from six sites in eastern Ontario. Drinking water from 22 other Canadian cities contained TCEP at 0.3 to 52 ng/L while water from 7 other cities contained no detectable TCEP (Ref. 29, Williams and LeBel, 1981). In a survey of drinking water from the Great Lakes at twelve Canadian cities, Williams et al. (Ref. 30, 1982) found concentrations of TCEP at 0.3 to 13.8 ng/L in water at 11 of the cities. In a survey of infant and toddler diets from October 1979 through September 1980, Gartrell et al. (Ref. 8, 1985b) reported TCEP in composite fruit and fruit juice samples at an average concentration of 0.2 ug/L. It was not detected in other foods tested. Fish from the Okayama Prefecture in Japan contained from less than 0.005 ug/g up to 0.019 ug/g TCEP (Ref. 14, Kenmochi et al., 1981).

TCEP and other widely used tris(chloroalkyl)phosphate flame retardants appear to be widely distributed in the environment, especially in water, at low concentrations. It is not known whether the environmental concentrations are increasing with time or whether these anthropogenic phosphates have attained some steady-state, low-level concentrations.

II. Chemical Fate Information

A. *Transport.* The water solubility of TCEP is reported to be from 7,000 (Ref. 17, LeFaux, 1968) to 8,300 mg/L (Ref. 11, Ichikawa et al., 1985a). A measured value of 7,943 mg/L was reported by Yoshioka et al. (Ref. 31, 1986). A measured value for the log octanol/water partition coefficient was reported as 1.7 (Ref. 31, Yoshioka et al., 1986). These data indicate that TCEP, following release to the environment, will partition largely to water with little accumulation in sediments or biota. Vapor pressure data at environmentally relevant temperatures were not found, but the Henry's Law constant reported by Muir (Ref. 21, 1984) indicates no significant volatilization from water. The monitoring evidence (see preceding paragraph I.B.) demonstrates widespread occurrence of TCEP in water with some partitioning to air, sediments and biolipids.

B. *Persistence.* The trialkylphosphates, in general, are resistant to hydrolysis and free-radical oxidations although hydrolysis at the pH of sea water (approximtely 8.5) may be significant. TCEP is expected to demonstrate similar resistance to hydrolysis and oxidation, although no data were found. Biodegradation is probably the major degradation mechanism in nature but the available data, which indicate that biodegradation is slow, are mostly circumstantial. There are reports of very little biodegradation of TCEP as it passes through drinking water sand filtration units (Ref. 24, Piet et al., 1981) and through sewage treatment and night soil treatment facilities (Ref. 11, Ishikawa et al., 1985a). TCEP was reported to be hardly degraded after 50 hours in activated sludge (Ref. 11, Ishikawa, et al., 1985a).

C. *Rationale for chemical fate recommendations.* There is widespread contamination of the environment by TCEP (and other tris(chloroalkyl)phosphates) at very low concentrations. There is some evidence that TCEP may be resistant to biodegradation. Based on its water solubility and octanol/water partition coefficients, TCEP released to the environment is expected to partition largely to water. No data were found on its vapor pressure at ambient temperatures. Since TCEP has been and will continue to be released to both water and soil (landfill) environments, there is a need to obtain measured vapor pressure data and to evaluate its biodegradability in natural waters. It also is recommended that appropriate follow-on monitoring studies be conducted at sites sampled in the 1970's and early 1980's in an attempt to determine whether environmental concentrations are increasing with time.

III. Biological Effects of Concern to Human Health

A two-year gavage study with rats and mice has recently been completed under the National Toxicology Program (Ref. 22, NTP, 1988) and is currently in the histopathology stages. Given this information, the Committee has deferred its review of TCEP for health effects pending receipt and review of data from the NTP study.

IV. Ecological Effects of Concern

A. *Acute and subchronic (short-term) effects.* The 96-hour LC50 of TCEP was reported to be 210 mg/L with killifish (*Orizias latipes*) and 90 mg/L with goldfish (*Carassius auratus*) (Ref. 26, Sasaki et al., 1981). These authors also reported spine deformations (caused by convulsive muscle contractions) in killifish with exposure to 200 mg/L of TCEP for 72 hours and protrusion of killifish eyes after 24 to 72 hours exposure to 200 mg/L. Yoshioka et al. (Ref. 31, 1986) reported LC50 values of 251 mg/L with red killifish (*Orizias latipes*), 1,000 mg/L with a daphnia species (*Moina macrocopa*) and 158 mg/L with a flatworm (*Dugesia japonica*). Another literature report (Ref. 5, Eldefrawi et al., 1977) stated that 5 mg/L TCEP had no observable effects on goldfish after 7 days exposure.

B. *Chronic (long-term) effects.* No information on chronic effects was found. Sasaki et al. (Ref. 26, 1981), as noted in the preceding paragraph, reported spine deformations and eye bulging in killifish exposed to 200 mg/L for 72 hours. Eldefrawi et al. (Ref. 5, 1977) reported that TCEP is a weak inhibitor of acetyl-cholinesterase and this may produce some chronic effects.

C. *Other ecological effects (biological, behavioral, or ecosystem processes).* No information was found.

D. *Bioconcentration and food-chain transport.* The bioconcentration of TCEP was examined by Sasaki et al. (Ref. 26, 1981 and Ref. 27, 1982) in both static and continuous-flow studies. Static tests with killifish and goldfish showed bioconcentration factors (BCFs) of 2 and 1, respectively. A BCF of 1 was observed for killifish in continuous-flow studies over a 10-day period. When the fish were placed in clean water there was rapid depuration with half gone in 0.7 hours after cessation of exposure.

E. *Rationale for ecological effects recommendation.* The widespread occurrence of TCEP in environmental samples raises concerns for its

ecological effects. On the other hand, the available data indicate that acute toxicity levels for fish and aquatic invertebrates are 1,000 times or more greater than observed environmental concentrations. However, there were no data on plants and it is recommended that TCEP be tested for acute toxicity to aquatic and terrestrial plants. There appear to be chronic exposures to low concentrations of TCEP in aquatic environments and reports of spine deformations raise concerns for chronic effects. Therefore, it is recommended that TCEP also be tested for chronic toxicity to fish.

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2.3.b *Tris(chloropropyl)phosphates—Summary of recommended studies.* It is recommended that tris(2-chloro-l-propyl)phosphate (CAS No. 6145–73–9) and tris(1-chloro-2-propyl)phosphate (CAS No. 13674–84–5) be tested for the following:

1. *Chemical fate.* Environmental monitoring; water solubility; vapor pressure; octanol/water partition coefficient; biodegradation.

2. *Health effects.* Acute and subchronic effects; including cholinesterase inhibition, 90-day subchronic effects and reproductive effects.

3. *Ecological effects.* Acute toxicity to fish, aquatic invertebrates and algae; chronic toxicity to fish. It is further recommended that tris(1,3-dichloro-2-propyl)phosphate (CAS No. 13674–87–8) be tested for the following:

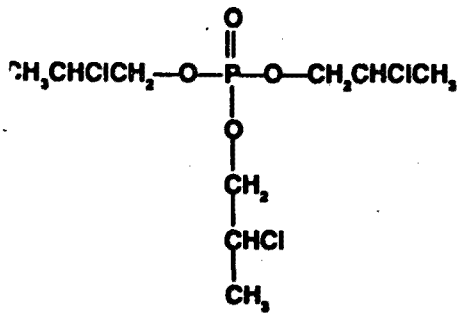
1. *Chemical fate.* Environmental monitoring; water solubility; vapor pressure; octanol/water partitioning coefficient; biodegradation.

2. *Health effects.* None.

3. *Ecological effects.* Acute toxicity to fish, aquatic invertebrates and algae; chronic toxicity to fish.

PHYSICAL AND CHEMICAL INFORMATION

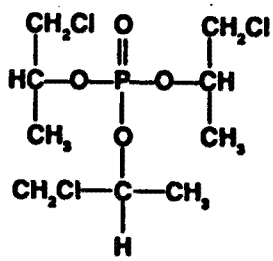
CAS No. 6145-73-9	
9 CI Name	1-Propanol, 2-chloro-, phosphate (3:1).
Synonyms	2-Chloro-1-propanol phosphate; Tris(beta-chloropropyl)-phosphate; Tris(2-chloropropyl)phosphate; FYROL PCF.
Acronym	TCPP.
Structural Formula:	



Empirical Formula	$C_9H_{18}Cl_3O_4P$.
Molecular Weight	327.55.
Melting Point (°C)	No information was found.
Boiling Point (°C)	No information was found.
Vapor Pressure (mmHg)	No information was found.
Solubility in Water (mg/L)	No information was found.
Specific Gravity	No information was found.
Log Octanol/Water Partition Coefficient	No information was found.

Physical and Chemical Information

CAS No. 13674-84-5	
9 CI Name	2-Propanol, 1-chloro-, phosphate (3:1).
Synonyms	1-Chloro-2-propanol phosphate; Tris(2-chloroisopropyl)-phosphate; Phosphoric acid, tris(2-chloro-1-methylethyl) ester; Tris(1-chloromethylethyl)-phosphate.
Acronym	TCIP.
Structural Formula:	

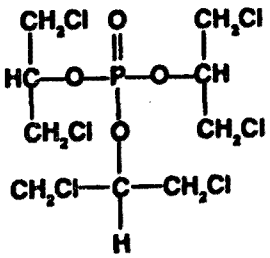


Empirical Formula	$C_9H_{18}Cl_3O_4P$.
Molecular Weight	327.55.
Melting Point (°C)	No information was found.
Boiling Point (°C)	No information was found.
Vapor Pressure (mmHg)	No information was found.
Solubility in Water (mg/L)	No information was found.
Specific Gravity	No information was found.
Log Octanol/Water Partition Coefficient	No information was found.

Physical and Chemical Information

CAS No. 13674-87-8	
9 CI Name	2-Propanol, 1,3-dichloro-,phosphate (3:1)

PHYSICAL AND CHEMICAL INFORMATION—Continued

Synonyms	1,3-Dichloro-2-propanol phosphate; Tris(1,3-dichloro-2-propyl)-phosphate; Tris(1,3-dichloroisopropyl)-phosphate; Tris(1-chloromethyl-2-chloroethyl)phosphate; FYROL FR2; PF38
Acronyms	TDCP; TDCPP.
Structural Formula:	
Empirical Formula	$C_9H_{15}Cl_6O_4P$.
Molecular Weight	430.88.
Melting Point (°C)	26.7 (Ref. 18, Stauffer, 1979).
Boiling Point (°C)	No information was found.
Vapor Pressure (mmHg)	No information at environmentally relevant temperatures and pressures was found.
Solubility in Water (mg/L)	7 at 24°C (Ref. 2, Hollifield 1979); 100 at 25°C (Ref. 11, Muir, 1984); 1000 at 30°C (Ref. 18, Stauffer, 1979).
Specific Gravity	1.515 at 20/20° (Ref. 18, Stauffer, 1979).
Log Octanol/Water Partition Coefficient (log P)	3.8 (Ref. 13, Sasaki et al., 1981).

Rationale for Recommendations

I. Exposure Information

A. *Production/use/release to environment.* TCPP, TCIP and TDCP are each produced in substantial annual amounts in the U.S. but actual production volumes are classified as confidential business information. TCPP and TDCP are used as additive flame retardants in various plastic materials. TDCP is known to be used primarily in flexible polyurethane foams. No information was found on the use of TCIP but it appears likely that it too is used as an additive flame retardant. Most of the production eventually will be released to the environment as the plastic materials containing them are scrapped or disposed of in dumps and landfills. Some may be released during thermal decomposition (accidental fires and waste incineration). A report by Cho and Klaus (1980) stating that 32 percent of TDCP remains intact after thermal oxidation in air at 370° C was cited by Muir (Ref. 11, 1984). It was reported by Paciorek et al. (Ref. 12, 1978) that TDCP underwent 68 percent thermal oxidation at 370° C. It is unlikely that there is any natural production of these phosphates.

B. *Evidence for environmental exposure.* No information was found on TCPP or TCIP and there was no indication that they have been looked for in the environment. TDCP, in common with many similar tris(haloalkyl)phosphates, has been found in many environmental samples throughout the world, at very low concentrations. TDCP was found in Great Lakes water at 4 of 5 Canadian sites (Ref. 9, LeBel et al., 1987). TDCP was found by LeBel et al. (Ref. 7, 1981) at 0.2 to 1.8 ng/L in drinking water at six eastern Ontario sites. Drinking water from 15 other Canadian cities contained TDCP at 0.3 to 23 ng/L while water from 14 other cities contained no detectable TDCP (Ref. 21, Williams and LeBel, 1981). In a survey of drinking water from the Great Lakes at twelve Canadian Cities, Williams et al. (Ref. 22, 1982) found concentrations of TDCP at 0.1 to 15.7 ng/L. A study of activated carbon filter beds used at 40 U.S. drinking water treatment plants found tris(chloropropyl)phosphate (not further identified) on the carbon (Ref. 11, Millington et al., 1983).

Fish and shellfish from the Okayama prefecture in Japan were reported to contain tris(2, 3-dichloropropyl)phosphate (Ref. 6, Kenmochi et al., 1981).

In an examination of Swedish products thought to contain additive flame retardants (Ref. 16, Sellestroem and Jansson, 1987), 11 of 104 samples were found to contain TDCP. It was most common in polyurethane products such as sound absorbing materials and liners for cars and buses. These same authors also examined the contents of vacuum cleaner bags from one new and one older (15-year old) house and found TDCP in the dust from the older house.

In analyses of human adipose tissues, LeBel and Williams (Ref. 8, 1983) found TDCP in 5 of 16 samples at 0.5 to 110 ng/g. TDCP also was found at 5 to 50 ppb in 34 of 123 human seminal plasma samples (Ref. 3, Hudec et al. 1981).

Japanese studies have reported finding tris(chloropropyl)-phosphate (CAS No. 26248-87-3) and tris(dichloropropyl)phosphate (CAS No. 26604-51-3) (Ref. 1, Haraguchi et al., 1985) and tris(3-chloropropyl)phosphate (CAS No. 1067-98-7) and tris(2, 3-dichloropropyl)phosphate (CAS No. 78-43-3) (Ref. 4, Ishikawa et al., 1985a) in air and treatment plant influents and effluents in Japan. The first three CAS numbers are not listed in the TSCA Inventory and the fourth CAS number is

a compound that is produced in low amounts in the U.S. It may be that Japanese industry uses tris(chloropropyl)phosphate flame retardants not commonly used in the U.S. and that those compounds may be introduced into the U.S. environment from imported products.

TDCP and other widely used tris(chloroalkyl)phosphate flame retardants appear to be widely distributed in the environment. When they are looked for, they often are found. No information was found on monitoring studies designed to look for TCPP or TCIP and monitoring should be conducted if continued high production and use are confirmed. Additional monitoring studies to evaluate the concentrations of TDCP in the environment should be conducted to determine whether its concentration in the environment is increasing with time.

I. Chemical Fate Information

A. *Transport.* The water solubility of TDCP is reported to be from 7 to 1,000 mg/L (Ref. 2, Hollifield, 1981, Ref. 11, Muir, 1984, Ref. 18, Stauffer, 1979). The log octanol/water partition coefficient is reported to be 3.8 (Ref. 14, Sasaki et al., 1981). No information was found for TCPP and TCIP. The monitoring evidence (see I.B., above) for TDCP demonstrates widespread occurrence of TDCP in water with some partitioning to sediments and biolipids. TCPP and TCIP are expected to behave similarly.

B. *Persistence.* No information was found for TCPP, TCIP or TDCP. However, Ishikawa et al. (Ref. 5, 1985b) reported that influent and effluent data for activated sludge treatment showed no biodegradation of tris(chloropropyl)phosphate (CAS No. 1067-98-7) and tris(2,3-dichloropropyl)phosphate (CAS No. 78-43-3).

C. *Rationale for chemical fate recommendations.* There is widespread contamination of the environment by TDCP. There may be persistent background levels of TCPP and TCIP in the environment but this is unknown. There is a need to conduct appropriate monitoring studies to determine if TCDD and TCIP, like similar tris(chloroalkyl)phosphate flame retardants, are present in the environment at low concentrations and whether the environmental concentrations of TDCP are increasing. There also is a need to obtain reliable, measured water solubility, vapor pressure and octanol/water partition coefficient data on these flame retardants to better estimate their transport in the environment and to evaluate their biodegradability in natural waters.

III. Biological Effects of Concern to Human Health

The Committee determined that tris(1,3-dichloro-2-propyl)phosphate (CAS No. 13674-87-8) has been studied extensively for health effects and concluded that additional studies are not required. Therefore, health effects testing is not being recommended at this time.

A. *Metabolism and toxicokinetics.* No information was found for TCPP or TCIP.

B. *Acute (short-term) effects.* No information was found for TCPP. An LD50 of 56 mg/kg, administered intravenously in mice, was found for TCIP (U.S. Army data, cited in Ref. 13, RTECS, 1988). The reliability of this information cannot be assessed since experimental details are not available.

Stauffer (cited in Ref. 20, USEPA, 1981) reported studies on the neurotoxic potential of TDCP, a structurally similar phosphate, on adult hens. At 10 g/kg, the maximum tolerated dose, there was 7 percent inhibition of brain neurotoxic esterase. In positive controls, treated with tri-o-cresyl phospate at 0.5 g/kg, there was an 85 percent inhibition.

No subchronic effects data were found for TCIP. The neurotoxic potential of TCPP in adult white Leghorn hens was evaluated by Sprague et al. (Ref. 17, 1981). A group of 18 hens received an initial oral dose of 13.23 g TCPP/kg, followed by the same treatment 3 weeks later. The animals were sacrificed 3 weeks after the second dose. Loss of body weight, transient reductions in food consumption and one death were reported for the treated animals. Egg production ceased shortly after the first dose and there was severe feather loss. No behavioral or histological evidence of delayed neurotoxicity was observed.

C. *Genotoxicity.* No information was found for TCPP or TCIP.

D. *Oncogenicity.* No information was found for TCPP or TCIP. A structurally similar compound, TDCP, was tested for oncogenicity in rats of both sexes and produced a significantly increased incidence of hepatocellular carcinoma and interstitial cell tumors of the testes (Ref. 19, Stauffer, 1981).

E. *Chronic (long-term) effects.* No information was found for TCPP or TCIP.

F. *Reproductive and developmental effects.* No information was found for TCPP or TCIP.

G. *Observations in humans.* No information was found for TCPP or TCIP.

H. *Rationale for health effects recommendations.* Three tris(chloropropyl)phosphates (TCPP, TCIP and TDCP) are produced in substantial amounts in the U.S. and used as additive flame retardants. TDCP is widely distributed in the environment at low concentrations. No exposure information (occupational, consumer or environmental) is available for TCPP or TCIP. It is assumed that use of the latter two compounds as flame retardants will eventually lead to the release of TCPP and TCIP to the environment. TDCP appears to be well studied for potential health effects but there is very little health effects information on TCIP and TCPP. The health effects information is limited to a LD50 for TCIP in mice by intravenous exposure and a subchronic evaluation of the neurotoxic potential of TCPP in hens. An evaluation of neurotoxicity should be conducted for a period of 90 days.

In view of the lack of health effects information on TCIP and TCPP and given the acute effects, oncogenicity and neurotoxicity of TDCP, it is recommended that TCIP and TCPP be tested for acute effects, including cholinesterase inhibition, 90-day subchronic effects and reproductive effects. Based on the results of the recommended studies, the need for long-term studies should be considered.

IV. Ecological Effects of Concern

A. *Acute and subchronic (short-term) effects.* No information was found for TCPP or TCIP.

The 96-hr LC50 for TDCP was reported to be 3.6 mg/L with killifish and 5.1 mg/L with goldfish (Ref. 14, Saaski et al., 1981). These authors also reported spine deformations (caused by convulsive muscle contractions) in killifish after 24 hours exposure at 3.5 mg/L TDCP.

B. *Chronic (long-term) effects.* No information on chronic effects was found. However, as noted in the preceding paragraph, Sasaki et al. (Ref. 14, 1981) reported spine deformations in killifish exposed to 3.5 mg/L TDCP for 24 hours.

C. *Other ecological effects.* No information was found.

D. *Bioconcentration and food-chain transport.* The bioconcentration of TDCP was examined by Sasaki et al. (Ref. 14, 1981 and Ref. 15, 1982) in both static and continuous flow studies. Static tests with killifish and goldfish showed bioconcentration factors of 47 to 107 with killifish and 3 to 5 with goldfish. In continuous-flow studies, the bioconcentration factor for TDCP was 31 to 59 for up to 32 days exposure. There

was a rapid depuration following cessation of exposure to TDCP in the continuous-flow studies, with half gone in 1.7 hours.

E. *Rationale for ecological effects recommendations.* The widespread occurrence of TDCP in environmental samples and the likely contamination of the environment by TCPP and TCIP raise concerns for their ecological effects. Each should be tested for acute toxicity to fish, aquatic invertebrates and algae to better evaluate the hazard associated with chronic exposures to low environmental concentrations. The observation of spine deformations in fish exposed to TDCP and the widespread occurrence of TDCP at low concentrations also raises concerns for chronic effects. It is recommended that each of these tris(chloropropyl)-phosphates be tested for chronic toxicity to fish.

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2.3.c *Tetrakis(2-chloroethyl)ethylene diphosphate—Summary of recommended studies.* It is recommended that tetrakis(2-chloroethyl)ethylene diphosphate (TCEED) be tested for the following:

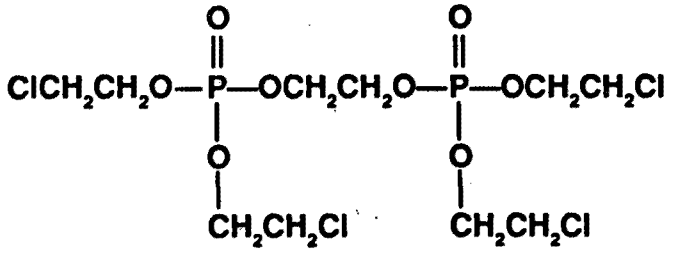
1. *Chemical fate.* Environmental monitoring; water solubility; vapor pressure; octanol/water partition coefficient; biodegradtion.

2. *Health effects.* None.

3. *Ecological effects.* Acute toxicity to fish, algae and aquatic invertebrates.

PHYSICAL AND CHEMICAL INFORMATION

CAS No. 33125-86-9	
Synonyms	Phosphoric acid, 1,2-ethanediyl (2-chloro-ethyl) ester (9Cl); Thermolin 101.
Acronym	TCEEP.
Structural Formula:	



PHYSICAL AND CHEMICAL INFORMATION—Continued

CAS No. 33125-86-9	
Empirical Formula	$C_{10}H_{20}Cl_4O_8P_2$.
Molecular Weight	471.9.
Melting Point (°C(	No information was found.
Boiling Point (°C)	No information was found.
Vapor Pressure (mmHg)	0.85 at 25°C (Ref. 3, Olin, 1987).
Solubility in Water (mg/L)	3000 at 24°C (Ref. 3, Olin, 1987).
Specific Gravity	1.45 at 25°C (Ref. 3, Olin 1987).
Log Octanol/Water Partition Coefficient (log P)	1.16, estimated (Ref. 2, CLOGP, 1987).
Henry's Law Constant	1.76×10^{-4} atm m^3/mol (calculated)
Log Adsorption Coefficient	2.0 (Ref. 1, CHEMEST, 1987)
Description of Chemical	Dark liquid under ambient conditions. (Ref. 3, Olin, 1987).

Rationale for Recommendations

I. Exposure Information

A. *Production/use.* Tetrakis(2-chloroethyl)ethylene diphosphate (TCEEP) is produced in substantial annual amounts in the U.S. but actual production volumes are classified as confidential business information. TCEEP is used as an additive flame retardant in flexible polyurethane foams and may be used as a flame retardant in various resins. There is no known natural production of TCEEP.

B. *Environmental release.* It is likely that most of the TCEEP production is eventually released to the environment as furniture, automobiles, construction materials, etc. are scrapped and disposed of in dumps and landfills. Some TCEEP may be released during thermal decomposition (in accidental fires and incinerators) but no information was found on thermal decomposition.

C. *Evidence for environmental exposure.* No information was found. Related chloroalkyl phosphate flame retardants (e.g., tris(2-chloroethyl)phosphate and tris(1,3-dichloropropyl)-phsophate), when looked for in the environment, have been found at low concentrations in a wide variety of environmental media in industrialized countries. It is not known whether anyone has looked for TCEEP in the environment.

II. Chemical Fate Information

A. *Transport.* The water solubility, vapor pressure and estimated octanol/water partition coefficient for TCEEP suggest significant transport to both air and water, with little sorption to soil or sediment. The calculated Henry's law constant, if true, would produce a half-life for volatilization from water of about 1 to 2 days. A related phosphate, the tris(2-chloroethyl)-phosphate, has a reported Henry's constant of 1.81×10^{-7} atm m^3/mol for a predicted half-life in water of about 1.4 years. It is difficult to believe that there would be such a great difference between these two phosphates and the water solubility and vapor pressure used to calculate the Henry's constants should be reliably measured. If this phosphate behaves similarly to the tris(chloroalkyl)phosphate flame retardants, it will partition largely to water following release to the environment.

B. *Persistence.* No information was found.

C. *Rationale for chemical fate and recommendations.* TCEEP, like the related tris(chloroalkyl)phosphate flame retardants, may partition largely to the aquatic environment and be relatively persistent. The related tris(chloroalkyl)phospates have been found throughout the industrialized world in a variety of environmental media at low concentrations. There is a need for monitoring studies that look for TCEEP to determine if it also appears at low concentrations in the environment. In addition, it is recommended that studies be conducted to determine the water solubility, vapor pressure and octanol/water partition coefficient of TCEEP and to evaluate its biodegradability in natural waters.

III. Biological Effects of Concern to Human Health

The Committee, at the conclusion of its Sixth Scoring Exercise, concluded that it would not review TCEEP for health effects (52 FR 10409, April 1, 1987). Therefore, no health effects studies are being recommended at this time.

IV. Ecological Effects of Concern

A. *Acute and subchronic (short-term) effects.* No information was found.

B. *Chronic (long-term) effects.* No information was found.

C. *Other ecological effects.* No information was found.

D. *Bioconcentration and food-chain transport.* No information was found.

E. *Rationale for ecological effects recommendations.* It is likely that TCEEP has been and will continue to be released to the environment in significant quantities where it may persist and accumulate. Studies should be conducted to evaluate the acute toxicity of TCEEP to fish, aquatic invertebrates and algae.

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2.4 *Chemicals recommended without being designated for response within 12 months—*

2.4.a *Butyraldehyde—Summary of recommended studies.* It is recommended that butyraldehyde be tested for the following:

1. *Chemical fate.* Monitoring in the vicinity of major manufacturing and use sites.

2. *Health effects.* In depth toxicology evaluation if warranted by monitoring data.

3. *Ecological effects.* Toxicity studies with representative biota if warranted by monitoring data.

PHYSICAL AND CHEMICAL INFORMATION

CAS No. 123-72-8	
Synonyms	Butanal (9CI); Butyraldehyde (8CI); n-Butyraldehyde; Butal; Butyric aldehyde; n-Butyraldehyde; Butanaldehyde; Butyric aldehyde.
Structural Formula: $CH_3CH_2CH_2CHO$	
Empirical Formula	C_4H_8O.
Molecular Weight	72.10.
Melting Point (°C)	−99 (Ref. 61, Windholz, 1983).
Boiling Point (°C)	−74.8 (Ref. 61, Windholz, 1983).
Vapor Pressure (mmHg)	92 @ 20° (Ref. 14, Eastman, (1988).
Solubility in water (mg/L)	6,000 (Ref. 14, Eastman, 1988).
Specific Gravity	0.8016 (Ref. 61, Windholz, 1983).
Log Octanol/Water Partition Coefficient (log P)	0.88 (Ref. 15, ENVIROFATE, 1988).
Henry's Law Constant	1.4×10^{-4} (calculated).
Vapor Density in Air (air=1)	2.5 (Ref. 14, Eastman, 1988).
Description of Chemicals	Colorless liquid with characteristic pungent, aldehyde odor (Ref. 25, Hawley, 1987).

Rationale for Recommendations

I. Exposure Information

A. *Production/use/release to environment.* Butyraldehyde is produced and used in the U.S. at a rate in excess of one billion pounds per year. SRI reported U.S. production of butyraldehyde in 1987 at 1.835 billion pounds by five manufacturers at six sites spread across Texas (Ref. 52, SRI International, 1987). Greater than 90 percent of the production is used as a chemical intermediate to synthesize n-butanol and 2-ethylhexanol. Domestic production of n-butanol and 2-ethylhexanol was 935 million and 638 million pounds, respectively, in 1987 (Ref. 9, C&EN, 1988). Other important uses for butyraldehyde include its use as a solvent for surface coatings and its combination with polyvinyl alcohol to form a resin in laminated safety glass (Ref. 8, CEH, 1985).

Butyraldehyde occurs naturally in many plants, including fruits and vegetables, and in cheese, meats and wines. It has FDA approval as a direct food additive for use as a synthetic flavoring substance and as an indirect food additive as a component of packaging (21 CFR 172.515; 21 CFR 175.105; and Ref. 44, Opdyke, 1979).

The major releases of butyraldehyde to the environment will occur at the manufacturing sites in Texas and at major use sites elsewhere in the U.S. This volatile water soluble chemical may be released to water and air in significant quantities. One company (Ref. 14, Eastman, 1988) reported 1987 emissions at its Texas plant of about 831,000 pounds with 90 percent of the emissions listed as fugitive emissions to air. Toxic chemical release inventory reporting forms submitted to the EPA in response to the Toxic Chemical Release Reporting rule (53 FR 4500; February 16, 1988) provide information on substantial releases to air (from 54,000 to 836,000 lbs. per year) at six manufacturing and use sites (Ref. 55, USEPA, 1988).

B. *Evidence for human and environmental exposure.* According to the National Occupational Hazard Survey (NOHS) conducted by the National Institute for Occupational Safety and Health (NIOSH) from 1972 to 1974, 1,259 workers were potentially exposed to butyraldehyde in the workplace in 1970 (Ref. 38, NIOSH, 1976). Preliminary data available from the National Occupational Exposure Survey (NOES), conducted by NIOSH from 1980 to 1983, indicate that 5,392 workers, including 950 women, were potentially exposed to butyraldehyde in the workplace in 1980 (Ref. 39, NIOSH, 1984). Since domestic production has been increasing since 1982 (Ref. 56, USITC 1983) it is expected that more workers are exposed today.

Occupational exposure limits have not been established by the American Conference of Governmental Industrial Hygienists or the Occupational Safety and Health Administration.

One company (Ref. 14, Eastman, 1988) reported that the major points of worker exposure to n-butyraldehyde are in sampling, loading, and unloading shipping containers, and maintaining the equipment. Also, during production at its Texas plant, from 4 to 8 workers are potentially exposed daily, and from 1 to 2 maintenance workers are potentially exposed for approximately 120 days per year. The same company reported that during use of n-butyraldehyde to manufacture other chemicals, 12 to 18 workers are potentially exposed at its Tennessee plant. These processes run from 180 to 360 days per year. Personal monitoring of production workers (42 samples) indicated air concentrations of n-butyraldehyde averaging less than 1.0 ppm (8-hour TWA) with no sample above 1.25 ppm. Personal monitoring of materials handling workers (7 samples) indicated a geometric mean (8-hour TWA) of 3.7 ppm n-butyraldehyde. Five of the seven samples were under 1.0 ppm, the other two were 21.3 and 4.57 ppm. (Ref. 14, Eastman, 1988).

Another company (Ref. 26, Hoechst-Celanese, 1988) reported that 120 employees were working in the butyraldehyde unit of its Texas processing plant. It reported no monitoring data collected in previous years, and only one sample collected in 1988 which "was 1 ppm for an 8 hour period." It was not reported whether this was a personal or area sample. Its Texas purification plant (Ref. 26, Hoechst-Celanese, 1988) reported 4 to 6 workers exposed to n-butyraldehyde with monitoring data indicating exposure levels less than 10 ppm. However, no information was given concerning the collection of monitoring data.

There are no monitoring data available showing general population exposure to n-butyraldehyde. Exposures may be significant for populations living near major manufacturing sites since

toxic release information indicates substantial fugitive emissions from manufacturing and use sites (Ref. 14, Eastman, 1988; Ref. 55, USEPA, 1988). One company (Ref. 26, Hoechst-Celanese, 1988), however, reported community exposure near its Texas processing plant to be less than 0.0004 ppm n-butyraldehyde although fugitive emissions of butyraldehyde at the plant exceeded 106,000 pounds per year. Details of the sampling and other procedures used to determine this number were not reported.

Butyraldehyde was detected but not quantified in the respired air of a heterogenous nonsmoking control population living in Chicago and the surrounding suburbs; however, it was not detected in the respired air of two other populations examined in the study: A prediabetic group and a diabetic group. The total sample was 62 persons. The authors classified butyraldehyde as a physiologic volatile metabolite but did not suggest a mechanism for its generation (Ref. 34, Krotoszynski and O'Neill, 1982).

No information was found concerning drinking water exposures to n-butyraldehyde.

Many of the monitoring studies that report environmental concentrations of butyraldehyde have dealt with urban air in areas where smogs are a problem. This appears to be due to the presence of butyraldehyde in the emissions from internal combustion engines and the involvement of butyraldehyde in smog formation. Grosjean et al. have conducted several of these studies in Southern California (Ref. 17, Fung et al., 1981; Ref. 21, Grosjean, 1982; Ref. 22, Grosjean et al., 1983; Ref. 23, Grosjean and Wright, 1983; and Ref. 24, Grosjean and Fung, 1984). Similar studies have been conducted in Sweden (Ref. 31, Jonsson et al., 1985). Isodorov (Ref. 28, 1985) reported on the emissions of butyraldehyde into the atmosphere by ferns in the forests of northern Russia. Little or no monitoring data were found on the presence of butyraldehyde in the air near major manufacturing and use sites although toxic release information reveals substantial fugitive emissions at manufacturing and use sites.

Some monitoring studies have looked for butyraldehyde in surface, ground and drinking waters and it has been found at very low concentrations in a few samples (Ref. 11, Corwin, 1969; Ref. 16, Ewing et al., 1977; and Ref. 58, Viar, 1988). No data were found on monitoring conducted on water samples obtained near manufacturing and use sites.

Ito et al. (Ref. 29, 1980) reported finding butyraldehyde in fish in Japan.

II. Chemical Fate Information

A. *Transport.* Based on its vapor pressure, water solubility and log P, butyraldehyde released to the environment will partition to both water and air. The Henry's law constant for butyraldehyde indicates that butyraldehyde in surface waters will volatilize rapidly with a half-life in water of about 12 hours.,

B. *Persistence.* Butyraldehyde released to the environment will not persist. It will be rapidly degraded in the atmosphere by reaction with hydroxyl radicals with an atmospheric half-life of 4 to 9 hours (Ref. 14, Eastman, 1988). Butyraldehyde is readily biodegraded under both aerobic and anaerobic conditions by acclimated microorganisms.

C. *Rationale for chemical fate recommendations.* Butyraldehyde released to the environment will not persist and concerns for potential adverse effects are low in most parts of the U.S. However, the large production volumes at sites in Texas and the toxic release data on substantial releases to air at manufacturing and use site raise concerns with respect to environmental concentrations of butyraldehyde in air and water at those sites. Those emissions will occur on a nearly continuous basis and butyraldehyde may be present in the air and water at significant concentrations that represent a balance between rates of release and rates of removal by degradation processes. It is recommended that monitoring studies be conducted to determine butyraldehyde concentrations in air and water in the vicinity of the major manufacturing and use facilities. Monitoring for the presence of low molecular weight, volatile, hydrophilic compounds in water samples, as noted by Ogawa and Fritz (Ref. 43, 1985), can be very difficult and special care should be taken to assure realistic results.

III. *Biological Effects of Concern to Human Health*

A. *Metabolism and pharmacokinetics.* Aldehydes are oxidized to the corresponding acid by the enzyme aldehyde dehydrogenase (Ref. 59, Weiner, 1980) Three isozymes have been identified from human liver, all of which oxidized several aldehydes, including butyraldehyde (Ref. 30, Jones and Teng, 1983).

Butyraldehyde has been detected in mother's milk (6 or 8 samples) obtained from urban areas in the U.S. (Ref. 45, Pellizzari et al., 1982) and in the sera of normal and diabetic patients (Ref. 62, Zlatkis et al., 1980).

In virto studies indicate that butyraldehyde at concentrations of 0.1 to 1 mM inhibits multiplication of mouse sarcoma cells in culture (Ref. 46, Pilotti et al., 1975; Ref. 13, Curvall et al., 1984), and inhibits chemotaxis and reduces viability of human polymorphonuclear leukocytes at 90 mM (Ref. 3, Bridges et al., 1977). Other *in vitro* effects included: damage to the cell membranes of human fibroblasts at 25 mM (Ref. 54, Thelestam et al., 1980; Ref. 13, Curvall et al., 1984) and human red blood cells at 1mM (Ref. 47, Poli et al., 1987), and interference with lipolysis and glucose metabolism in adipose tissue cells at concentrations of 1 to 20 mM (Ref. 20, Giudicelli et al., 1973).

B. *Acute and subchronic (short-term) effects.* The acute toxicity data for butyraldehyde are summarized in the following Table 3.

TABLE 3.—TOXICITY OF BUTYRALDEHYDE IN LABORATORY ANIMALS

Species	LC50		LD50		Reference
	Duration (hours)	Concentration (mg/m³)	Oral (mg/kg)	Dermal (mg/kg)	
Rat			2,490		Marhold (1972, as cited in RTECS, Ref. 48).
Rat	4	* >23,590	5,890		Smyth et al. (1951, Ref. 51).
Rat	0.5	174,000			Skog (1950, Ref. 50).
Mouse	2	44,610			Izmerov (1982, as cited in RTECS, Ref. 48).
Rabbit				3,560	Union Carbide Data Sheet (1967, as cited in RTECS, Ref. 48).
Guinea pig				>16	Brabec (1981, Ref. 2).

* One of six animals died.

Inhalation toxicity in males of two mouse strains was defined by a 50 percent reduction in respiratory rate (RD50) following exposure of 3 or 4 mice per dose (dose range not specified) for 10 minutes (Ref. 53, Steinhagen and Barrow, 1984). An RD50 of 1,532 ppm (4,518 mg/m^3) was determined for B6C3F$_1$ mice, and an RD50 of 1,015 ppm (2,993 mg/m^3) was determined for Swiss-Webster mice. An RD50 of 5,572 ppm (16,431 mg/m^3) was determined for male rats under similar conditions (Ref. 1, Babiuk et al., 1985).

Inhalation exposure of ten Sprague-Dawley derived CD rats to measured concentrations of 1,820 ppm (5,367 mg/L) butyraldehyde for 4 hours caused irritation of the ocular and respiratory mucous membranes during the exposure and subsequent 4 hours (Ref. 26, Hoechst-Celanese, 1988). No other treatment-related effects were reported during the 14-day observation period or at necropsy.

Inhalation exposure of rats to 1,000 ppm (2,949 mg/m^3) butyraldehyde for twelve 6-hour exposures produced no observable toxic signs (Ref. 18, Gage, 1970.

Oral administration of butyraldehyde to rats at dose levels of 0.075, 0.15, 0.3, 0.6, or 1.2 g per kg, daily for 5 days per week for 13 weeks caused irritation, inflammation, necrosis, hyperplasia, and lesions in the forestomach and gastric mucosa (Ref. 40, NTP, 1988). The increased incidence of these lesions was dose-related and affected 100 percent of the males and 90 percent of females at the highest does level, 1.2 g/kg.

Dermal exposure of rabbits to butyraldehyde (2.5 mL/kg) for 24 hours caused severe dermal lesions that became infected and led to termination of the study after 7 days (Ref. 26, Hoechst-Celanese, 1988). Extensive necrosis and severe edema were exhibited by all animals at 24 hours; eschar developed about day 4 or 5. Toxic signs evident in several animals during the 24-hour application period included ataxia, fine tremors, hypoactivity, and respiratory anomalies. Tremors, hypoactivity, hypopnea and respiratory arhythmia persisted in a few aniamls for an unspecified period of time. Apart from the dermal lesions, no other treatment-induced changes were evident at necropsy.

Butyraldehyde is a severe skin and eye irritant in rabbits (Ref. 26, Hoechst-Celanese, 1988). It exhibits little or no potential to produce dermal sensitization in guinea pigs (Ref. 26, Hoechst-Celanese, 1981). After a 3-week induction period consisting of nine 6-hour applications of butyraldehyde, there was no dermal response from guinea pigs challenged with 10 percent butyraldehyde. A second challenge at 25 percent elicited an equivocal response in only 2 of 20 animals.

C. *Genotoxicity.* In the *Salmonella* assay, butyraldehyde was not mutagenic in strains TA1535, TA1537, TA98, or TA100, with or without activation (Ref. 35, Mortelmans et al., 1986). No increase in chromosomal aberrations was detected in Chinese hamster ovary cells at butyraldehyde concentrations of 59 to 135 ug/mL with or without metabolic activation, but sister chromatid exchange was induced in these cells at nontoxic levels ranging from 9 to 90 ug/mL (Ref. 19, Galloway et al., 1987). The lowest effective doses were less than 9 ug/mL without activation and 30 ug/mL with activation. When butyraldehyde was administered to male mice (Q strain) in the drinking water at 0.2 mg/L for 50 days, chromosomal aberrations were evident as polyploidy at all stages of spermatogenesis and abnormal pairing of chromosomes at metaphase I (Ref. 37, Moutschen-Dahmen, 1976). Butyraldehyde did not increase sister chromatid exchange in human lymphocytes treated *in vitro* at a concentration of 2×10^{-3} percent (v/v) without metabolic activation (Ref. 42, Obe and Beck, 1979). No increase was reported in sex-linked recessive lethals of *Drosophila melanogaster* fed butyraldehyde at a concentration of 2,000 ppm in 5 percent aqueous sucrose (Ref. 57, Valencia et al., 1985).

D. *Oncogenicity.* No information was found on the subject compound. Plans for a chronic inhalation bioassay of butyraldehyde were dropped by NTP because of technical difficulties in generating the atmosphere for exposure (Ref. 41, NTP, 1988). A related compound, isobutyraldehyde, is scheduled for a chronic inhalation bioassay starting in February 1989 under the National Toxicology Program. Other structural analogues of n-butyraldehyde including formaldehyde and acetaldehyde have shown sufficient evidence for carcinogenicity in animal studies; the evidence in humans is considered by IARC to be limited for formaldehyde and inadequate for acetaldehyde (Ref. 27, IARC, 1987).

E. *Chronic (long-term) effects.* No information was found.

F. *Reproducitve and developmental effects.* A single intraperitoneal injection of 1 mg butyraldehyde per animal produced chromosomal damage and meiotic anomalies including degenerative nuclei, multispindle cells and polyploid cells at all stages of spermatogenesis in male mice 1 month following the treatment (Ref. 36, Moutschen-Dahmen et al., 1975). In a later study (Ref. 37, Moutschen-Dahmen et al., 1976), one group of male mice received a single intraperitoneal dose of 30 mg butyraldehyde per kg, and a second group received 0.2 mg/L in their drinking water for 50 days. Administration of butyraldehyde by either route damaged the spermatogenic cells of the seminiferous tubules. In addition to gross degeneration, polyploidy was observed at all stages of spermatogenesis and abnromal pairing of sex chromosomes occurred at metaphase I; there was increased incidence of spermatozoa without acrosomes in the vas deferens.

G. *Observations in humans.* Among 12 individuals of Oriental ancestry characterized as susceptible to cutaneous flushing after ingestion of ethanol, all reacted positively (with erythema) to patch testing with 75 percent butyraldehyde (Ref. 60, Wilkin and Fortner, 1985).

Butyraldehyde was found to be mildly irritating when applied in epicutaneous tests (Ref. 44, Fiser and Pokorny, 1965, as cited in Opdyke, 1979), whereas 1 percent butyraldehyde in petrolatum produced no irritation after a 48-hour closed patch test (Ref. 44, Kligman 1977, as cited in Opdyke, 1979). One out of 25 tested with 1 percent butyraldehyde in petrolatum had a positive but nonspecific sensitization reaction in a maximization test.

Butyraldehyde vapor (230 ppm) was nonirritating to the eyes of 15 men during a 30 minute exposure (Ref. 49, Sim and Pattle, 1957).

H. *Rationale for health effects recommendations.* Annual domestic production of n-butyraldehyde is about 1.8 billion pounds by five manufacturers at six sites in Texas. Preliminary data indicate that over 5,000 workers (including 950 women) were potentially exposed to n-butyraldehyde in the workplace in 1980. Since domestic production has been increasing since 1982, it is expected that more workers are exposed today.

Sizeable airborne fugitive emissions have been reported (from 54,000 to 836,000 lbs. per year) from six major manufacturing and use sites. Therefore, there is potential for significant community population exposure in the vicinity of manufacturing and use sites.

Structural analogues of n-butyraldehyde including formaldehyde and acetaldehyde have shown carcinogenic effects in animals. IARC considers that there is sufficient evidence from animal studies for the carcinogenicity of formaldehyde and acetaldehyde whereas the evidence in humans is limited or inadequate,

respectively. The National Toxicology Program is scheduled to perform a 2-year inhalation study with isobutyraldehyde. There are, however, no data available to assess the carcinogenicity of n/butyraldehyde itself. The Committee noted the data indicating impaired spermatogenesis in male mice. Considering the lack of definitive data, the Committee recommends that testing addressing carcinogenicity and reproductive and developmental effects of butyraldehyde should be conducted if warranted by monitoring data.

IV. Ecological Effects of Concern

A. *Acute and subchronic (short-term) effects.* Acute toxicity (LC50) values have been reported as shown below.

Organism	Endpoint	Butyraldehyde Conc. (mg/L)	Reference
Fathead minnow	96-hr LC50	25.8	Ref. 12, Curtis and Ward, 1981.
Golden Orfe	96-hr LC50	57 & 114	Ref. 32, Juhnke and Ludemann, 1978.
Aedes aegypti larva	4-hr LC50	2,000	Ref. 33, Kramer et al., 1983.

B. *Chronic (long-term) effects.* No information was found.

C. *Other ecological effects.* In a series of articles, Bringmann and Kuhn reported on minimum inhibitory concentrations for a large number of chemicals and a variety of aquatic organisms. The definition of minimum inhibitory concentration varied according to the organism being tested. For daphnids it was described as the maximum tested concentration at which all of the daphnids were able to retain their swimming capability following 24 hours exposure to the test chemical. For protozoa the minimum inhibitory concentration was the concentration that caused cell counts in test cultures to be 5 percent or more below the counts in control cultures with 48 hours exposure. For algae, the minimum inhibitory concentration was the concentration of test material that inhibited cell multiplication in test versus control cultures during 8 days exposure. For the bacterium, *Pseudomonas putida,* the endpoint was inhibition of cell multiplication after 24 hours exposure, as determined by turbidity measurements of test versus control cultures (Ref. 4, Bringmann, 1978; Ref. 5, Bringmann and Kuhn, 1980; Ref. 6, Bringmann and Kuhn, 1981; and Ref. 7, Bringmann and Kuhn, 1982). Their results with butyraldehyde are summarized below:

Organism	Minimum inhibitory concentration (mg/L)
Microcystis aeruginosa algae	19
Scenedesmus guadricauda algae	83
Entosiphon sulcatum protozoa	4.2
Urunema parduczi protozoa	98
Chilomonas paramaecium protozoa	44
Daphnia magna	100
Pseudomonas putida bacterium	100

The butyraldehyde concentrations that inhibited the swimming capability of 50 percent and 100 percent of *Dcphnia magna* populations after 24-hours exposure also were reported by Bringmann and Kuhn (Ref. 7, 1982) to be 195 and 383 mg/L, respectively.

Chou et al. (Ref. 10, 1978) reported that butyraldehyde was relatively non-toxic to methanogenic bacteria.

In a study on the use of bacteria as an indication of toxicity to fish, Curtis et al. (Ref. 12, 1981) reported a 5-minute EC50 of 16.4 mg/L for *Photobacterium phosphoreum* exposed to butyraldehyde.

D. *Bioconcentration and food-chain transport.* An examination of fish in Japan revealed the presence of butyraldehyde at low concentrations (Ref. 29, Ito et al., 1980). The significance of this information in unclear since butyraldehyde is produced naturally and is found in many food products. Based on its high water solubility and low octanol/water partitioning coefficient, butyraldehyde is not expected to bioconcentrate.

E. *Rationale for ecological effects recommendations.* Butyraldehyde is produced in very large annual quantities at several locations in Texas. There are reports of substantial emissions of butyraldehyde to air at manufacturing and use sites. There may be significant concentrations of butyraldehyde in the air and surface waters in the vicinity of one or more of the manufacturing and use sites. Few data are available on the acute toxicity of butyraldehyde to aquatic species and none were found for terrestrial plants and animals. No chronic toxicity information was found. It is recommended that appropriate toxicity studies be conducted with representative species of biota if warranted by monitoring data.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 712 and 716

[OPTS-84029; FRL-3476-3]

Preliminary Assessment Information and Health and Safety Data Reporting; Addition of Chemicals

AGENCY: Environmental Protection Agency (EPA)

ACTION: Final rule.

SUMMARY: The Interagency Testing Committee (ITC) in its Twenty-third Report to EPA recommended that EPA give priority consideration to six chemical substances in proposing chemical test rules. To assist EPA in its determination of which, if any, tests are needed for these substances, EPA is adding the six substances to two model information-gathering rules: The Toxic Substances Control Act (TSCA) section 8(a) Preliminary Assessment Information Rule (PAIR), and the TSCA section 8(d) Health and Safety Data Reporting Rule.

EFFECTIVE DATE: This rule shall become effective on December 16, 1988.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. EB-44, 401 M St., SW., Washington, DC 20460, Telephone: (202-554-1404), TDD: (202-554-0551).

SUPPLEMENTARY INFORMATION: This rule adds six chemical substances to the PAIR and the section 8(d) Health and Safety Data Reporting Rule. Manufacturers, processors, and importers of these chemicals will be required to report end use, exposure, volume, and unpublished health and safety data to the Agency.

Public reporting burden for this collection of information is estimated to average 32.7 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

I. Background

Section 4(e) of TSCA established the ITC and authorized it to recommend to EPA chemical substances and mixtures (chemicals) to be given priority consideration in proposing chemical test rules. For some of these chemicals the ITC may designate that EPA must respond to its recommendations within 12 months. In this time, EPA must either initiate a rulemaking to test the chemical or publish in the **Federal Register** its reasons for not doing so. For the remainder of the recommended substances, no time limit for Agency response is imposed.

Elsewhere in today's issue of the **Federal Register**, EPA is announcing the receipt of the Twenty-third Report of the ITC, which was transmitted to EPA on November 1, 1988. The Twenty-third Report revises and updates the Committee's priority list of chemicals and adds six substances to the section 4(e) priority list. This rule adds these six substances to the PAIR and the section 8(d) Health and Safety Data Reporting Rule which will require manufacturers, importers, and processors to report volume, end use, exposure, and unpublished health and safety data to EPA. In addition, one chemical substance which had been recommended with intent-to-designate by the ITC in its Twenty-second Report, 2-Butenal, CAS No. 4170-30-3, is now designated for response within 12 months. This revision does not trigger any new reporting requirements because following the recommendation with intent-to-designate, 2-Butenal (also known as Crotonaldehyde), was added to the PAIR (53 FR 18211, May 20, 1988) and the section 8(d) Health and Safety Data Reporting Rule (51 FR 2890, January 22, 1986), as published in the **Federal Register** of May 20, 1988 (53 FR 18196).

To assist EPA in responding to the ITC recommendations, EPA has developed two model information-gathering rules (PAIR and the section 8(d) Health and Safety Data Reporting Rule) which provide for the automatic addition of ITC priority list substances. Whenever EPA announces the receipt of an ITC report, EPA may, at the same time without notice and comment, amend the two model information-gathering rules by adding the recommended substances. The amendment adding these substances to the PAIR and the Health and Safety Data Reporting Rule becomes effective 30 days after publication.

EPA issued PAIR under section 8(a) of TSCA (15 U.S.C. 2607(a)), and it is codified at 40 CFR Part 712. This model section 8(a) rule established standard reporting requirements for manufacturers and importers of the chemicals listed in the rule. These manufacturers and importers are required to submit a one-time report on general volume, end use, and exposure information using the Preliminary Assessment Information Manufacturer's Report (EPA Form No. 7710-35). EPA uses this model section 8(a) rule to gather current information on substances of concern quickly.

EPA issued the model Health and Safety Data Reporting Rule under section 8(d) of TSCA (15 U.S.C. 2607(d)), and it is codified at 40 CFR Part 716. EPA revised the section 8(d) model rule on September 15, 1986 (51 FR 32720). The section 8(d) model rule requires past, current, and prospective manufacturers, importers, and processors of listed chemical substances and mixtures to submit to EPA copies and lists of unpublished health and safety studies on the listed chemicals that they manufacture, import, or process. These studies provide EPA with useful information and have provided significant support for EPA's decisionmaking under TSCA sections 4, 5, 6, 8, and 9.

II. Chemicals to be Added

The following ITC priority list substances for which reporting is required under 40 CFR Parts 712 and 716 are listed by ITC designation in ascending Chemical Abstracts Service Registry Number (CAS No.) order:

A. *Designated for response within 12 months:*

CAS No. and Name

4170-30-3 2-Butenal (also known as Crotonaldehyde)

B. *Recommended with Intent-to-Designate:*

CAS No. and Name

115-96-8 Ethanol, 2-chloro-, phosphate (3:1) (also known as Tris(2-chloroethyl)-phosphate)

6145-73-9 1-Propanol, 2-chloro-, phosphate (3:1) (also known as Tris(2-chloro-1-propyl)phosphate)

13674-84-5 2-Propanol, 1-chloro-, phosphate (3:1) (also known as Tris(1-chloro-2-propyl)phosphate)

13674-87-8 2-Propanol, 1,3-dichloro-, phosphate (3:1) (also known as Tris(1,3-dichloro-2-propyl)phosphate)

33125-86-9 Phosphoric acid, 1,2-ethanediyl tetrakis(2-chloroethyl) ester (also known as Tetrakis(2-chloroethyl)ethylene disphosphate).

C. *Recommended without being designated for response within 12 months*:

CAS No. and name

123-72-8 Butanal (also known as Butyraldehyde).

III. Reporting Requirements

A. Preliminary Assessment Information Rule

All persons who manufactured or imported the substances named in this rule during their latest complete corporate fiscal year must submit a Preliminary Assessment Information Manufacturer's Report (EPA Form No. 7710-35) for each manufacturing or importing site at which they manufactured or imported a named substance. A separate form must be completed for each substance and submitted to the Agency no later than February 14, 1989. Persons who have previously and voluntarily submitted a Manufacturer's Report to the ITC or EPA should read § 712.30(a)(3). This section allows these persons to submit a copy of the original Report to EPA or to notify EPA by letter of their desire to have this submission accepted in lieu of a current data submission.

Complete details of the reporting requirements, including exemptions and a facsimile of the reporting form, are fully described in 40 CFR Part 712. Copies of the form are available from the TSCA Assistance Office at the address which procedes Unit I.

B. Health and Safety Data Reporting Rule

Listed below are the general reporting requirements of the section 8(d) model rule.

1. Persons who, in the 10 years proceding the date a substance is listed, either have proposed to manufacture, import, or process, or have manufactured, imported, or processed, the listed substance must submit to EPA:

A copy of each health and safety study which is in their possession at the time the substance is listed.

2. Persons who, at the time the substance is listed, proposed to manufacture, import, or process; or are manufacturing, importing, or processing the listed substance must submit to EPA:

a. A copy of each health and safety study which is in their possession at the time the substance is listed.

b. A list of health and safety studies known to them but not in their possession at the time the substance is listed.

c. A list of health and safety studies that are ongoing at the time the substance is listed and are being conducted by or for them.

d. A list of each health and safety study that is initiated after the date the substance is listed and is conducted by or for them.

e. A copy of each health and safety study that was previously listed as ongoing or subsequently initiated and is now complete—regardless of completion date.

3. Persons who, after the time the substance is listed, propose to manufacture, import, or process the listed substance must submit to EPA:

a. A copy of each health and safety study which is in their possession at the time they propose to manufacture, import, or process the listed substance.

b. A list of health and safety studies known to them but not in their possession at the time they propose to manufacture, import, or process the listed substance.

c. A list of health and safety studies that are ongoing at the time they propose to manufacture, import, or process the listed substance, and are being conducted by or for them.

d. A list of each health and safety study that is initiated after the time they propose to manufacture, import, or process the listed substance, and is conducted by or for them.

e. A copy of each health and safety study that was previously listed as ongoing or subsequently initiated and is now complete—regardless of the completion date.

Detailed guidance for reporting unpublished health and safety data is provided in the section 8(d) Health and Safety Data Reporting Rule published in the **Federal Register** of September 15, 1986 (51 FR 32720) (40 CFR 716.60). Also found there are the reporting exemptions.

C. Submission of PAIR Reports and Section 8(d) Studies

PAIR reports and section 8(d) health and safety studies must be sent to: TSCA Document Processing Center (TS-790), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. ATTN: (insert either PAIR or 8 (d) Reporting).

D. Removal of Chemicals From the Rules

Any person who believes that section 8(a) or (d) reporting required by this rule is unwarranted, should promptly submit to the Agency in detail the reasons for that belief. EPA may then remove the substance from the rule, EPA will issue a rule amendment for publication in the **Federal Register**.

IV. Release of Aggregate Data

The Agency will follow procedures for the release of aggregate statistics as prescribed in a rule related notice published in the **Federal Register** of June 13, 1983 (48 FR 27041). Included in the notice are procedures for requesting exemptions from the release of aggregate data. Exemption requests concerning the release of aggregate data on any chemical substance must be received by EPA no later than February 14, 1989.

V. Economic Analysis

A. Preliminary Assessment Information Rule

EPA estimates the PAIR reporting cost of this rule is $33,635. To calculate this figure EPA used the TSCA Inventory to generate a list of manufacturers and importers of these substances. Since no companies qualify as small businesses as defined in 40 CFR 712.25(c), EPA expects thirteen firms to report a total of twenty-five reports.

Reporting cost (dollars:	
(a) 25 reports expected at $807/report	$20,175
(b) 20 familiarization cases at $673/case	13,460
Total	33,635
Average cost per site	$1,681
Average cost per firm	2,587
Reporting burden (hours):	
(a) familiarization: 18 hours per site × 20 sites	360
(b) reporting: 16 hours per report × 25 reports	400
Total (hours)	760
EPA cost:	
Processing Cost = 25 reports × $91/report	$2,275

B. Health and Safety Data Reporting Rule

EPA estimates the total reporting costs for establishing section 8(d) reporting requirements for these substances is $19,680. This cost estimate is relatively high, because the Agency is uncertain about the likely number of respondents to the rule. Although EPA has used the best available data to make its economic projections, much of the data is not current. Therefore, EPA intends to overestimate rather than underestimate the reporting burden.

Nevertheless, the cost of this rule is low in comparison with its potential benefits. Health and safety studies concerning these substances would improve EPA's ability to identify potential public health and environmental problems with regard to these chemicals. The Agency therefore

would be better able to determine whether further regulatory action would be necessary.

The estimated reporting costs are broken down as follows:

Initial corporate review	$3,510
Site identification	2,430
File searches at affected sites	5,022
Title listing	252
Photocopying	842
Managerial review	4,860
Reporting on newly-initiated studies	120
Submissions after initial reporting period	2,060
Total	19,680

VI. Rulemaking Record

The following documents constitute the record for this rule (docket control number OPTS-84029). All of these documents are available to the public in the TSCA Public Docket Office from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The TSCA Public Docket Office is located at EPA Headquarters, Rm. NE-G004, 401 M St., SW., Washington, DC.

1. This final rule.
2. The economic analyses for this rule.
3. The Twenty-third Report of the ITC.

VII. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and, therefore, subject to the requirement of a Regulatory Impact Analysis. This rule is not major because it will not result in an effect on the economy of $100 million or more, an increase in costs or prices, or any of the adverse effects described in the Executive Order.

This amendment was not submitted to the Office of Management and Budget (OMB) for review, because the automatic listing of designated substances is provided for in 40 CFR 712.30(c) and 716.18(b)—final rules which have been previously reviewed by OMB under the terms of the Executive Order.

B. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by OMB under the provisions of the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq.* and have been assigned OMB control numbers 2070-0054 and 2070-0004.

Public reporting burden for this collection of information is estimated to average 32.7 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

List of Subjects in 40 CFR Parts 712 and 716

Chemicals, Environmental protection, Hazardous substance, Health and safety data, Recordkeeping and reporting requirements.

Dated: November 4, 1988.

Joseph J. Merenda,

Director, Existing Chemical Assessment Division, Office of Toxic Substances.

Therefore, 40 CFR Chapter I is amended as follows:

PART 712—[AMENDED]

1. The authority citation for Part 712 continues to read as follows:

Authority: 15 U.S.C. 2607(a).

2. Section 712.30 is amended by adding the following substances to paragraph (w) in CAS Number order as follows:

§ 712.30 Chemical lists and reporting periods.

* * * * *

(w) * * *

CAS No.	Substance	Effective date	Reporting date
*	* * * * * * *		
115-96-8	Ethanol, 2-chloro-, phosphate (3:1)	12/16/88	2/14/89
*	* * * * * * *		
123-72-8	Butanal	12/16/88	2/14/89
*	* * * * * * *		
6145-73-9	1-Propanol, 2-chloro-, phosphate (3:1)	12/16/88	2/14/89
*	* * * * * * *		
13674-84-5	2-Propanol, 1-chloro-, phosphate (3:1)	12/16/88	2/14/89
13674-87-8	2-Propanol, 1,3-dichloro-, phosphate (3:1)	12/16/88	2/14/89
33125-86-9	Phosphoric acid, 1,2-ethanediyl tetrakis(2-chloroethyl) ester	12/16/88	2/14/89
*	* * * * * * *		

(Approved by the Office of Management and Budget under control number 2070-0054.)

PART 716—[AMENDED]

1. The authority citation for Part 716 continues to read as follows:

Authority: 15 U.S.C. 2607(d).

2. By adding substances to § 716.120(a) numerically by CAS Number to read as follows:

§ 716.120 Substances and listed mixtures to which this subpart applies.

* * * * *

(a) * * *

CAS No.	Substance	Special exemptions	Effective date	Sunset date
*	* * * * * * *			
115-96-8	Ethanol, 2-chloro-, phosphate (3:1)		12/16/88	12/16/98

CAS No.	Substance	Special exemptions	Effective date	Sunset date
*	*	*		
123-72-8	Butanal		12/16/88	12/16/98
*	*	*		
6145-73-9	1-Propanol, 2-chloro-, phosphate (3:1)		12/16/88	12/16/98
*	*	*		
13674-84-5	2-Propanol, 1-chloro-, phosphate (3:1)		12/16/88	12/16/98
13674-87-8	2-Propanol, 1,3-dichloro-, phosphate (3:1)		12/16/88	12/16/98
33125-86-9	Phosphoric acid, 1,2-ethanediyl tetrakis (2-chloroethyl) ester		12/16/88	12/16/98
*	*	*		

(Approved by the Office of Management and Budget under control number 2070-0004.)

[FR Doc. 88-26305 Filed 11-15-88; 8:45 am]

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Wednesday
November 16, 1988

Part VI

Department of Transportation

Research and Special Programs Administration

14 CFR Parts 217 and 241

Aviation Economic Regulations; Report of Traffic and Capacity Statistics; Collection of Service Segment and Charter Data; The "T-100 System"; Final Rule

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

14 CFR Parts 217 and 241

[Docket No. 44999; Amendment No. 217-2; 241-57]
[RIN 2137-AA97, 2137-AB01]

Aviation Economic Regulations; Report of Traffic and Capacity Statistics; Collection of Service Segment and Charter Data; The "T-100 System"

AGENCY: Research and Special Programs Administration, DOT.

ACTION: Final rule.

SUMMARY: This final rule prescribes the collection of scheduled and nonscheduled service traffic data from foreign air carriers which provide service to and from the United States and for the domestic and international operations of United States carriers. These data will augment the charter data already reported by foreign air carriers serving the United States. At the same time, the Department of Transportation, hereafter referred to as DOT or the Department, is establishing a single automated system for collecting traffic data from both U.S. and foreign air carriers. This system: (1) Replaces the collection of U.S. and foreign air carriers' charter data on Form 217; (2) eliminates most of the burden associated with the recurrent hard-copy submissions of Form 217 and Form 41 "T" schedules; (3) reduces the number of traffic and capacity data elements for U.S. air carriers; and (4) through summarization, it simplifies submissions from all reporting air carriers. This more closely aligns the data collected by the Department with that necessary to fulfill its aviation responsibilities under the Federal Aviation Act of 1958, as amended.

EFFECTIVE DATES: January 1, 1989, for foreign air carriers; January 1, 1990 for U.S. air carriers.

FOR FURTHER INFORMATION CONTACT: Donald Bright or Richard King, Office of Aviation Information Management, DAI-10, Research and Special Programs Administration, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, (202) 366-4384, or 366-4375, respectively.

SUPPLEMENTARY INFORMATION:

Periodic Review

The Department plans to review the reporting results experienced under the T-100 data collection system after two years, and to request comments on the effectiveness of these regulations in achieving the DOT objectives, including whether there are less burdensome reporting methods. These may include some data alternatives, impracticable today, that become possible due to future technological or other advances, such as the rapidly evolving computer innovations and reservations processes, which may enable air carriers to provide these market-oriented traffic data with much less burden than presently feasible systems.

Background

The Airline Deregulation Act (Pub. L. 95-504, October 24, 1978) (ADA), as amended by the Civil Aeronautics Board Sunset Act of 1984 (Pub. L. 98-443, October 4, 1984), revised section 329(b)(1) of Title 49 of the United States Code to require the Secretary of Transportation to collect and disseminate information on civil aeronautics and to continue certain data collection activities of the former Civil Aeronautics Board (CAB). These activities include continuing the collection and dissemination of data on the number of passengers traveling by air in interstate and overseas (i.e., domestic) air transportation without flight number identification, unless the flight is providing domestic essential air service, in which case flight numbers may be required.

In 1970 the CAB adopted Economic Regulation ER-586 to provide for the collection of traffic and capacity data on a service segment basis (a pair of airports served by a single flight stage), from certificated air carriers, with submission of the data on computer magnetic tape or other Automatic Data Processing (ADP) media. A few air carriers did submit modified service segment data on a hard-copy form. Although much of the economic regulation over domestic air transportation was eliminated by the ADA, and other changes have taken place within the aviation industry, the Department continues to need data for nonstop segments and for on-flight markets, but in much less detail than has been reported in Service Segment Data (SSD). Besides Service Segment Data, the Department has collected traffic and capacity data from large certificated air carriers on nine Research and Special Programs Administration (RSPA) Form 41 "T" (traffic) schedules, and on RSPA Form 217 "Report of Civil Aircraft Charters Performed by U.S. Certificated and Foreign Air Carriers." Other sources of air carrier traffic data have included: foreign trade data collected from importers by the Department of Treasury's Customs Service and from exporters by the Department of Commerce's Bureau of Census; and the passenger data collected by the Department of Justice's Immigration and Naturalization Service (INS) on Form I-92.

This final rule implements a consolidated set of schedules and procedures for reporting all traffic and capacity statistics that both modernizes the process and significantly reduces air carrier burden. The new set of schedules includes only (1) the Schedule T-100(f) for foreign air carriers, and (2) for large U.S. air carriers holding 401 certificate authority, it includes the T-100 Schedule, plus the reduced and redesignated supplemental Form 41 Schedules T-1, T-2 and T-3. The T-100(f) collects from foreign air carriers for the first time certain limited data related to scheduled service operations in the U.S. market. As a whole, these schedules are known as the T-100 system.

For U.S. air carriers, the T-100 system replaces the former Form 41 Schedules T-1(a,b,c), T-2, T-3(a,b,c) and T-9, along with the ER-586 Service Segment Data and Form 217 reporting. The heart of the final rule is the T-100 report, which collects nonstop segment data and on-flight market information by equipment type and by service class. In the T-100 system, air carriers are no longer required to submit data on down-line deplanements or to report specific flight numbers for international operations (consistent with the previous elimination of flight numbers in domestic U.S. operations). Much of the information formerly collected on hard-copy Schedules T-1(a,b,c), T-2, and T-3(a,b,c) will be derived directly from the computerized T-100 detail reports, thus eliminating much of the air carrier burden associated with the preparation of these reports. However, the Department still finds it necessary to retain portions of these supplemental schedules to obtain summary data elements not collected on the Schedule T-100.

Foreign air carriers holding 402 permits, or exemption authority, and using aircraft with a maximum seat capacity of more than sixty seats or a maximum payload capacity of more than 18,000 pounds, will file Schedule T-100(f). The T-100(f) only applies to nonstop segments and on-flight markets where one or both points are within the U.S. and its possessions. When carriers are granted a foreign carrier permit or exemption authority by the Department, they will also receive a letter from the Department of Transportation, Research and Special Programs Administration,

Office of Aviation Information Management (DOT, RSPA, OAIM) advising them of their reporting obligations.

Public Comments

Forty-seven public comments were received, including six U.S. air carriers (Air Berlin, American, Delta, Northwest, USAir and United); three trade associations (Aerospace Industries Association of America, Inc. (AIA), Air Transport Association of America (ATA) and the International Air Transport Association (IATA)); one embassy (British); four U.S. Government agencies (Department of State-Office of Aviation Programs and Policy, Department of Labor-Bureau of Labor Statistics, Department of Commerce-U.S. Travel and Tourism Administration and Department of Commerce-Bureau of Economic Analysis); thirty foreign air carriers; one airport (Stewart); one data service firm; and one data user (USAF).

Initial Reporting and Phase-in Period Before Reporting Begins

Avensa wants a 6 month interval between adoption of a final rule and the first period for which reports are due, and it requested a quarterly report, rather than monthly, particularly for the first year, to ease the transition.

Singapore Airlines, Lufthansa and ATA ask that the effective date of the final T-100 rule be delayed for at least 6 months after it is published to provide time for all interested persons and governments to act.

Swissair wants foreign carrier reporting delayed at least a year after the final rule is enacted, to allow sufficient time for reprogramming.

The T-100 reporting system will be implemented in two stages over a year. Foreign air carriers will be required to begin reporting on January 1, 1989, while U.S. carriers will begin a year later. The Department feels that several months lead time is sufficient for foreign carriers to design their initial reporting systems to report 11 data items monthly. However, since it is a completely new system for foreign carriers, the Department's limited staff resources can be used to their fullest extent in helping them with any problems they may have before the U.S. carriers are brought on board. Further, the need for data from foreign air carriers is much more critical, since the Department has no data on their scheduled operations in the U.S. market, but does have data for U.S. carriers. The Department does not expect as many implementation problems from U.S. carriers, because they will be modifying existing systems instead of implementing new systems. Finally, the Department feels a year is necessary for assisting foreign carriers, because there are potentially about three times more foreign carriers than U.S. carriers, there could be language problems, the communicating distance is much greater, and not as much is known about their information systems. This approach will produce the greatest benefits and correctly focus the Department's efforts while preserving the flow of U.S. carrier data.

Costs and Burdens

In general, the U.S. air carriers did not express significant concerns about cost burdens or about personnel training and procedural changes that may impact them as a result of the T-100 system. Burden did figure more prominently in foreign air carrier responses.

United said that the T-100 system for foreign air carriers is long overdue, but Delta is opposed to the T-100 system, which it considers very burdensome to U.S. carriers, and unnecessary; separating tickets by three classes of service instead of the current two sorts would cost almost $200,000 in reprogramming effort alone, it estimates. Delta believes that the revenue data by fare class that are included in the current DOT data collection, "Passenger Origin-Destination Survey," could be used to derive middle cabin data, if DOT will reformat the information already reported. Codes for services such as middle cabin vary so widely that inconsistent data would be the end result; although DOT treats the terms "middle cabin" and "business class" as though they were interchangeable, they are not, Delta contends.

The Air Transport Association (ATA) is concerned about burden. ATA estimates that to implement the new T-100 system would result in an aggregate cost to its members that would be in excess of $1,000,000. More than 20 U.S. air carriers are members of ATA, including Delta.

British Airways (BA) estimated a cost of 180 man-hours per year, plus computer time and associated costs, which would appear to indicate a cost estimate of several thousand dollars annually. BA disputes that monthly traffic and capacity data of such detail is necessary to bilateral negotiations, and said DOT has not stated the changed circumstances that would justify imposition of new regulatory burdens. BA said that INS reductions will not reduce these costs, and that the I-92 is already a "batching" document for I-94. Since British Airways has a large presence in U.S. markets relative to many other foreign air carriers, it may be expected that only a few other foreign carriers would equal or exceed its burden hours.

Air Canada, Air Jamaica, Balair, Condor and Philippines believe that the T-100 system is, contrary to assertions, enormously burdensome and unnecessary. For an annual period, these 5 carriers allege that their burden will increase from 94 forms to 3,056 and for all foreign air carriers reporting would increase from a few hundred to 75,000 forms annually, since they must include scheduled service on the T-100(f) reports. Air Afrique opposed the T-100 system as an unjustifiable reporting burden, 6 separate reports each month for its 2 weekly flights to the U.S., 72 a year.

Canadian Airlines International (CAI) said the proposal is burdensome and redundant; it suggested that such data can be derived from true O&D exchanged quarterly by the U.S. and Canada. CAI said the burdensome, costly T-100(f) would not be offset by I-92 report reductions, because Canadian carriers do not file the INS data.

Caricargo believes its reporting burden will increase; although Form 217 will be eliminated, the 217 data will continue to be reported on T-100(f). Caricargo has no ADP capability, and would submit burdensome manual reports.

Finnair considers T-100(f) a burden that is not justified by any need for additional data; the statistics supplied to ICAO and to IATA should be sufficient. If collected, the T-100(f) should be collected quarterly, not monthly, to reduce reporting burden. IATA said there would be unnecessary duplication and conflicting data requirements; it suggested that DOT satisfy its data needs through existing IATA data collection programs. IATA said it may be possible for IATA to expand its programs to collect the data that DOT needs. Japan Air, Lufthansa, Singapore Airlines, and Swissair want DOT to defer the final T-100 rule pending revision of the IATA/ICAO data reporting systems, which they believe will provide market data that will satisfy DOT's needs. Avianca, Mexicana, LAV, LACSA, and VASP also feel that the current ICAO data, or INS data, or data exchanges between governments are adequate, and that the portion of the rulemaking (14 CFR Part 217) applicable to foreign air carriers should be withdrawn. Avianca, Finnair, Japan Air, LACSA, Lufthansa, Mexicana, Swissair and VASP are members of IATA.

Aeromexico, TAP and Nippon Cargo believe that burden is not reduced, but

will increase. Air France said the T-100(f) would be very burdensome and opposed the burden as a step backward from the deregulation championed by the U.S. Alitalia believes burdens to foreign carriers are greater than benefits to DOT; *ad hoc* information should be sufficient. KLM objects to burden, saying much of the requested T-100(f) data is not currently available to KLM, and would have to be generated. Avensa considers the proposal more complex and costly than the present level of reporting and is opposed to the T-100 system.

The British Embassy said that the Schedule T-100(f) reporting in the T-100 system would be an unjustified expense and staff burden.

The Department is not convinced there would be an overwhelming paper reporting burden, since foreign carriers would not be faced with a manual system if they adopt the modern, efficient computer oriented system that DOT envisions. It is likely that only the smallest foreign air carriers, or those with very little U.S. traffic volume, and hence a very small burden, would elect to submit the manual paper reports.

An analysis of 12 foreign carriers' reporting on the Schedule T-100(f) using the June 1988 Official Airline Guide schedules discloses that one of the largest carriers would only have 61 lines of entry for its scheduled service operation in the U.S. market for June using the redesigned Schedule T-100(f) (see next paragraph on the redesigned form). This carrier serves 17 U.S. points from 3 homeland points with 4 different aircraft types and had over 1300 departures. The number of lines would be considerably decreased if the number of points were less and/or the number of different aircraft types were less. A typical small carrier would have only 6 lines of data for 18 departures serving 1 U.S. point from 3 homeland points. The average number of lines of data for the whole group was about 20. This analysis included a cross section of foreign carriers ranked into 12 groups based on scheduled service passenger volumes for calendar year 1987. The groups ranged from under 10,000 passengers (smallest group) to over 2 million passengers (largest group). The reporting for one carrier was analyzed from each group. A review of reporting for several purely charter carriers disclosed that the number of line entries generally would be the same as for Form 217. For those carriers which reported different flight stages, the T-100 would require 50 percent fewer line entires than previously.

Twenty lines of data per month for a foreign carrier is not an unreasonable burden in view of the Department's need for the data. Nevertheless, the Department is sensitive to foreign carrier concerns in this area and wants to minimize any potential reporting burden on carriers as much as possible. In this context, the Schedule T-100 has been redesigned to permit 20 lines of data on each form in lieu of multiple submissions on separate forms. In an "extreme" case scenario, even the foreign air carriers with the most extensive service in U.S. markets should not expect to submit more than 12 monthly ADP reports each, per annum, or a few hundred lines of data each year. Virtually all foreign carriers except Canadian carriers should realize a substantial decrease in INS reporting burden. Reporting burden is related to the size of a carrier's U.S. operations, and the sophistication of its data retrieval system. We believe most foreign carriers do generate this data for their own business purposes. The burden is to conform their data to the DOT rule, and that burden is justified in light of the benefits to be derived for aviation information collection, use and dissemination.

Data collections conducted by ICAO or IATA are not viable alternatives to the T-100 system as some carriers suggest for a many reasons. All foreign carriers are not members of IATA, and all carriers are not reporting to ICAO. Either data base might suffice if the broad picture was the focus. The Department's needs are much more narrow. That is, country to country is the primary focus and if a carrier is not reporting and is the only carrier of that country, then the Department has no data to use. See caption entitled "Alternative Data Sources" for more information.

The Department does not dispute that there will be some costs to reprogram for U.S. carriers, whether it is approximately $50,000 per carrier as ATA estimates or $200,000 as Delta estimates for its own program, the Department believes in the long run that there will be cost savings since there is less data to report to the Department and INS.

The Department considers as quite reasonable both the potential costs to each foreign carrier of reporting (which are estimated at from $100 to $2,000 per each monthly submission, based upon the size of the carrier's reported operations) and the possible manpower burdens to the air carriers (which are estimated at from 1 to 20 staff hours per submission). Further, it may be somewhat disingenuous for carriers to suggest that the Department wants thousands of reports each year when only one ADP submission or a few pages of a hardcopy report per month is required.

The Department has reexamined its need to collect two capacity data elements (available seats and available payload weight) from foreign air carriers. In lieu of requiring that these elements be reported to DOT, the Department will rely, for a trial period, upon existing data sources in the private sector. The Department will generate estimated seat capacity data from the Official Airline Guides (OAG) semiannual seat configuration data voluntarily supplied by the foreign air carriers. Similarly, the Depatment will also estimate available payload weight. If the experiment is only partially successful and private sector data gaps exist for a very few carriers, the Department may employ *ad hoc* reporting pursuant to 14 CFR 385.27. However, if the private sector data are substantially inadequate, DOT may require foreign air carriers to submit actual capacity data on Form 41 Schedule T-100(f), as originally proposed.

Eliminating collection of capacity information reduces the proposed 13 data elements to 11. Several of these data elements are merely labels (namely: Air carrier, report date, origin airport, destination airport, service class, and aircraft type), and only the remaining few (passengers, freight kilograms, and aircraft departures) represent hard data items that foreign carriers must report.

Confidentiality and Access to Detail T-100 System Information

Many of the carrier comments dealt with the question whether limited or permanent confidential treatment should be accorded the T-100 system's detailed data by carrier. Comments ranged from urging immediate release to permanent confidentiality.

Avensa wants the data collected to be released immediately; it said DOT should require simultaneous disclosure of all individual carrier market data as to a particularly country to each carrier, U.S. or foreign, serving the market.

American would make the T-100 data of U.S. and foreign carriers public 90 days after the end of the reporting month—or not collect it at all. American does not believe that the data can be kept confidential or that it should be restricted from release to the public. American urged that prompt public dissemination of on-board and on-flight market data of both U.S. and foreign air carriers will assist the nation's airlines in more intelligently distributing their

capacity and enhancing competition, leading to a more efficient national airline industry. Keeping the data confidential for 3 years will deny airline management the information that allows them to optimize their resources and offer the best service to the traveling public.

USAir would permanently preclude the availability of its data to its competitors because it contends that detailed on-board and on-flight market data remain valuable to potential competition even after 36 months. It believes that such data would not be disclosed in an unregulated industry.

Aeromexico objects to any disclosure before or after a 3-year period, because it has fundamental problems regarding public disclosure of highly sensitive competitive information. Both Aeromexico and British Airways feel disclosure should be limited to the U.S. government and to parties who have obtained the prior written consent of the foreign air carrier owning the data. Air Canada, Air Jamaica, Balair, Condor and Philippine (Joint comment) and Qantas also make the same argument concerning sensitivity and would object to the U.S. releasing their data to other governments. They would prefer an absolute veto power regarding any request for their data. Cathay Pacific also does not want the U.S. to be able to release one foreign government's data to another country.

Air Afrique wants assurances the data will be kept confidential for 3 years, with no exceptions. Canadian Airlines International is concerned that sensitive data must be held in strict confidence. KLM said it is anti-competitive for governments to collect and disseminate such sensitive commercial information. Jointly, Avianca, Mexicana, LAV, LACSA, and VASP expressed their concern for adequate safeguards ensuring the confidentiality of data.

Japan Air, Lufthansa, Singapore Airlines, and Swissair are concerned with safeguarding sensitive data, but want the U.S. to share the data, to the extent that it is collected, with affected foreign governments with whom the U.S. is involved in bilateral negotiations, and they object to the data being available to any other party, such as their U.S. carrier competitors.

Nippon Cargo wants protection for its confidential traffic data, including restrictions on release by an Administrative Law Judge. The carrier said that the proposed regulations provide intolerable latitude for DOT to release Nippon Cargo's data to anyone who can show significant need, if DOT finds it in the public interest.

IATA said individual market share data should not be publicly disclosed. Such data are often protected by privacy and confidentiality laws in an airline's own country. There should be no exception to confidentiality unless the foreign government concerned specifically concurs.

The Aerospace Industries Association (AIA) said it would prefer to have access to the T-100 data within 12 months. Stewart International Airport said that the final rule should include provisions that assure access to T-100 data for U.S. airports.

The Department has decided to keep U.S. carrier data confidential for 3 years with limited access, as proposed. The T-100 final rule conforms with the DOT policy on "confidential commercial information" which provides business submitters of data both notification and an opportunity to object before a disclosure determination is made. Therefore, the Department will take into account the views of the carriers providing data before deciding whether to release it to non-U.S. Government parties requesting access. Certainly, the Department has no intention of prematurely releasing sensitive carrier data to competing carriers or other governments. The objective is to collect limited data that DOT needs, and to provide adequate safeguards while allowing reasonable current releases of aggregate data. The Department intends to continue publishing summary level data, as it has in the past, that are derived from the reported data, such as the Airport Activity Statistics and the Monthly Air Carrier Traffic Statistics. Also, the Department will release country-to-country passenger data without carrier detail, similar to INS data.

The Department has established a reasonable period of time during which it will prevent unauthorized access to detail traffic data that the reporting carriers consider to be sensitive commercial information. However, the Department cannot accept that these data should be kept confidential forever, or even after 3 years, because there are public interest benefits in making these data available. A 3-year restricted release period is considered to be adequate protection to the reporting carriers, and to the extent that subsequent release may lead to constructive competition, that is found to be in the public interest.

The Department assures foreign governments and foreign air carriers that the data carriers submit will not be released prematurely to other airlines or other foreign governments. Further, the reporting carriers' views will be sought regarding public requests for access to their data, and these views will be accorded significant weight by the Department in its decision whether to release the requested data. The IATA noted that ICAO does not publish on-flight O&D data where only one carrier provides service in a market, which eliminated about one-half of all origin/destination city pairs. The Department's final rule is more stringent than ICAO (which has no restrictions on disclosure of its annual Form C "Traffic by Flight Stage" data and does not publish monopoly markets or release individual carrier data from its quarterly Form B "On-Flight Origin and Destination"), because T-100 detail traffic data by carrier will not be available to the public during the 3-year restricted release period; even summary data in an on-flight market (country-to-country data) will not be available, unless three or more carriers are represented.

On balance, the Department's considered opinion is that these regulations provide adequate protection to sensitive commercial information during the 3-year period when release would be most critical and potentially harmful to the interests of the reporting carriers, while still making them public after that restricted release period so that they are available for relevent research and academic studies to enhance and promote healthy competition in the industry.

International Reciprocity

A number of foreign carriers expressed the common theme that the T-100 data collection system would reduce reliance on current cooperative data endeavors and may impact bilateral negotiation policy on data exchanges. Some foreign carriers believe Congress did not intend for DOT to collect foreign carrier data on a regular, recurrent basis as is proposed, although wide latitude in data collection authority is conferred upon the Department in section 407(a) of the Act. Their opinion is that international principles of comity and reciprocity preclude such unilateral data collection efforts. Some question the legality of the T-100 system under current bilaterals and suggest their governments would forbid their compliance. Further, potential foreign "retaliation" was raised as an issue in that some countries that do not already collect data from U.S. carriers may opt to collect equivalent data or more.

American expects foreign governments to require similar data of U.S. air carriers. British Airways said the T-10 system is "pregnant" with

international controversy; scheduled data have not been needed for 50 years, except in limited, episodic bilateral negotiations, and many years may pass between negotiations. Therefore, the T-100(f) is unnecessary and will provoke similar requirements from foreign governments on U.S. air carriers. The British Embassy said the T-100(f) was unnecessary and will lead to the imposition of similar burdens by many other governments; it urges that DOT reconsider. Her Majesty's Government does not consider that the case for seeking this information has been made and would therefore question the need for it.

Aeromexico says T-100(f) data are needed only on a country-to-country basis, not on an expensive carrier-by-carrier basis, and they are too sensitive to be collected in the form prescribed by DOT. Nippon Cargo said such data should be submitted, if at all, on a bilateral, government-to-government basis; Nippon Cargo considered the requirement to be unprecedented and inconsistent with the principles of international comity and reciprocity.

Air Afrique sees no basis or justification for not continuing the reciprocal exchange of market data on a government-to-government basis. Air France said bilateral and competitive implications of reporting such data could require it to obtain detailed instructions from its government. Air France alleges that the T-100 system is a complex change of reporting responsibilities, much of which would be first time requirements for foregin flag carriers. The complex pattern of services operated by Air France to the U.S., or via the U.S. to third countries, would probably be misinterpreted in such reports. Due to the magnitude of potential for competitive damage, the only data Air France would even consider reporting are market data, limited to passenger statistics. Sabena said the U.S./Belgium Air Agreement does not provide for such statistical data; therefore, any request for data by DOT would not be in accord with the Agreement, and it must put the matter before Belgian authorities.

Air Indian said DOT must defer to the recently concluded bilateral agreement between the U.S. and India, which provides for a far more detailed exchange of traffic data than DOT proposes. It suggests a waiver from the T-100 system reports in cases where an aviation bilateral agreement provides for an exchange of substantially equivalent detail. Alitalia questioned DOT's authority to collect such data, and questioned the propriety of attempting to implement the T-100 system in view of the existence of the U.S./Italian bilateral agreement. Alitalia believes such collection should be implemented only after bilateral consultations and negotiations. Canadian Airlines International said the Canada/U.S. Air Transport Agreement has no provision for Canadian carriers to submit data such as would be reported on Schedule T-100(f). Even if it did, Canadian carriers should be exempted, due to the current informal bilateral exchange of true O&D data. KLM cited Netherlands/U.S. air transport agreement which agreed to minimize the administrative burdens of filing requirements. KLM objects to the T-100 system, believing it is against the interests of competition in international aviation to have governments collect and disseminate market information.

Alitalia, Japan Air, Lufthansa, Singapore Airlines, Swissair, Air Canada, Air Jamaica, Balair, Condor, and Philippine Airlines indicated that the unilateral imposition of T-100(f) by DOT may violate existing international aviation agreements. Government-to-government consultations under existing aviation agreements are considered necessary. They believe the data collection is contrary to the intent of Congress, and cited the legislative history of the International Air Transportation Competition Act of 1979 (IATCA) (Pub. L. 96-192, 94 Stat. 38, (1979)). The authority granted by section 407(a) of the FAAct, with respect to foreign air carriers, was to be exercised with great discretion. Some carriers cited statements in that legislative history by former officials of the State Department, CAB and DOT who said the U.S. must use great caution in asking for data from foreign air carriers. The carriers said foreign retaliation is likely, as well as bilateral confrontations.

In a separate comment, in addition to the joint statement with other carriers, Lutfhansa said the Department should be aware that, pursuant to its operating authority granted by the Federal Republic of Germany, Lufthansa is precluded from submitting data, such as would be required, without the consent of its Government. Accordingly, Lufthansa might be unable to comply. Further, it believes the T-100 system is contrary to the intent of Congress; Lufthansa said Congress did not intend in section 407(a) "to authorize a wide-ranging periodic reporting requirement such as is proposed in the NPRM."

It is clear that section 407(a) of the FAAct authorizes the T-100 system of data collection. The T-100 element for scheduled service traffic as adopted in this rule are designed to impose the least practicable amount of burden. Also, foreign air carriers have been submitting detail charter flight traffic statistics under DOT/CAB regulations for many years without substantial objections.

The Department promulgated this reporting requirement to obtain information enabling it more adequately to meet its statutory requirements in a number of program areas. It is not the intention of the Department to impose an unreasonable burden on foreign carriers or to require a more onerous report which represents a dramatic deviation from those commonly collected from U.S. carriers by foreign aviation authorities. In exercising its authority under section 407(a) of the FAAct to require the T-100 system, the Department conducted a thorough study that concluded that the T-100 system was absolutely essential to the efficient and effective performance of the Department's responsibilities under the law. Several persuasive factors have influenced the Department's decision, not the least of which is the increasing technological sophistication of the air carrier information systems, which tends to facilitate better reporting, at less cost than a munual system. While the T-100 system data may have been somewhat burdensome for larger U.S. or foreign carriers if it could only be submitted manually, the increasing computerization of the aviation industry information systems greatly facilitate the carriers' accumulation of these data at minimal cost.

While it is true that DOT and before it, the CAB, has used estimates, it can no longer continue to collect less than it needs, given the current intense competition in the marketplace, the maturity of the industry, and the ability of the air carriers to report more detailed data. The Administration is on record as taking a closer look at the trade between countries to ensure that U.S. trade interests are properly protected in negotiations on air routes and other rights. In order to carry out the U.S. international aviation policy effectively, as required by the Congress and the Administration, the Department requires more precise data as prescribed in the T-100 reporting system.

With the cooperation of the U.S. Department of State (DOS), the Department conducted a survey, in May and June 1988, of foreign country traffic reports submitted by U.S. airlines to determine whether the complexity and reporting requirements proposed in the T-100 system represented a more onerous reporting burden or dramatic

deviation from the information customarily collected from U.S. carriers by other countries.

The survey analyzed the traffic reporting requirements of 20 countries which represented a broad geographical distribution. While most of these countries are among the United States' major aviation trading partners, there was a wide range in the volume of traffic in the United States market. In total, these 20 countries in 1987 represented about two-thirds of the U.S.'s international air passenger volume and almost 60 percent of the U.S. international air freight tonnage. While the reports are quite diverse in terms of content, the survey concluded that the T-100 system is well within the limits of common international reporting practices, and is by no means as extensive as many of the reports that U.S. carriers are required to file abroad. Of the 20 countries, only 2 do not have periodic traffic reporting requirements. Two other countries' requirements are slightly less than those of the T-100. Of the remaining 16 country reports, all have one or more significant features which make them as detailed and in most cases more extensive or budensome than the T-100 system. For example, 13 have daily or per flight reporting requirements. Like the T-100 system, two provide for monthly reporting, while one is an annual report. Eight require two or more different reports. While 15 of the 16 reports have more data elements than the T-100 system, we have decided to reduce the number of data elements on the Form 41 Schedule T-100(f) from 13 to 11. Three of the foreign governments even require financial reporting of U.S. carrier operations. Some countries, that do not require detailed traffic reports, require that U.S. air carriers submit copies of each flight passenger manifest and copies of all airway bills and tickets, from which the government has the ability to compile exact traffic and revenue statistics.

Therefore, the Department has concluded that the T-100 system is not unduly budensome to foreign carriers and that it is well within the scope of the types of data that foreign countries commonly collect form U.S. air carriers.

Need for Aviation Data by Other U.S. Government Agencies

The United States' Department of State—Office of Aviation Programs and Policy (DOS) believes DOT should collect data on passenger traffic originating or destined for foreign points "behind" or "beyond" those homeland points served by non-stop flights to/from the U.S DOS said carriers operating directly to the U.S. appear, incorrectly, to carry a much larger share of total traffic than do those serving points via connections at intermediate stops; thus, SAS appears to carry most of the traffic from Scandinavia, while U.S. carriers serving Scandinavia as a beyond point through, for instance, connections in London, do not appear to carry Scandinavian traffic. DOS also suggested that DOT require reporting in the T-100 system of traffic to "behind" or "beyond" points involving international air cargo services.

The U.S. Department of Commerce-U.S. Travel and Tourism Administration (USTTA) opposes loss of citizenship on Form I-92 and flight number detail from Service Segment Data, saying that the data needs of other agencies require consideration. It may be easier for DOT to collect a few supplemental data items from air carriers to meet their needs than for USTTA to create a whole new air carrier data collection.

The U.S. Department of Commerce-Bureau of Economic Analysis (BEA) wants the number of U.S. citizens on foreign air carriers, the number of foreign citizens on U.S. air carriers, and the total number of U.S. citizens traveling by air. These data are used in computing the U.S. balance of payments, gross national product, and U.S. input-output account.

The U.S. Department of Labor-Bureau of Labor Statistics (BLS) International Price Program (IPP) and the Consumer Price Index (CPI) are current users of DOT data for their air passenger fare price indexes. The IPP uses Form I-92 data to calculate the balance-of-payments expenditure weights for the export air passenger fares indexes, and as the sampling frame for the foreign carrier and import air passenger fares series. Since BLS' programs need U.S. resident and alien passenger counts for U.S. and foreign gateway port pairs in order to calculate accurate balance-of-payment weighing factors, it strongly opposes loss of citizenship data. BLS also asks for data that DOT did not porpose in the T-100 system—a fourth fare class (coach discount), in addition to first class, business and coach. BLS has found it difficult to obtain information about the fare class seating distributions for foreign carriers, and asks DOT to extend its reporting of on-flight markets connected to a U.S. gateway to include points beyond the homeland of the foreign carrier.

The United States Air Force (USAF) said the T-100 proposal posed no problems for its military Airlift Command (MAC) ratemaking, but expressed concern that DOT should not futher reduce the Form 41.

The Department is acutely aware of the importance of the DOT aviation data bases to other Federal Government agencies. However, with the exception of two service class codes (N and R) collected specifically for the Department of Defense-United States Air Force (USAF) with the concurrence of OMB, the rule provides for only the data needed by the Department.

Reporting Period

Avensa, Qantas and Swissair request 45 days following the subject month, in which to submit the form 41 Schedule T-100(f) data. Qantas believes that, in view of the volume of data requested by the Department, the processing time needed to accurately produce data in the format specifically required, and the time required to deliver the data to the Department, the 30 day filing requirement is unreasonably short.

Finnair wants the T-100(f) data to be submitted quarterly, similar to the reporting period prescribed for Form 217.

The Department understands the carriers' desire for a longer interval to submit the report. Once the reporting system is in place, we feel the carriers will be able to submit the data to the Department within 30 days. The majority of carriers are meeting the 30 day deadline on the Form 217 report. Carriers are able to report within 30 days without undue difficulties, since many carriers have traffic data systems that provide fully-edited, final traffic data to management within 5 to 15 days after the end of the reporting month. The comment suggesting an increase in the reporting period, from monthly to quarterly, is not a viable alternative. The first month's data of the quarter would be several months old when the Department receives it. This is to much of a lag for the Department to keep on top of the changes taking place in the scheduled service sector.

Collection of T-100 Data by Cabins (First, Middle, Coach)

The Notice of Proposed Rulemaking proposed adding a middle cabin (business class) category to the existing data elements (first class and coach) collected from Group III U.S. air carriers; that is, these carriers would report passengers enplaned and transported, and available seats by these classes.

American believes both foreign and U.S. carriers should identify three separeate cabins (classes) for domestic and international routes. On the other hand, Delta opposes the T-100 proposal

to collect middle cabin data, and supports simply continuing the first class and coach class data collection.

The ability to gauge the increasing significance of middle (business) cabin service within the international sector of the industry is an important feature of the T-100 collection system. The Department historically has needed U.S. carrier data by cabin, and continues to need such data to make decisions and to analyze the relative costs and revenues of U.S. air carriers and their foreign competitors.

Foreign carriers are not required to report any traffic statistics by cabin, or passenger revenue data.

Because business class fares are more extensively used in the air carriers' international operations (versus domestic operations), the Department has decided that business class, along with first class and coach class cabins, will be reported by Group III air carriers in the international sector only. Also, the Department has decided that no cabin distinctions are needed for domestic operations of any air carrier group. To the extent that the Department needs domestic traffic data segregated into first class, middle (business class) and coach cabin categories, it will rely upon *ad hoc* requests as provided by the authority in 14 CFR 385.27.

In summary, Group III U.S. air carriers will report first, coach and middle (business class) cabin data only for international operations. All domestic operations and the international operations of Groups I and II U.S. air carriers will be reported by summarizing the three classes and reporting them on Schedule T-100 in the total category provided for Available Seats, Passengers Transported, and Passengers Enplaned.

Because of the many innovative air fares developed since deregulation, and the heavy use of discount air fares, the Department's definition of fare classes (first class, coach, etc.) may very well be outmoded for statistical purposes. The Department plans ro review the fare class definitions and propose any necessary revisions or additions in the traffic and revenue requirements commensurate with the Department's needs (Regulatory Agenda, 53 FR 14040, RIN 2137-ABOO).

Form 41 Revenue Passenger Data by Fare Class

In an issue not a part of the T-100 system, the Department proposed in the NPRM to combine the two passenger revenue categories (Accounts 3901.1 First Class and 3901.2 Coach) on Form 41 Schedule P-1.2 "Statement of Operations" into a single revenue account, "3901 Transport Revenues—Passenger." Based upon further analysis, the Department has decided to retain Accounts 3901.1 and 3901.2 on Schedule P-1.2 and to require the reporting of these data only for international operations of Group III air carriers. In all other instances, a single category of passenger revenue is reported in Account 3901. However, U.S. air carriers may continue to report first class and coach revenue data, if they conclude that such voluntary reporting would be less burdensome than changing their existing financial reporting system.

Classes of Service

On a T-100 issue, American wants foreign carriers to have the same charter and scheduled service categories (service classes) as required from U.S. carriers.

Although IATA suggests its system as a supplement to or a substitute for aspects of the T-100 system, the Department has not found any alternative data collection system from IATA, ICAO, or any other source, that could substitute for the T-100 system. IATA said its ODS (On-Flight Origin and Destination Traffic Statistics) system is similar in most respects to the T-100 system proposed by DOT, except that it contains only scheduled service data, and IATA does not collect capacity data (such as tons and seats available for sale) by segments (city pairs). IATA's ODS system does have passengers segregated into cabins (First, Business, and Economy).

The Department recognizes the merit in American Airlines's position that U.S. and foreign carrier data service classes should be aligned as closely as possible for scheduled or charter service operations, and has adopted uniform service class codes for both.

INS Reports

Stewart International Airport wants DOT to collect citizenship data or to ensure that INS Form I-92 is continued because access to such data is critical to Stewart's promotional efforts to attract more airlines and develop a full pattern of service, including scheduled service airlines.

USDOC-USTTA wants "I-92" data continued, or replicated in the T-100 reports, so it will have citizenship and flight number data. These data are essential to USTTA's programs to promote tourism.

USDOC-BEA requests that citizenship data be transferred from the I-92 data collection to the T-100 reporting system. BEA programs rely on these data.

USDOL-BLS wants INS Form I-92 continued, because it needs citizenship data for the International Price Program (IPP) and Consumer Price Index (CPI).

American Airlines is opposed to discountinuing the submission of the INS Form I-92 to INS. It said these reports are necessary to help identify the U.S. citizen/alien distribution for the various on-off (on-flight market) segments of international journeys. Understanding this mix is important to a successful international marketing effort and should be protected or enhanced rather than potentially reduced, according to American Airlines.

TAP is concerned INS may not eliminate I-92 data, and it believes it will have to submit duplicate data to INS and to DOT.

The Department cannot provide any assurances as to INS actions regarding its data collections on INS Forms I-92 and I-94. Whether these data systems will continue unchanged, or will be greatly reduced, must be decided by INS (although we note that INS has informed DOT of its continuing efforts to reduce the number of data elements in these data collections and that I-92 data are no longer required by them, except as batch control totals). The Department has identified the data required by its programs. Except for citizenship data, the T-100 system virtually eliminates the Department's need for INS data.

Reporting of "Freedom" Traffic

Northwest suggested that the T-100 should divide traffic between locally enplaned and through traffic. Northwest views the lack of this data as a concession to foreign airlines that all traffic to and from the homeland point is "third" and "fourth freedom".

The term "freedom" refers to various transit or transport rights existing and negotiated among sovereign nations. The "Freedoms of the Air" deal with the passage of aircraft within the airspace of a nation; for example, the first freedom is the freedom of an air carrier to fly across the airspace of another country without landing; the second freedom provides for non-traffic technical and refueling stops; the third freedom regards transport of traffic between an air carrier's homeland and a foreign country; the fourth freedom regards transport of traffic from a foreign county to the air carrier's homeland; the fifth freedom regards transport of traffic between two foreign countries, neither of which is the air carrier's homeland; and the sixth freedom is a traffic right that is exercised from behind the air carrier's homeland gateway.

The provisions of this final rule are a reflection of the Department's data

needs rather than a concession to foreign air carriers. Where the Department needs to segregate locally enplaned and through traffic into the various "freedom" categories, it will.

DOS said DOT should collect passenger traffic originating or destined for foreign points "behind" or "beyond" those served by non-stop flights to/from the U.S. Its concerns also extended to "behind" and "beyond" cargo traffic, as well. DOS said a strong U.S. negotiating posture depends in part on having accurate information on traffic volume to and from the U.S., and the improved data collection procedures to account for "sixth freedom" traffic is of paramount concern. Both the current data and the proposed T-100 system are distorted, because connecting traffic from third countries is not well documented, and the relative importance of such countries to the U.S. as traffic generators and actual market shares by air carriers are not apparent.

The Department has decided that it will not separately collect in the T-100 system data for city-pairs behind a foreign homeland or for city-pairs beyond a third country to another country. Although these behind and beyond homeland data by city pairs will not be separately reported, these data will be included with the homeland data and reported as traffic enplaned or deplaned at the homeland. The Department does require all U.S.-related market data to be reported for any nonstop market that includes a U.S. airport. The data which are not reported by foreign carriers are, for instance, homeland-to-homeland markets. In its decision not to specifically identify such behind and beyond markets, the Department took into consideration the fact that it is extremely rare for other countries to collect such information.

Foreign Carrier Available Capacity by Aircraft Type and Airport

Lufthansa argues that available capacity data cannot be prepared on a meaningful basis, because only partial segments (to and from the U.S., involving homeland Germany) on a flight are reported. Such piecemeal capacity data would be misleading and useless, Lufthansa believes.

Swissair wants to report the typical seating pattern of the relevant aircraft type, rather than the slightly varying number of seats available for sale. Thus, Swissair would prefer to report available capacity, if at all, as a standard number of seats for each aircraft type—and asks to report all required traffic data by city-pairs, as opposed to the required airport-pairs.

As stated under another caption, the Department has re-evaluated its proposal to collect foreign air carrier available capacity information. Accordingly, data on the number of available seats and available payload weight for sale by aircraft type and flight segment will not be reported to DOT. Instead, the Department will rely upon private sector data, and to the extent that the Official Airline Guides or other private sector data are not sufficient, may rely upon *ad hoc* reporting, under the authority in 14 CFR 385.27.

Other Comments

Data Base Products was in favor of the T-100 system, but said DOT would make a serious policy mistake to restrict public availability of the T-100 data for 3 years, since in a deregulated environment, immediate public access to data should improve market efficiencies and ensure the benefits of deregulated competition to consumers. Air Berlin asked to be excused from T-100 reporting. Canadian Airlines International asked for a waiver from the T-100(f) reporting, citing voluntary exchanges of true O&D data between the U.S. and Canada; they also noted they are not required to file INS Form I-92 data.

While Data Base Products' view is understandable, the provisions in this rule, as further explained under the caption on confidentiality, represent the appropriate balance in the Department's judgment between the legitimate security needs of the data providers and the public benefits from disclosure of the data. Air Berlin will not report data under the T-100 reporting system, because its current operations are not performed pursuant to a 401 certificate, and thus do not meet the reporting criteria of the rule. Regarding Canadian carrier data, the Department still requires the T-100 system while fully aware of the benefits of the exchanges of true O&D data with Canada.

Reporting of Code Sharing, Wet Leases, Part Charters and Blocked Space

The Department will use *ad hoc* reporting under the authority in 14 CFR 385.27 to collect data for joint services, rather than complicating the regular monthly reporting for a few international arrangements dealing with code sharing, wet leases, part charters and blocked space agreements. *Ad hoc* reporting will only be used if additional data is needed. That is, there could be occasions where the Department does not need any additional data on the joint service agreement. When *ad hoc* reporting is used it will normally be on an annual basis with sufficient lead time for the carrier to make the necessary adjustments in its information system to provide the data at a minimum cost and burden.

Collection of Military Charter Data by Aircraft Type

The Department's objective is to collect only the data required for its programs. In addition, the Department will collect data required for the programs of other Federal agencies, if OMB has determined that it is less burdensome for the Department to collect for those agencies and has designated DOT as the central collection point. The Department only needs summary data on military flights by U.S. air carriers for industry analysis purposes (for instance, total revenue passengers enplaned on Schedule T-1 and total aircraft departures in the Airport Activity Statistics on Schedule T-3). Therefore, an overall military summary service class (V, Nonscheduled) is adequate for the Department's needs. However, in a prior rulemaking (50 FR 232), the Department of the Air Force (USAF) specified a need for the breakout by aircraft type of military charter data on Schedule T-1 by Service Class Codes N (Nonscheduled Military Passenger/Cargo) and R (Nonscheduled Military Cargo). In the proposed rule, the Department requested USAF to reaffirm its need for service class codes N and R.

The USAF submitted a statement in the docket which indicated that the Department should continue collecting separate military service classes (N and R). The Department interprets the USAF statement as being a request for data collection that is subject to the provisions in 5 CFR 1320.15. Therefore, with OMB approval, the Department will continue to require air carriers to segregate service class codes N and R in reporting nonscheduled data on Form 41 Schedule T-1, rather than reporting an overall summary service class (V, Nonscheduled), as proposed in the NPRM.

Traffic Data Collection (Foreign Air Carriers)

RSPA Form 41 Schedule T-100(f)

Prior to this final rule, foreign air carrier recurrent reporting of traffic data to the Department was limited to charter operations to and from the United States. Charter traffic flow information was reported quarterly to the Department by foreign air carriers on RSPA Form 217 "Report of Civil Aircraft Charters Performed by U.S. Certificated and Foreign Air Carriers." These charter

data are required to assess the impact of charter traffic on specific international markets for use in international aviation negotiations, evaluating foreign air carrier requests for operating authority to serve U.S. points, and monitoring international fares and rates. In addition to Form 217, the Department has used the Immigration and Naturalization Service's INS Form I-92 "Aircraft Vessel Report" and freight data obtained from the Department of Commerce to estimate foreign air carriers' scheduled operations activity. Form I-92 has provided arriving and departing passenger count data at gateways, and has been used as a measure of the scheduled passenger traffic for such points. Both U.S. and foreign air carriers, excluding Canadian carriers, operating to and from the U.S. are required to file INS Form I-92. The Department of Commerce, Bureau of Census "Airborne Trade" data provided a similar measure for freight data, although these statistics combine sheduled and charter traffic, and a differentiation between the two services has not been possible, although DOT needs this data.

Under the provisions of the International Air Transportation Competition Act of 1979, the Secretary of Transportation is charged with developing an international air transportation negotiating policy which includes, among other responsibilites:

(1) The strengthening of the competitive position of United States air carriers to at least assure equality with foreign air carriers;

(2) The freedom for U.S. air carriers and foreign air carriers to offer fares and rates corresponding with consumer demand;

(3) The fewest possible restrictions on charter air transportation;

(4) The maximum degree of multiple and permissive international authority for United States air carriers so that they will be able to respond quickly to shifts in market demand;

(5) The elimination of operational and marketing restrictions to the greatest extent possible;

(6) The provision of opportunities for foreign air carriers to increase their access to United States points if exchanged for benefits of similar magnitude for United States carriers or the traveling public with permanent linkage between rights granted and rights given away; and

(7) The elimination of discrimination and unfair competition.

In carrying out this mandate in the highly competitive international marketplace, the Department operates mainly within the framework of bilateral aviation agreements which exist between the United States and most foreign countries. In evaluating existing and proposed changes to bilateral air service agreements, a determination is made of the air transportation commerce between the U.S. and foreign countries. Examples of traffic data elements needed to make these evaluations include passenger and freight traffic volume. Within today's continuously changing competitive environment, these determinations have become an item of critical importance in U.S. aviation relations with foreign governments.

This environment has created an awareness of the importance of the availability of timely and accurate aviation information in discovering and responding to short-notice changes in the marketplace. In addition to timeliness and accuracy, the Department has also identified certain inherent problems with the data available for estimating foreign air carrier scheduled traffic flows to/from the United States. In estimating traffic for scheduled service operations, the Department has been forced to use diverse and somewhat incompatible data sources, such as INS Form I-92 data, even though such sources were not always directly responsive to program needs. Such data are used to supplement the foreign air carrier charter data reported on Form 217. Because Form I-92 is an INS, not a DOT, data collection, the Department has not had the flexibility to quickly revise the data collected in order to respond to changing information needs.

In reviewing its overall aviation responsibilities and related data requirements, the Department has concluded that it may increase the reliability of its international aviation information data base while mitigating foreign carrier reporting burden. To accomplish this, the Department is prescribing a Schedule T-100(f) reporting system for foreign air carriers. This system is a minimum-level uniform nonstop segment and on-flight market data collection system that is compatible with the Schedule T-100 reporting system for U.S. air carriers that may reduce their reporting burden-hours by 48%.

By comparison, foreign air carriers are required to report on a monthly basis only 11 of the total 24 data items that are reported by Group III U.S. air carriers. The 11 items fall into 3 major informational groupings:

Service Pattern Information: Carrier code, Report date, Origin airport code, Destination airport code, and Service class code;

Nonstop Segment Information: Aircraft type code, Revenue aircraft departures performed, Total revenue passengers transported and Revenue freight transported; and

On-Flight Market Information: Total revenue passengers in market, and Total revenue freight in market.

The 11 items encompass scheduled, charter and nonscheduled operations. Foreign air carriers do not separate behind homeland traffic from homeland traffic since for the purpose of the T-100(f) report, traffic is considered to enplane or deplane at the first or last homeland point reportable on the segment or market report.

The above data base closes critical data gaps for scheduled passenger and scheduled cargo services affecting the U.S. that are operated by foreign air carriers. While providing for data collections more consistent with current needs, the Department also is taking advantage of technological innovations in computer reporting and processing capabilities to reduce carrier burden. Under the T-100 system, foreign air carriers are able to (and are urged to) report their traffic data by using ADP media. The Schedule T-100(f) automated reporting system is designed to be an essential part of the Department's integrated traffic and capacity reporting system.

Adoption of the T-100 system eliminates the need for foreign and U.S. air carriers to report their charter operations on Form 217. Except for citizenship data, it also virtually eliminates the Department's need for INS Form I-92.

Traffic And Capacity Data Collection (U.S. Air Carriers)

RSPA Form 41 Schedule T-100 System

The Department is continuously reviewing its aviation information requirements and data collection activities to ensure that the data collected are sufficient to meet the Department's program needs at a minimum of reporting burden to the affected air carriers. To this end, various data collection alternatives, such as ADP media instead of hardcopy formats, were considered. The Department identified the Form 41 traffic and capacity system as an area for burden reduction. During the course of its review, the Department reassessed the specific traffic and capacity data it requires for meeting its program responsibilities and concluded that, beyond the data now collected and used, it requires a standard aircraft size cutoff of 18,000 pounds of available

capacity payload; a limited amount of traffic information from foreign air carriers; and some additional information on service classes operated by those large U.S. certificated air carriers reporting as Group III air carriers.

Essentially, the Department is prescribing a reporting system, hereafter referred to as the RSPA Form 41 Schedule T-100 Reporting System (T-100 system), to collect scheduled, nonscheduled, and charter traffic and capacity data from both U.S. and foreign air carriers that is assembled into a uniform data base. This new system eliminates most of the burden from filing the current Form 41 "T" schedules for U.S. air carriers. Of the Form 41 "T" schedules, only Schedule T-8 "Report of Domestic All-Cargo Operations" remains unchanged. Schedule T-8 is still needed to provide critical financial and traffic information on domestic all-cargo operations.

This final rule incorporates the Form 217 charter reporting into the T-100 system. This new system consists of the Form 41 Schedule T-100 and three simplified supplemental schedules for U.S. air carriers. The supplemental schedules would collect miscellaneous data not provided for in the basic Schedule T-100, such as "Aircraft Days Assigned to Service-Carrier's Equipment". On the Schedule T-100, U.S. air carriers would report nonstop segment and on-flight market information. On the new supplemental schedules (T-1, T-2, and T-3), U.S. air carriers would report data for domestic passenger and cargo charters, domestic scheduled all-cargo, and domestic or international military charters excluded from the Schedule T-100.

The T-100 system also replaces the current Service Segment Data collection system. Under the T-100 system, Group III U.S. air carriers submit a maximum of 24 data items (only 18 data items for carriers other than Group III), representing a significant reduction in the 49 SSD data elements previously collected. Collection of downline deplaning data is also eliminated.

Burden reductions also result from the elimination of data elements that are no longer required due to the summarization of data by on-flight market without regard to intermediate stops, and summarizing data by nonstop segment without regard to international flight numbers. The Department has not required flight numbers to be reported in the domestic entity since 1984.

Overall, the traffic and capacity data elements reported by U.S. air carriers are reduced by 61% and the burden hours are reduced by 48%. The Group III U.S. carriers have 24 Schedule T-100 data items (18 for other U.S. air carriers that do not report multiple cabin data—First, Coach and Middle) that are reported in 3 categories:

Service Pattern Information: Carrier entity code, Report date, Origin airport code, Destination airport code, and Service class code;

Nonstop Segment Information: Aircraft type code, Revenue aircraft departures scheduled (520), Revenue aircraft departures performed (510), Available capacity payload (270), Available seats—first cabin (311), Available seats—middle (business) cabin (313), Available seats—coach (312), Revenue passengers transported—Frist Cabin (133), Revenue passengers Transported—middle (business) cabin (133), Revenue passengers transported—coach (132), Revenue freight transported (237), Revenue mail transported (239), Revenue aircraft hours (ramp-to-ramp) (630), Revenue aircraft hours (airborne) (610); and

On-Flight Market Information: Total revenue passengers enplaned in market—First cabin (111), Total revenue passengers enplaned in market—middle (business) cabin (113), and revenue passengers enplaned in market—coach (112), Total revenue freight enplaned in market (217), and Total revenue mail enplaned in market (219).

The T—100 system eliminates the filing of much of the data now reported on Form 41 Schedules T-1(a,b,c), T-2, and T-3(a,b,c,). However, there are two areas in domestic service not covered by the Schedule T-100 detail reports: (1) Domestic all-cargo operations, and (2) domestic charter operations. Also, domestic and international military charter data are not collected in the Form 41 Schedule T-100 reports. To provide statistics needed for assessing total air carrier operations, the Department is prescribing revised Schedules T-1 and T-3 for carriers to report only the data elements needed for these operations that are not otherwise reported. Schedule T-2 will also be retained, in part, to collect miscellaneous factors by aircraft type not required in the detail T-100 schedule.

In general, the traffic and capacity statistical elements previously reported on the eliminated hard-copy Form 41 schedules that are still needed will be submitted in computer media, such as magnetic tape or "floppy" diskette. T-100 data entry forms (paper) will be provided for those U.S. carriers without any computer capability that obtain a "hardship" waiver to submit data in noncomputer media. The Department plans to produce computer outputs from the T-100 data system in essentially the same formats as are now available in the hardcopy Form 41 "T" schedules. Thus, the Department is simplifying and modernizing data collection procedures to eliminate even minor duplicate data collections from air carriers, resulting in substantial burden reductions in terms of reports submitted by carriers.

Alternatives Data Sources

As previously stated in response to the IATA public comment, the Department has considered various alternatives to the T-100 system. In reviewing its requirements for RSPA Form 41 Schedules T-100, T-1, T-2, T-3 and T-100(f) data, the Department was unable to identify any viable alternative data sources.

In this research, the Department investigated the possible use of alternative international data sources to determine whether the information contributed by member carriers of the International Air Transport Association (IATA) and the data collections of the International Civil Aviation Organization (ICAO) could be used by the Department, in whole or in part, in lieu of the T-100 system.

The Department compared these potential alternatives with its data needs in areas involving content, frequency and coverage and found that these data did not meet its requirements.

As a result, the Department has decided that reliance upon nonair carrier entities as suppliers of data (such as IATA or ICAO) would present insurmountable problems for the Department, such as the timely availability of data, and therefore the T-100 system has been designed as a stand-alone system for the Department only.

Executive Orders 12291, 12612 and 12630, Regulatory Flexibility Act, Paperwork Reduction Act of 1980, Federalism, and Takings

This final rule has been reviewed under Executive Order 12291, and it has been determined that this is not a major rule. It will not result in an annual effect on the economy of $100 million or more. There will be no increase in production costs or prices for consumers, individual industries, Federal, State or local governments, agencies or geographical regions. Furthermore, this proposed rule would not adversely affect competition, employment, investment, productivity, innovation, and will enhance the ability of United States based enterprises to compete with foreign based enterprises in domestic or exports markets. This proposed regulation would result in a

net reduction in reporting burden. Accordingly, a regulatory impact analysis is not required.

This regulation is significant under the Department's Regulatory Policies and Procedures, dated February 26, 1979, because it involves important Departmental policies. Its economic impact should be minimal and a full regulatory evaluation is not required.

It is certified that this rule will not have a significant economic impact on a substantial number of small entities. The proposed amendments would affect only large U.S. certificated and large foreign air carriers.

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

This rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12630, and it has been determined that it does not pose the risk of a taking of constitutionally protected private property.

Public reporting burden for this collection of information is estimated to vary from 1 hour to 20 hours per monthly response, depending upon the size of the carriers' operations subject to the reporting requirement, with an average of 7 hours per monthly response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Director, Office of Aviation Information Management, DAI-1, U.S. Department of Transportation, Research and Special Programs Administration, 400 Seventh Street, SW., Washington, DC 20590; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

List of Subjects in 14 CFR Parts 217 and 241

U.S. air carriers, Foreign air carriers, Reporting and recordkeeping requirements.

Final Rule

Accordingly, the Department of Transportation amends Chapter II of 14 CFR, as follows:

1. Part 217 is revised to read:

PART 217—REPORTING TRAFFIC STATISTICS BY FOREIGN AIR CARRIERS IN CIVILIAN SCHEDULED, CHARTER, AND NONSCHEDULED SERVICES

Sec.
217.1 Definitions.
217.2 Applicability.
217.3 Reporting requirements.
217.4 Data collected (service classes).
217.5 Data collected (data elements).
217.6 Extension of filing time.
217.7 Certification.
217.8 Reporting procedures.
217.9 Waivers from reporting requirements.
217.10 Instructions.
217.11 Reporting compliance.

Authority: 49 U.S.C. 1301, 1324, 1371, 1373, 1374, 1377, 1381, 1386, 1482.

§ 217.1 Definitions.

As used in this part:

"Foreign Air Carrier" means a non-U.S. air carrier holding a foreign air carrier permit or exemption authority from the Department of Transportation.

"Large Aircraft" means an aircraft designed to have a passenger capacity of more than 60 seats or a payload of more the 18,000 pounds.

"Small Aircraft" means an aircraft that is not a large aircraft.

"Statement of Authorization" under this Part means a statement of authorization from the Department, pursuant to 14 CFR Part 207, 208, or 212, as appropriate, that permits joint service transportation, such as blocked space agreements, part-charters, code-sharing or wet-leases, between two direct air carriers holding underlying economic authority from the Department.

§ 217.2 Applicability.

This part applies to foreign air carriers that are authorized by the Department to provide civilian passenger and/or cargo scheduled, nonscheduled and charter services to or from the United State, whether performed pursuant to a permit or exemption authority. Operations conducted wholly with small aircraft are exempt from the requirements of this part. Where the service operations involve both large and small aircraft, only the large aircraft services must be reported.

§ 217.3 Reporting requirements.

(a) Each foregin air carrier shall file RSPA Form 41 Schedule T-100(f) "Foreign Air Carrier Traffic Data by Nonstop Segment and On-flight Market." All traffic statistics shall be compiled in terms of each flight stage as actually performed.

(b) The traffic statistics reported on Schedule T-100(f) shall be accumulated in accordance with the data elements prescribed in § 217.5 of this part, and these data elements are patterned after those in section 19-5 of Part 241 of this chapter.

(c) One set of Form 41 Schedule T-100(f) data shall be filed.

(d) Schedule T-100(f) shall be submitted to the Department within thirty (30) days following the end of each reporting month.

(e) Schedule T-100(f) shall be filed with the Research and Special Programs Administration at the address referenced in § 217.10 and the Appendix to § 217.10 of this part.

§ 217.4 Data collected (service classes).

(a) The statistical classifications are designed to reflect the operating elements attributable to each distinctive class of service offered for scheduled, nonscheduled and charter service.

(b) The service classes that foreign air carriers shall report on Schedule T-100(f) are:

(1) F Scheduled Passenger/Cargo
(2) G Scheduled All-Cargo
(3) L Nonscheduled Civilian Passenger/Cargo Charter
(4) P Nonscheduled Civilian All-Cargo Charter
(5) Q Nonscheduled Services (Other than Charter). This service class is reserved for special nonscheduled cargo flights provided by a few foreign air carriers under special authority granted by the Department.

§ 217.5 Data collected (data elements).

(a) Within each of the service classifications prescribed in § 217.4, data shall be reported in applicable traffic elements.

(b) The statistical data to be reported on Schedule T-100(f) are:

(1) *Air carrier.* The name and code of the air carrier reporting the data. The carrier code is assigned by DOT. The Office of Aviation Information Management (OAIM) will confirm the assigned code upon request; OAIM's address is in the Appendix to § 217.10 of this part.

(2) *Reporting period date.* The year and month to which the reported data are applicable.

(3) *Origin airport code.* This code represents the industry designator as described in the Appendix to § 217.10 of this part. A common private industry source of these industry designator codes is the *Official Airline Guides* (OAG). Where none exists, OAIM will furnish a code upon request. OAIM's address is in the Appendix to § 217.10 of this part.

(4) *Destination airport code.* This represents the industry designator, from the source described in § 217.5(b)(3).

(5) *Service class code.* For scheduled and other services, the applicable service class prescribed in § 217.4 of this part shall be reported.

(6) *Aircraft type code.* This code represents the aircraft type, as specified in the Appendix to § 217.10 of this part. Where none exists, OAIM will furnish a code upon request.

(7) *Revenue aircraft departures performed (Code 510).* The number of revenue aircraft departures performed in scheduled service and extra sections.

(8) *Revenue passengers transported (Code 130).* The total number of revenue passengers on board over a flight stage, including those already on the aircraft from previous flight stages. Includes both local and through passengers on board the aircraft.

(9) *Revenue freight transported (kilograms) (Code 237).* The volume, expressed in kilograms, of revenue freight that is transported. As used in this part, "Freight" means revenue cargo other than passengers or mail.

(10) *Total revenue passengers in market (Code 110).* The total number of revenue passengers enplaned in a market, boarding the aircraft for the first time. While passengers may be transported over several flight stages in a multi-segment market, this data element (code 110) is an unduplicated count of passengers originating within the market.

(11) *Total revenue freight in market (kilograms) (Code 217).* The amount of revenue freight cargo (kilograms) that is enplaned in a market, loaded on the aircarft for the first time.

§ 217.6 Extension of filing time.

(a) If circumstances prevent the filing of a Schedule T-100(f) report on or before the due date prescribed in section 22 of part 241 of this chapter and the Appendix to § 217.10 of this part, a request for an extension must be filed with the Director, Office of Aviation Information Management.

(b) The extension request must be received at the address provided in § 217.10 at least 3 days in advance of the due date, and must set forth reasons to justify granting an extension, and the date when the report can be filed. If a request is denied, the air carrier must submit the required report within 5 days of its receipt of the denial of extension.

§ 217.7 Certification

The certification for RSPA Form 41 Schedule T-100(f) shall be signed by an officer of the air carrier with the requisite authority over the collection of data and preparation of reports to ensure the validity and accuracy of the reported data.

§ 217.8 Reporting procedures.

Reporting guidelines and procedures for Schedule T-100(f) are prescribed in the Appendix to § 217.10 of this part.

§ 217.9 Waivers from reporting requirements.

(a) A waiver from any reporting requirement contained in Schedule T-100(f) may be granted by the Department upon its own initiative, or upon the submission of a written request of the air carrier to the Director, Office of Aviation Information Management, when such a waiver is in the public interest.

(b) Each request for waiver must demonstrate that: Existing peculiarities or unusual circumstances warrant a departure from the prescribed procedure or technique; a specifically defined alternative procedure or technique will result in substantially equivalent or more accurate portrayal of the operations reported; and the application of such alternative procedure will not adversely affect the uniformity in reporting applicable to all air carriers.

§ 217.10 Instructions

(a) Foreign air carriers shall submit Form 41 Schedule T-100(f) on either floppy discs produced on microcomputers or on other ADP media, such as magnetic tape, or hardcopy reports.

(b) The detailed instructions for preparing Schedule T-100(f) are contained in the Appendix to this section. Blank copies of Schedule T-100(f) are available from the Office of Aviation Information Management, DAI-1, Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh St., SW., Washington, DC 20590.

APPENDIX to Section 217.10 of 14 CFR Part 217—Instructions to Foreign Air Carriers for Reporting Traffic Data on Form 41 Schedule T-100(f)

(a) General instructions.

(1) Description. Form 41 Schedule T-100(f) provides flight stage data covering both passenger/cargo and all cargo operations in scheduled and nonscheduled services. The schedule is used to report all flights which serve points in the United States or its territories as defined in this part.

(2) Applicability. Each foreign air carrier holding a 402 permit, or exemption authority, and operating aircraft with seating configurations of more than sixty seats and/or available capacity (payload of passengers and cargo) of more than 18,000 pounds shall file Form 41 Schedule T-100(f). Reference to 402 is to section 402 of the Federal Aviation Act of 1958, as amended (FAAct).

(3) Address for filing reports: Data Administration Division, DAI-2, Room 4125, Office of Aviation Information Management, Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590.

(4) Filing period. Form 41 Schedule T-100(f) shall be filed monthly and is due at the Department thirty (30) days following the end of the reporting month to which the data are applicable.

(5) Number of copies. A single set of legible Form 41 Schedule T-100(f) data and certification shall be submitted.

(6) Foreign air carrier certification. Each foreign air carrier shall submit a certification statement (illustrated at the end of this Appendix) as an integral part of each monthly Schedule T-100(f), as prescribed in § 217.5 of this part.

(7) Alternative filing on Automatic Data Processing (ADP) media. Foreign air carriers are encouraged to use ADP equipment to reduce the manual effort of preparing Schedule T-100(f). Foreign air carriers may use the floppy disk medium. ADP submission requirements for floppy discs are prescribed in paragraph (f).

(b) Preparation of Form 41 Schedule T-100(f):

(1) Explanation of nonstop segments and on-flight markets. There are two basic categories of data, one pertaining to nonstop segments and the other pertaining to on-flight markets. For example, the routing (A-B-C-D) consists of three nonstop segment records A-B, B-C, and C-D, and six on-flight market records A-B, A-C, A-D, B-C, B-D, and C-D.

(2) Guidelines for reporting a nonstop segment. A nonstop segment is reported when one or both points are in the United States or its territories. These data shall be merged with that for all of the other reportable nonstop operations over the same segment. Nonstop segment data must be summarized by aircraft type, under paragraph (h)(1), and class of service, paragraph (g)(1)(v).

(3) Rules for determining a reportable on-flight market. On-flight markets are reportable when one or both points are within the U.S., with the following exceptions: (i) Do not report third country to U.S. markets resulting from flight itineraries which serve a third country prior to a homeland point in flights passing through the homeland bound for the U.S.; and (ii) do not report U.S. to third country markets resulting from itineraries serving third country points subsequent to a homeland point in flights outbound from the U.S. and passing through the homeland. In reporting data pertaining to these two exceptions, the traffic moving to or from the U.S. relating to the applicable prior or subsequent third countries (referred to as "behind" or "beyond" traffic) is to be combined with the applicable foreign homeland gateway point, just as though the traffic were actually enplaned or deplaned at the homeland gateway, without disclosure of the actual prior or subsequent points. Applicable flights are illustrated in examples (6) and (7) under paragraph (c).

(c) Examples of flights. Following are some typical flight itineraries that show the reportable nonstop segment and on-flight market entries. The carrier's homeland is the

key factor in determining which on-flight markets are reportable.

(1) SQ flight # 11 LAX—NRT—SIN. This is an example of a flight with an intermediate foreign country. It is not necessary to report anything on the NRT—SIN leg.

SQ—Singapore Airlines
LAX—Los Angeles, USA
NRT—Tokyo-Narita, Japan
SIN—Singapore, Singapore

A-3—Airport code	A-4—Airport code	A-5—Service class (mark an X)					By aircraft type—				Sum of all aircraft types—	
Origin	Destination	F	G	L	P	Q	B-1—Aircraft type code	B-2—Revenue aircraft departures	B-3—Revenue passengers transported	B-4—Revenue freight transported (kg)	C-1—Total revenue passengers in market	C-2—Total revenue freight in market (kg)
LAX	NRT	X					8161	12	2400	4800	400	500
LAX	SIN	X									2000	4300

(2) SQ flight #15 LAX— HNL— TPE— SIN. This is an example of two U.S. points, an intermediate third country, and a homeland point. Information is reportable on only the on-flight markets and nonstop segments that consist of one or both U.S. points.

SQ—Singapore Airlines
LAX—Los Angeles, USA
HNL—Honolulu, USA
TPE—Taipei, Taiwan
SIN—Singapore, Singapore

A-3—Airport code	A-4—Airport code	A-5—Service class (Mark an x)					By aircraft type—				Sum of all aircraft types—	
Origin	Destination	F	G	L	P	Q	B-1—Acft. type code	B-2—Revenue aircraft departures	B-3—Revenue passengers transported	B-4—Revenue freight transported (kg)	C-1—Total revenue passengers in market	C-2—Total revenue freight in market (kg)
LAX	HNL	X					8161	12	2700	5300	0	0
LAX	TPE	X									700	1300
LAX	SIN	X									2000	4000
HNL	TPE	X					8161	12	2200	6800	1200	800
HNL	SIN	X									1000	6000

(3) LB flight # 902 LPB-VVI-MAO-CCS-MIA. This flight serves two homeland points and two different foreign countries before terminating in the U.S. Nonstop segment information is required only for the nonstop segment involving a U.S. point. On-flight market information is required in 4 of the 10 markets, LPB-MIA and VVI-MIA, since these involve homeland and U.S. points; MAO-MIA is necessary to show traffic carried into the U.S., and CCS-MIA for the same reason, and also because in all cases where a nonstop segment entry is required, a corresponding on-flight market entry must also be reported.

LB—Lloyd Aero Boliviano
LPB—La Paz, Bolivia
VVI—Santa Cruz-Viru Viru, Bolivia
MAO—Manaus, Brazil
CCS—Caracas, Venezuela
MIA—Miami, USA

A-3—Airport code	A-4—Airport code	A-5—Service class (mark an x)					By aircraft type—				Sum of all aircraft types—	
Origin	Destination	F	G	L	P	Q	B-1—Acft. type code	B-2—Revenue aircraft departures	B-3—Revenue passengers transported	B-4—Revenue freight transported (kg)	C-1—Total revenue passengers in market	C-2—Total revenue freight in market (kg)
CCS	MIA	X					8161	31	6900	71000	0	0
LPB	MIA	X									1100	20000
VVI	MIA	X									4000	30000
MAO	MIA	X									1000	12000

(4) LY flight #005 TLV-AMS-ORD-LAX. This flight serves a single foreign intermediate point and two U.S. points after its homeland origination. The information on the TLV-AMS leg is not reportable.

LY—El Al Israel Airlines
TLV—Tel Aviv, Israel
AMS—Amsterdam, Netherlands
ORD—Chicago, USA
LAX—Los Angeles, USA

A-3—Airport code	A-4—Airport code	A-5—Service class (mark an x)					By aircraft type—				Sum of all aircraft types—	
Origin	Destination	F	G	L	P	Q	B-1—Acft. type code	B-2—Revenue aircraft departures	B-3—Revenue passengers transported	B-4—Revenue freight transported (kg)	C-1—Total revenue passengers in market	C-2—Total revenue freight in market (kg)
AMS	ORD	X					8161	1	350	10000	50	1500
TLV	ORD	X									150	4000
TLV	LAX	X									125	3000
ORD	LAX	X					8161	1	150	4500	0	0
AMS	LAX	X									25	1500

(5) QF flight #25 SYD—BNE—CNS—HNL—YVR. This flight serves three homeland points, a U.S. point, and a subsequent third country. Nonstop segment information is required on the respective legs into and out of the United States. All on-flight market entries involving the U.S. point HNL are also required. Data are not required on the homeland to homeland markets, or the homeland—third country markets.

QF—Qantas Airways (Australia)
SYD—Sydney, Australia
BNE—Brisbane, Australia
CNS—Cairns, Australia
HNL—Honolulu, USA
YVR—Vancouver, Canada

A-3—Airport code	A-4—Airport code	A-5—Service class (mark an x)					By aircraft type				Sum of all aircraft types	
Origin	Destin.	F	G	L	P	Q	B-1—Acft. type code	B-2—Revenue aircraft departures	B-3—Revenue freight transported	B-4—Revenue freight transported (kg)	C-1—Total revenue passengers in market	C-2—Total revenue freight in market (kg)
CNS	HNL	X					8161	5	2200	41000	400	8000
SYD	HNL	X									600	10000
BNE	HNL	X									600	9000
HNL	YVR	X					8161	5	750	15700	150	1700

(6) JL flight #002 HKG—NRT—SFO. This flight originates in a third country prior to the homeland. No data is required on the HKG-NRT leg, but the HKG-SFO passengers and cargo shall be shown as enplanements in the NRT-SFO on-flight market entry. These volumes are included by definition in the passenger and cargo transported volumes of the NRT-SFO nonstop segment entry.

JL—Japan Air Lines
HKG—Hong Kong, Hong Kong
NRT—Tokyo-Narita, Japan
SFO—San Francisco, USA

A-3—Airport code	A-4—Airport code	A-5—Service class (mark an x)					By aircraft type				Sum of all aircraft types	
Origin	Destin.	F	G	L	P	Q	B-1—Acft. type code	B-2—Revenue aircraft departures	B-3—Revenue passengers transported	B-4—Revenue freight transported (kg)	C-1—Total revenue passengers in market	C-2—Total revenue freight in market (kg)
NRT	SFO	X					8161	3	1200	18000	1200	18000

(7) JL flight # 001 SFO-NRT-HKG. This flight is the reverse sequence of flight #-002 above; it requires a nonstop segment entry covering SFO-NRT, and a single on-flight market entry also for SFO-NRT. In this case, the on flight traffic enplaned at SFO and destined for HKG, a beyond homeland point, shall be included in the SFO-NRT entry; a separate SFO-HKG entry is not required.

JL—Japan Air Lines
SFO—San Francisco, USA
NRT—Tokyo-Narita, Japan
HKG—Hong Kong, Hong Kong

A-3—Airport code	A-4—Airport code	A-5—Service class (mark an x)					By aircraft type				Sum of all aircraft types	
Origin	Destin.	F	G	L	P	Q	B-1—Acft. type code	B-2—Revenue aircraft departures	B-3—Revenue passengers transported	B-4—Revenue freight transported (kg)	C-1—Total revenue passengers in market	C-2—Total revenue freight in market (kg)
SFO	NRT	X					8161	1	400	20000	400	20000

(8) BA flight # 5 LHR-ANC-NRT-OSA. This example contains a single homeland point and a single U.S. point followed by two third country points. It is necessary to report the nonstop segments into and out of the U.S., and all three of the on-flight markets which have the U.S. point ANC as either an origin or destination.

BA—British Airways
LHR—London, England
ANC—Anchorage, USA
NRT—Tokyo-Narita, Japan
OSA—Osaka, Japan

A-3—Airport code	A-4—Airport code	A-5—Service class (mark an x)					By aircraft type			Sum of all aircraft types		
ORIGIN	DESTIN.	F	G	L	P	Q	B-1—Acft. type code	B-2—Revenue aircraft departures	B-3—Revenue passengers transported	B-4—Revenue freight transported (kg)	C-1—Total revenue passengers in market	C-2—Total revenue freight in market (kg)
LHR	ANC	X					8161	10	3000	50000	100	1000
ANC	NRT	X					8161	10	3150	55000	100	2500
ANC	OSA	X									150	1500

(d) Provisions to reduce paperwork:

(1) Nonstop Segment Entries. The flight stage data applicable to nonstop segment entries must be summarized to create totals by aircraft equipment type, within service class, within pairs-of-points.

(2) On-flight Market Entries. The applicable on-flight market entries shall be summarized to create totals by service class within pair-of-points.

(e) Preparation of hard copy Schedule T-100(f):

(1) Section A—Indicative and flight pattern information. A copy of Schedule T-100(f) is shown at the end of this Appendix. Section A defines the origin and destination points and the service class code to which the nonstop segment data in Section B and the on-flight market data in Section C are applicable. Section A information, along with the carrier code and report date, must be included on each schedule.

(2) Section B—Nonstop segment information. Section B of the schedule is used for reporting nonstop segment information by aircraft type. To reduce the number of schedules reported, space is provided for including data on multiple different aircraft types. Similarly, the on-flight market section has been included on a single Schedule T-100(f), along with the nonstop segment data, rather than on a separate schedule.

(3) Section C—On-flight market information. Section C of the schedule is used for reporting on-flight market data. There will always be an on-flight market that corresponds to the nonstop segment. Because the on-flight market data are reported at the service class level rather than by aircraft type, a specific flight may produce more on-flight markets than nonstop segments, (see examples in paragraph (c) of this Appendix), resulting in data reported in sections A and C only.

(f) ADP media reports:

(1) ADP report format. A foreign air carrier may, in accordance with the following guidelines, use personal computers (and in some cases mainframe or minicomputers) to report Schedule T-100(f) data.

(i) Reporting medium. ADP data submission of T-100(f) information must be on IBM compatible floppy disk, including diskettes, floppy disks, or flexible disks. The particular type of acceptable minidisk is 5¼ inch, double-sided/double density, with a capacity of approximately 360,000 characters of data (360K). Carriers using mainframe or minicomputers shall download (transcribe) the data to the required floppy disk. Carriers wishing to use a different ADP procedure must obtain written approval to do so from the Director, OAIM, under the waiver provisions in § 217.9 of this part. Requests for approval to use alternate methods must disclose the proposed data transmission methodology.

(ii) File characteristics. OAIM files are reported in ASCII delimited format, sometimes called Data Interchange Format (DIF). This form of recording data provides for variable length fields (data elements) which, in the case of alphabetic data, are enclosed by quotation marks (") and separated by a comma (,); numeric data elements are recorded without editing symbols and separated by a comma. The data is identified by its juxtaposition within a given record. Each record submitted by an air carrier shall contain the specified number of data elements all of which must be juxtapositionally correct.

(iii) Schedule T-100(f) record layout. Each minidisk record shall consist of data fields for recording a maximum of eleven (11) elements. The order and description of the data fields are as follows:

(1). Carrier code: Alphanumeric
(2). Report date: Numeric
(3). Origin airport: Alphabetic
(4). Destination airport: Alphabetic
(5). Service class code: Alphabetic
(6). Aircraft type code: Numeric
(7). Aircraft departures performed: Numeric
(8). Revenue passengers transported: Numeric
(9). Revenue freight transported: Numeric
(10). Total revenue passengers in market: Numeric
(11). Total revenue freight in market: Numeric

(A) Fields numbered 1 through 11 must always be provided. Therefore, enter a zero (0) or space when there is no reportable data for a given element. See paragraph (g)(1) through (g)(3) for a detailed definition of each data element.

(B) The following are sample disk records:

	1	2	3	4	5	6	7	8	9	10	11
Sample No. 1	"CCC"	8701	"JFK"	"LHR"	"F"	8161	29	59	69	79	89
Sample No. 2	"CCC"	8701	"JFK"	"LHR"	"F"	6901	299	599	0	0	0
Sample No. 3	"CCC"	8701	"JFK"	"LHR"	"G"	7102	299	0	599	0	799
Sample No. 4	"CCC"	8701	"JFK"	"LHR"	"F"	0	0	0	0	699	799

Sample No. 1 represents a full record, using the applicable fields for reporting both the nonstop segment (6 through 9) and the on-flight market information (10 and 11). The service class is "F" indicating scheduled passenger/cargo service; the aircraft type code is 8161; the 816 indicates a Boeing 747-100, and the 1 in the units position indicates the standard "passengers-above and cargo-below" configuration.

Sample No. 2 contains nonstop segment information only. It is needed in this example to report the volumes transported on the same nonstop segment, but with a second aircraft type.

Sample No. 3 contains nonstop segment and on-flight market information for the same points, but for another service class (code letter "G" indicates all-cargo service). Also, the units position of aircraft type is a 2, indicating a cargo cabin. Field numbers 8 and 10 are for reporting passengers. In this case both contain a zero, indicating no passengers, while at the same time maintaining the required juxtaposition.

Sample No. 4 shows the reporting of only on-flight market information for a pair-of-points for which there is no corresponding nonstop segment information.

(2) External labeling requirements: Physical label. The following data must be clearly printed on a label affixed to the minidisk or its container.

Carrier Name
Carrier code (as prescribed by DOT, RSPA, OAIM)
File identification = "T-100(F) DATA"
Report date (year, month to which data applies)

(3) Collating sequence, optional. If practical, the records should be sorted by origin and destination airport codes, service class, and aircraft type. However, the sequence is optional. Data may be submitted in any sequence including random.

(4) Summarization. See summarization rules as specified in paragraph (d)(1).

(g) Data element definitions:

(1) Service pattern information.

(i) Line A-1 Carrier code. Use the carrier code established by the Department. This code is provided to each carrier in the initial reporting letter from the Office of Aviation Information Management (OAIM). If there are any questions about these codes, contact the OAIM Data Administration Division at the address in paragraph (a)(3) of this Appendix.

(ii) Line A-2 Report date. This is the year and month to which the data are applicable. For example, 8901 indicates the year 1989, month of January.

(iii) Line A-3 Orgin airport code. This is the departure airport, where an aircraft begins a flight segment, and where the passengers originate in an on-flight market. Use the 3-letter code from the City/Airport Codes section of the *Official Airline Guide Worldwide Edition*. If no 3-letter code is available, OAIM will assign one; the address is in paragraph (a)(3) of this Appendix.

(iv) Line A-4 Destination airport code. This is the arrival airport, where an aircraft stops on a flight segment, and where passengers deplane (get off the flight) after reaching their destination in a market. Use the 3-letter code from the source described in paragraph (g)(1)(iii) of this Appendix.

(v) Line A-5 Service class code. Select one of the following single letter codes which describes the type of service being reported on a given flight operation.

F = Scheduled Passenger/cargo Service
G = Scheduled All-cargo Service
L = Nonscheduled Civilian Passenger/Cargo Charter
P = Nonscheduled Civilian All-Cargo Charter
Q = Nonscheduled Services (Other than Charter)

(2) Nonstop segment information:

(i) Line B-1 Aircraft type code. Use the four digit numeric code prescribed in paragraph (h)(1) of this Appendix. If no aircraft type code is available, OAIM will assign one. The address is in paragraph (a)(3) of this Appendix.

(ii) Line B-2 Aircraft departures performed. This is the total number of physical departures performed with a given aircraft type, within service class and pair-of-points. For information concerning joint service operations, refer to § 217.12.

(iii) Line B-3 Revenue passengers transported. This is the total number of revenue passengers transported on a given nonstop segment. It represents the total number of revenue passengers on board over the segment without regard to their actual point of enplanement.

(iv) Line B-4 Revenue freight transported. This item is the total weight in kilograms (kg) of the revenue freight transported on a given nonstop segment without regard to its actual point of enplanement.

(3) On-flight market information:

(i) Line C-1 Total revenue passengers in market. This item represents the total number of revenue passengers, within service class, that were enplaned at the origin airport and deplaned at the destination airport.

(ii) Line C-2 Total revenue freight in market. This item represents the total weight in kilograms (kg) of revenue freight enplaned at the origin and deplaned at the destination airport.

(h) Aircraft type codes and carrier codes. These codes are effective as of the date of issuance. Thereafter, as the carriers or their equipment types change, additional codes will be assigned. The Department may update these codes by Reporting Directives from the Office of Aviation Information Management. If there are any questions about these codes, contact the OAIM Data Administration Division on (202) 366-4391.

(1) Aircraft type codes. The aircraft type code is made up of four positions, in the format "TTTx" where "TTT" indicates the aircraft type code as shown in the table below, an "x" indicates cabin configuration. Each code must include the cabin configuration (a fourth position), as follows: A numeric "1" indicates a normal passenger/cargo aircraft configuration with passengers on the main deck and cargo below; a "2" indicates all-cargo (freighter); and a "3" indicates a main deck configuration that includes separate compartments for both cargo and passengers.

Aircraft Type Name and Aircraft Type Code

Aerospatiale Caravelle SE-210.....680x
Aerospatiale-British Aerospace (SSC-BAC) Concorde.....875x
Airbus Industrie Euro Airbus A300-B4.....690x
Airbus Industrie A310-200.....692x
Airbus Industrie A310-300.....693x
Airbus Industrie A320-200.....694x
Airbus Industrie Euro Airbus A300-B2.....695x
Aviation Traders ATL-98 Carvair.....222x
Boeing 707-100.....800x
Boeing 720.....812x
Boeing 727-100.....710x
Boeing 727-100C-QC.....711x
Boeing 727-200.....715x
Boeing 737-100/200.....620x
Boeing 737-300.....619x
Boeing 737-200C.....621x
Boeing 747F.....820x
Boeing 747C.....818x
Boeing 747-100.....816x
Boeing 747-300 SUD.....819x
Boeing 747-200.....817x
Boeing 747SP.....822x
Boeing 757-200.....622x
Boeing 767-200.....625x
Boeing 767-300.....626x
British Aerospace (BAC) One-Eleven BAC-1-11-400.....610x
British Aerospace (Hawker Siddeley) Trident.....780x
British Aerospace (Hawker Siddeley) Comet-4.....781x
British Aerospace 146 BAE-146-100.....866x
Canadair CL-44D.....520x
Convair CV-540.....420x
Convair CV-990.....830x
Dassault-Breguet Mercure.....682x
Dassault-Breguet Mystere-Falcon.....681x
DeHavilland Dash-Eight DHC-8.....483x
Fokker-VFW F28 Fellowship F-28-4000/6000.....602x
Ilyushin IL62.....888x
Ilyushin IL86.....889x
Lockheed Electra L-188A-08/188C.....550x
Lockheed L1011 L-1010-1100/200.....760x
Lockheed L1011-500 Tristar.....765x
McDonnell Douglas DC4/C54.....210x
McDonnell Douglas DC6.....216x
McDonnell Douglas DC7.....225x
McDonnell Douglas DC10-10.....730x
McDonnell Douglas DC8-10.....840x
McDonnell Douglas DC8-50F.....850x
McDonnell Douglas DC8-71.....860x
McDonnell Douglas DC8-63F.....852x
McDonnell Douglas DC9-10.....630x
McDonnell Douglas DC9-30.....640x
McDonnell Douglas DC9-50.....650x
McDonnell Douglas DC9-15F.....635x
McDonnell Douglas MD-80.....655x

(2) Foreign air carrier name and DOT code. Each reporting air carrier, based upon authority granted by the Department, will be advised of its reporting requirements by letters of instruction from the Office of Aviation Information Management (OAIM).

Foreign air carrier	Code	Homeland
Aer Turas Teoranta	QTQ	Ireland.
Aer Lingus P.L.C.	EI	Ireland.
AeroPeru—Empressa the Tran. Aer. del Peru	DPL	Peru.
Aeros Transportes Panamenos	ATQ	Panama.
GDIAS—Aeroflot Soviet Airlines	SU	USSR.
Aerolineas Argentinas	AR	Argentina.
Aerolineas Dominicanas, S.A.	YU	Dominican Republic.
Aerolineas El Salvador, S.A.	SZQ	El Salvador.
Aeromar, C. Por A.	ABQ	Dominican Republic.

Foreign air carrier	Code	Homeland
Aeronaves del Peru	ADQ	Peru.
Aerotransportes Entre Rios	RSQ	Argentina.
Aereo Transporti Italiani—A.T.I.-S.p.A.	BM	Italy.
Aeroservicios Equatorianos, C.A.	EOQ	Ecuador.
Aerotours Dominicanos, C. por A.	RTQ	Dominican Republic.
Avianca—Aerovias Nac. de Colombia	AV	Colombia.
Avensa—Aerovias Venezolanas	VE	Venezuela.
Air Afrique	RK	10 African nations.
Air Canada	AC	Canada.
SAFA—Air Charter	AQQ	France.
Air Europe	AE	United Kingdom.
Air France	AF	France.
Air Haiti, S.A.	HJQ	Haiti.
Air India	AI	India.
Air Jamaica Limited	JM	Jamaica.
Air Nauru	ON	Nauru.
Air New Zealand	TE	New Zealand.
Air Niugini	PX	Papua New Guinea.
Air Ontario	GX	Canada.
Air Pacific	FJ	Fiji.
Air Panama Internacional, S.A.	OP	Panama.
Alitalia—Linee Aree Italiane	AZ	Italy.
ANA—All Nippon Airways Co., Ltd.	NH	Japan.
ALM Dutch Antillean Airlines	LM	Netherlands-Antilles.
Anglo Airlines	AZQ	United Kingdom.
Andes Airlines	EDQ	Ecuador.
APA International Air, S.A.	7P	Domninican Republic.
Argo, S.A.	AGQ	Dominican Republic.
AVIACO—Aviacion Y Comercio	AO	Spain.
Aviateca—Empresa Guatemalteca	GV	Guatemala.
Bahamsair Holdings Ltd.	UP	Bahamas.
Balair Ag	BBQ	Switzerland.
Belize Air International Ltd.	ST	Belize.
Bradley Air Service d/b/a/ First Air	7F	Canada.
British Airtours Limited	BRQ	United Kingdom.
British Airways PLC	BA	United Kingdom.
Caledonian Airways/BCAL Air	BR	United Kingdom.
British Midland Airways Limited	BD	United Kingdom.
BWIA—British West Indian Airways	BW	Trinidad & Tobago.
CAAC—Civil Av. Admin. of China	CA	China.
Caicos Caribbean Airways	QW	Turks & Caicos—U.S.
Canadian Airlines Int'l. Ltd	CP	Canada.
Cargolux Airlines Int'l., S.A.	CV	Luxembourg.
Caribbean Air Cargo Co.—Caricargo	DC	Barbados.
British Caribbean Airways	TXQ	British V.I./Barbados.
Cathay Pacific Airways, Ltd.	CX	United Kingdom—Hong Kong.
Cayman Airways Limited	KX	United Kingdom—Cayman Islands.
C.L.T.M. Airlines, Inc.—Caraibische	CJQ	Netherlands Antilles.
CAL—China Airlines, Ltd.	CI	Taiwan.
Conair	SIQ	Denmark.
COPA—Co. Panamena de Aviacion	CM	Panama.
Condor Flugdienst	DFQ	West Germany.
CSA—Czechoslovak Airlines	OK	Czechoslovakia.
Dan-Air Services, Ltd.	DA	United Kingdom.
CDA—Dominicana De Aviacion, Compania	DO	Dominican Republic.
Ecuatoriana de Aviacion	EU	Ecuador.
Egyptair	MS	Egypt.
El Al Israel Airlines Ltd.	LY	Israel.
Faucett Peruvian, Compania de Aviacion	CF	Peru.
Finnair o/y	AY	Finland.
Garuda Indonesia Airways	GA	Indonesia.
German Cargo Services GMBH	GE	West Germany.
Guyana Airways Corporation	GY	Guyana.
Haiti Air Freight Int'l.	HAI	Haiti.
Hapag-Lloyd Flug	HAQ	West Germany.
Heavylift Cargo Airlines Ltd.	HLQ	United Kingdom.
Iberia Int'l. Air Lines of Spain	IB	Spain.
Icelandair	FI	Iceland.
Japan Air Lines Company, Ltd.	JL	Japan.
Japan Air System (formerly TOA Domestic)	JD	Japan.
Kar-Air o/y	KR	Finland.
KLM Royal Dutch Airlines	KL	Netherlands.
Korean Air Lines Co., Ltd.	KE	Korea, Republic of.
Kuwait Airways Corporation	KU	Kuwait.
LACSA—Lineas Aereas Constrricenses	LR	Costa Rica.
LADECO—Linea Aerea del Cobre	UC	Chile.
LAN—Chile Airlines	LA	Chile.
Le Pointe Air	LEQ	France.
Liat (1974) Limited	LI	Antigua.
LAV—Linea Aerospostal Venezolana	LV	Venezuela.
Lineas Aereas Del Caribe, S. A.	LAQ	Colombia.
Lineas Aereas Paraguayas	LPQ	Paraguay.

Foreign air carrier	Code	Homeland
LAM—Linhas Aereas the Mocambique	TM	Mozambique.
LAB—Lloyd Aereo Boliviana	LB	Bolivia.
Lufthansa German Airlines	LH	West Germany.
Luftransport-Unternehmen	LTQ	West Germany.
Maersk Air A/S	DM	Denmark.
MALEV—Magyar—Hungarian Airlines	MA	Hungary.
Martinair Holland	MSQ	Netherlands.
Mexicana de Aviacion, Compania	MX	Mexico.
Minerve	MVQ	France.
Nationair Int'l.	NX	Canada.
National Aviation Consultants, Ltd.	NTQ	Canada.
Nigeria Airways, Ltd.	WT	Nigeria.
Nippon Cargo Airlines Company, Ltd.	KZ	Japan.
Nordair Limited	ND	Canada.
North Coast Air Services Ltd.	NSQ	Canada.
Olympic Airways	OA	Greece.
Pacific Western Airlines, Ltd.	PW	Canada.
PIA—Pakistan Int'l Airlines Corp.	PK	Pakistan.
TAMPA—Panamericanos, S.A.	TMQ	Colombia.
Philippine Airlines, Inc.	PR	Philippines.
LOT—Polskie Linie Lotnicze	LO	Poland.
Polynesian Airlines Holdings, Ltd.	PH	Western Samoa.
Pomair, N.V.	PPQ	Belgium.
Qantas Airways Ltd.	QF	Australia.
Quebecair	QB	Canada.
Royal Air Maroc. Co. Nat. de Trans. Aeriens	AT	Maroc.
Royal Jordanian Airline—Alia	RJ	Jordan.
Sabena Belgian World Airlines	SN	Belgium.
SAHSA—Serv. Aereo de Honduras	SH	Honduras.
Saudia—Saudi Arabian Airlines	SV	Saudi Arabia.
Scanair	CIQ	Denmark/Norway/Sweden.
SAS—Scandinavian Airlines System	SK	Denmark/Norway/Sweden.
Seagreen Air Transport	ESQ	Antigua.
Servicio de Carga Aerea, S. A.	CMQ	Costa Rica.
Serv. de Transp. Aereos Fueguinos	SXQ	Argentina.
SIA—Singapore Airlines, Limited	SQ	Singapore.
Soc. Ecuatoriana de Transportes Aereos Saeta	EH	Ecuador.
SAM—Soc. Aeronautica de Medellin	MM	Colombia.
St. Lucia Airways Limited	SDQ	St. Lucia.
Spantax, S. A.	BXQ	Spain.
Sterling Airways A/S.	NBQ	Denmark.
Surinam Airways Limited.	PY	Surinam.
Swissair Transport Co., Ltd.	SR	Switzerland.
TACA Int'l. Airlines.	TA	El Salvador.
TAR—Tran. Aer. Rioplatense.	HRQ	Argentina.
Tarom—Romanian Air Transport.	RO	Romania.
Thai Airways Int'l Limited	GTG	Thailand
Time Air, Ltd.	9X	Canada.
Tradewinds Airways. Ltd.	MI	Singapore.
Trans-Meridian Airways	KKQ	United Kingdom.
Transvia Holland	HV	Netherlands.
Transbrasil Linhas Aereas	TR	Brazil.
TACV—Tran. Aereos de Cabo Verde	VR	Cape Verde.
TAN—Transportes Aereos Nacionales	TX	Honduras.
TAP—Transportes Aereos Portugueses	TP	Portugal.
Transportes Aereos Bolivianos	BOQ	Bolivia.
THY—Turkish Airlines, Turk Hava Yollari	TK	Turkey.
UTA—Union de Transports Aeriens	UT	France.
VARIG—Empressa de Via. Aer. Rio Grande	RG	Brazil.
VIASA—Venezuelan Int'l. Airways	VA	Venezuela.
VASP Brazilian—Via. Aer Sao Paulo	VP	Brazil.
Virgin Atlantic Airways, Ltd.	VS	United Kingdom.
Wardair Canada, Inc.	WD	Canada.
Wordways Canada, Ltd.	WWQ	Canada.
Worldwide A.C.T.S. d/b/a/ Air Charter	WLQ	Canada.
JAT—Yugoslavia Airlines	JU	Yugoslavia.
Zambia Airways Corp.	QZ	Zambia.
Zas—Zas Airlines of Egypt	ZAQ	Egypt.

(i) Joint Service.

(1) The Department may authorize joint service operations between two direct air carriers. Examples of these joint service operations are:

Blocked-space agreements;

Part-charter agreements;

Code-sharing agreements;

Wet-lease agreements, and similar arrangements.

(2) Joint service operations shall be reported in Form 41 Schedules T-100 and T-100(f) within the following guidelines: (i) Blocked space, part-charters and code-sharing arrangements shall be reported by the carrier in operational control of the flight. The traffic moving under those agreements is reported the same as any other traffic on board the aircraft. (ii) Wet lease agreements shall be reported by the lessee as though the leased aircraft and crew were a part of the lessee's own fleet. (iii) If there are questions about reporting a joint service operation, contact the Director, Office of Aviation

Information Management at the address in paragraph (a)(3) of this Appendix. (iv) The Department may require information pertaining to joint service operations in addition to that reported in Schedules T-100 and T-100(f) by U.S. and foreign air carriers. If additional information is needed, *ad hoc* reporting will be used by the Director, Office of Aviation Information Management (OAIM), under authority delegated in § 385.27 (b) and (d) of this chapter. *Ad hoc* reporting requirements will be communicated to the applicable carriers by letter.

(j) Schedules.

BILLING CODE 4910-62-M

SCHEDULE T-100(f)

FOREIGN AIR CARRIER TRAFFIC DATA

BY NONSTOP SEGMENT AND ON-FLIGHT MARKET

A-1. Air Carrier Name:_____ Code_____

A-2. Report Date:(Year)_____ (Month) _____

A. SERVICE PATTERN								B. NONSTOP SEGMENT INFORMATION				C. ON-FLIGHT MARKET	
Line	A-3 Airport Code	A-4 Airport Code	A-5 Service Class (Mark an x)					B-1 Air-Craft Type Code	B-2 Revenue Aircraft Departures	B-3 Revenue Passengers Transported	B-4 Revenue Freight Transported (kg)	C-1 Total Revenue Passengers In Market	C-2 Total Revenue Freight In Market (kg)
No.	ORIGIN	DESTIN.	F	G	L	P	Q		--- By aircraft type ---			-- Sum of all aircraft types --	
1.													
2.													
3.													
4.													
5.													
6.													
7.													
8.													
9.													
10.													
11.													
12.													
13.													
14.													
15.													
16.													
17.													
18.													
19.													
20.													

RSPA Form 41 Schedule T-100(f)

FOREIGN AIR CARRIER TRAFFIC DATA
BY NONSTOP SEGMENT AND ON-FLIGHT MARKET
SCHEDULE T-100(f)

FOREIGN AIR CARRIER CERTIFICATION

Carrier name _____

Address _____

_____

_____

_____

Carrier code _____

Report date (Year/Month) _____

I, the undersigned,

Title _____

Signature _____ Date _____

Print or type name _____

do certify that this report has been prepared under my direction in accordance with the regulations in 14 CFR Part 217 and 241. I affirm that, to the best of my knowledge and belief, this is a true, correct and complete report.

RSPA Form 41 Certification for Schedule T-100(f)

BILLING CODE 4910-62-C

§ 217.11 Reporting compliance.

(a) Failure to file reports required by this part will subject an air carrier to civil and criminal penalties prescribed in sections 901 and 902 of the Federal Aviation Act of 1958, as amended.

(b) Title 18 U.S.C. 1001, Crimes and Criminal Procedure, makes it a criminal offense subject to a maximum fine of $10,000 or imprisonment for not more than 5 years, or both, to knowingly and willfully make, or cause to be made, any false or fraudulent statements or representations in any matter within the jurisdiction of any agency of the United States.

PART 241—UNIFORM SYSTEM OF ACCOUNTS AND REPORTS FOR LARGE CERTIFICATED AIR CARRIERS

2. The authority for Part 241 continues to read as follows:

Authority: Secs. 101, 204, 401, 402, 403, 404, 407, 411, 416, 417, 901, 902, 1002, 1601, Pub. L. 85-726, as amended, 72 Stat. 737, 743, 754, 758, 766, 769, 774, 783, 788; 76 Stat. 145; 92 Stat. 1744; 49 U.S.C. 1301, 1324, 1371, 1372, 1373, 1374, 1377, 1381, 1472, 1482, 1551; sec. 43, Pub. L. 95-504, 92 Stat. 1750, 49 U.S.C. 1552.

3. Section 03 is amended by revising the definitions of *Airport-to-airport distance*, and *Freight* to read as follows:

Section 03—Definitions for Purposes of This System of Accounts and Reports

* * * * *

Airport-to-airport distance. The great-circle distance between airports, measured in statute miles in accordance with Part 247 of this Chapter.

* * * * *

Freight. Property, other than mail, transported by air.

* * * * *

4. Section 19—*UNIFORM CLASSIFICATION OF OPERATING STATISTICS* is amended by revising sections 19-1 through 19-6 to read as follows:

Sec. 19-1 Applicability.

(a) *United States air carrier.* Each large certificated U.S. air carrier shall file with the Department, on a monthly basis, Form 41 Schedule T-100 "U.S. Air Carrier Traffic and Capacity Data By Nonstop Segment and On-flight Market," and summary data as prescribed in this section and in sections 22 and 25 of this part. A carrier conducting only domestic all-cargo operations under Section 418 of the Act is not required to file Schedule T-100. The "Instructions to U.S. Air Carriers for Reporting Traffic and Capacity Data on Form 41 Schedules T-100, T-1, T-2 and T-3" (Instructions-U.S. Air Carriers) are contained in the Appendix to section 25 of this part.

(b) *Foreign (non-U.S.) air carrier.* Each foreign air carrier as required by Part 217 of this chapter shall file Form 41 Schedule T-100(f) "Foreign Air Carrier Traffic Data by Nonstop Segment and On-flight Market." The "Instructions to Foreign Air Carriers for Reporting Traffic Data on Form 41 Schedule T-100(f)," (Instructions-Foreign Air Carriers) are included in the Appendix to § 217.10 of this chapter.

(c) Each U.S. air carrier shall use magnetic computer tape or "floppy disc" for transmitting the prescribed data to the Department. Upon good cause shown, OAIM may approve the request of a U.S. air carrier, under section 1-2 of this part, to use hardcopy data input forms.

(d) On-flight market and nonstop segment detail data by carrier shall be made public only as provided in section 19-6.

Sec. 19-2 Maintenance of data.

(a) Each air carrier required to file Form 41 Schedule T-100 data shall maintain its operating statistics, covering the movement of traffic in accordance with the uniform classifications prescribed. Codes are prescribed for each operating element and service class. All traffic statistics shall be compiled in terms of each flight stage as actually performed.

(b) Each carrier shall maintain data applicable to the specified traffic and capacity elements prescribed in section 19-5 and section 25, and by general service classes prescribed in section 19-4 of this part.

(c) Operating statistics shall be maintained in accordance with the type of record, either nonstop segment or on-flight market.

Sec. 19-3 Accessibility and transmittal of data.

(a) Each reporting air carrier shall maintain its prescribed operating statistics in a manner and at such locations as will permit ready accessability for examination by representatives of the Department. The record retention requirements are prescribed in Part 249 of this chapter.

(b) Individual nonstop segment and on-flight market data for section 418 domestic all-cargo, domestic charter and military charter operations are not required to be reported on the Schedule T-100, but summary data for such operations shall be included in the T-1, T-2 and T-3 schedules that each U.S. air carrier shall transmit to the Department on a monthly or quarterly basis as prescribed in sections 22 and 25. For international military charters, only the U.S. airports are reported on Schedule T-3, and the foreign airports are combined and reported on a single line, as Airport "NON." International civilian charter and civilian all-cargo operations shall be reported in the T-100 data format, by nonstop segment and on-flight market.

(c) Form 41 Schedule T-100 reports shall be transmitted in accordance with the standard practices established by the Department, and must be received by the Department within 30 days following the end of each reporting month.

Sec. 19-4 Service classes.

The statistical classifications are designed to reflect the operating elements attributable to each distinctive class of service offered. The operating elements shall be grouped in accordance with their inherent characteristics as follows:

(a) Scheduled services. Scheduled services shall include traffic and capacity elements applicable to air transportation provided pursuant to published schedules and extra sections to scheduled flights. Scheduled Passenger/Cargo (Service Class F) is a composite of first class, coach, and mixed passenger/cargo service. The following classifications shall be reported, as applicable:

U.S. Air Carriers:
- K—Scheduled Services (F+G)
- F—Scheduled Passenger/Cargo
- G—Scheduled All-Cargo

Foreign Air Carriers:
- F—Scheduled Passenger/Cargo
- G—Scheduled All-Cargo

(b) Nonscheduled services. Nonscheduled services shall include all traffic and capacity elements applicable to the performance of nonscheduled aircraft charters, and other air transportation services not constituting an integral part of services performed pursuant to published flight schedules. The following classifications shall be reported, as applicable:

U.S. Air Carriers:
- V—Nonscheduled Services (L+N+P+R)
- L—Nonscheduled Civilian Passenger/Cargo
- P—Nonscheduled Civilian Cargo
- N—Nonscheduled Military Passenger/Cargo
- R—Nonscheduled Military Cargo

Foreign Air Carriers:
- L—Nonscheduled Civilian Passenger Cargo
- P—Nonscheduled Civilian All-Cargo Charters
- Q—Nonscheduled Services (Other

than Charter)

(c) All Services. This classification shall reflect, for the applicable elements, the aggregate amounts for all services performed by the operating entity:

U.S. Air Carriers:

Z—All Services (V+K)

Sec. 19-5 Air transport traffic and capacity elements.

(a) Within each of the service classifications prescribed in section 19-4, data shall be reported as applicable to specified air transport traffic and capacity elements.

(b) These reported items are as follows:

Code	Description	Type of Record: Segment	Type of Record: Market	Applicable Form 41 Schedule Number
	Carrier, carrier entity code	S	M	T-100(f)1,2,3
	Reporting period date	S	M	T-100(f)1,2,3
	Origin airport code	S	M	T-100(f)3
	Destination airport code	S	M	T-100(f)
	Service class code	S	M	T-100(f)1,2,3
	Aircraft type code	S		T-100(f)1,2,3
110	Revenue passengers enplaned		M	T-100(f)1,3
111	Total psgrs. in market—first cabin		M	T-100
113	Total psgrs. in market—middle cabin		M	T-100
112	Total psgrs. in market—coach cabin		M	T-100
130	Revenue passengers transported	S		T-100(f)
131	Passengers transported—first cabin	S		T-100
133	Passengers transported—middle cabin	S		T-100
132	Passengers transported—coach cabin	S		T-100
140	Revenue passenger-miles			CFD* 1,2
210	Revenue cargo tons enplaned			CFD*
217	Enplaned freight		M	T-100(f),3
219	Enplaned mail		M	T-100 3
230	Revenue tons transported			CFD*
237	Transported freight	S		T-100(f)
239	Transported mail	S		T-100
240	Revenue ton-miles			CFD* 1,2
241	Revenue ton-miles passenger			CFD* 1
247	Revenue ton-miles freight			CFD* 1,2
249	Revenue ton-miles mail			CFD* 1,2
270	Available capacity payload	S		T-100
280	Available ton-miles			CFD* 1,2
310	Available seats, total	S		T-100
311	Available seats—first cabin	S		T-100
313	Available seats—middle cabin	S		T-100
312	Available seats—coach cabin	S		T-100
320	Available seat-miles			CFD* 1,2
410	Revenue aircraft miles flown			CFD* 1,2
430	Revenue aircraft miles scheduled			CFD* 1
501	Interairport distance			CFD* 2
510	Revenue aircraft departures performed	S		T-100(f)1,2,3
520	Revenue aircraft departures scheduled	S		T-100 3
610	Revenue aircraft hours (airborne)	S		T-100 1,2
630	Aircraft hours (ramp-to-ramp)	S		T-100 1,2
650	Total aircraft hours (airborne)			2
810	Aircraft days assigned to service-equip			2
820	Aircraft days assigned to service-routes			2
921	Aircraft fuels issued (U.S. gallons)			2

*CFD = Computed by DOT from detail Schedule T-100 and T-100(f) data.
T-100 = Form 41 Schedule T-100 for U.S. air carriers
(f) = Form 41 Schedule T-100(f) for foreign air carriers
1 = Form 41 Schedule T-1; 2 = Schedule T-2; 3 = Schedule T-3
NOTE: Cabin data are reported only in Group III international operations; in all other instances, totals are reported in items 110, 130 and 310.

(c) These reported items are further described as follows:

(1) *Reporting period date.* The year and month or quarter to which the reported data are applicable.

(2) *Carrier, Carrier entity code.* Each foreign air carrier shall report its name and code (assigned by DOT). Each U.S. air carrier shall report its name and entity code (a five digit code assigned by DOT that identifies both the carrier and its entity) for its particular operations. The Office of Aviation Information Management (OAIM) will assign or confirm codes upon request; OAIM's address is in the Appendix to section 25 of this part and the Appendix to § 217.10 of this chapter.

(3) *Service class code.* The service class codes are prescribed in section 19-4 of this part. In general, classes are divided into two broad categories, either K (scheduled) or V (nonscheduled), where K=F+G for all carriers and V=L+N+P+R for U.S. air carriers and comprises L+P and Q for foreign air carriers. Refer to section 19-4 for the more information on service class codes F, G, L, N, P, R and Q.

(4) *Record type code.* This code indicates whether the data pertain to nonstop segment (record type S) or on-flight market (record type M).

(5) *Aircraft type code.* This code represents the aircraft types, as described in the Appendix to section 25 of this part.

(6) *Origin, Destination airport code(s).* These codes represent the industry designators described in the Appendix to section 25 of this part. A common

private industry source of these industry designator codes is the *Official Airline Guides* (OAG). OAIM will assign codes upon request if not listed in the OAG.

(7) *110 Revenue passengers enplaned.* The total number of revenue passengers enplaned at the origin point of a flight, boarding the flight for the first time; an unduplicated count of passengers in a market. Under the T-100 system of reporting, these enplaned passengers are the sum of the passengers in the individual on-flight markets. In the domestic entity, report only the total revenue passengers enplaned in item 110. Nonscheduled revenue passengers enplaned in any entity are reported in item 110. Cabin data (items 111 First, 112 Coach and 113 Middle, sometimes referred to as business class) are reported only for international operations of Group III air carriers; in all other instances, item 110 Revenue passengers enplaned is reported on Form 41 Schedule T-100 in column C-1, as follows.

Col.		Group III International Entity
C-1	111	Revenue psgrs. enplaned-total psgrs. in market-first cabin.
C-2	113	Revenue psgrs. enplaned-total psgrs. in market-middle cabin.
C-3	112	Revenue psgrs. enplaned-total psgrs. in market-coach cabin.
		All Other Carrier Groups and Entities
C-1	110	Revenue passengers enplaned.

(8) *130 Revenue passengers transported.* The total number of revenue passengers transported over single flight stage, including those already on board the aircraft from a previous flight stage. In the domestic entity, report only the total revenue passengers transported in item 130. Nonscheduled revenue passengers transported in any entity are reported in item 130. Cabin data (items 131 First, 132 Coach and 133 Middle) are reported only for international operations of Group III air carriers; in all other instances, item 130 Revenue passengers transported is reported on Form 41 Schedule T-100 in column B-7, as follows.

Col.		Group III International Entity
B-7	131	Revenue psgrs. transp.-total psgrs. transported-first cabin.
B-8	133	Revenue psgrs. transp.-total psgrs. transp.-middle cabin.
B-9	132	Revenue psgrs. transp.-total psgrs. transp.-coach cabin.
		All Other Carrier Groups and Entities
B-7	130	Revenue passengers transported.

(9) *140 Revenue passenger-miles.* Computed by multiplying the interairport distance of each flight stage by the number of passengers transported on that flight stage.

(10) *210 Revenue cargo tons enplaned.* The total number of cargo tons enplaned. This data element is a sum of the individual on-flight market figures for each of the following categories: 217 Freight and 219 mail. This element represents an unduplicated count of the revenue traffic in a market.

(11) *230 Revenue tons transported.* The number of tons of revenue traffic transported. This element is the sum of the following elements: 231 Passengers transported-total, 237 Freight, and 239 Mail.

(12) *240 Revenue ton-miles—total.* Ton-miles are computed by multiplying the revenue aircraft miles flown (410) on each flight stage by the number of tons transported on that stage. This element is the sum of 241 through 249.

(13) *241 Revenue ton-miles—passenger.* Equals the number of passengers times 200, times interairport distance, divided by 2000. A standard weight of 200 pounds per passenger, including baggage, is used for all operations and service classes.

(14) *247 Revenue ton-miles—freight.* Equals the volume of freight in whole tons times the interairport distance.

(15) *249 Revenue ton-miles—mail.* Equals the volume of mail in whole tons times the interairport distance.

(16) *270 Available capacity-payload.* The available capacity is collected in pounds. This figure shall reflect the payload or total available capacity for passengers, mail and freight applicable to the aircraft with which each flight stage is performed.

(17) *280 Available ton-miles.* The aircraft miles flown on each flight stage multiplied by the available capacity on the aircraft in tons.

(18) *310 Available seats.* The number of seats available for sale. This figure reflects the actual number of seats available, excluding those blocked for safety or operational reasons. In the domestic entity, report the total available seats in item 130. Nonscheduled available seats in any entity are reported in item 130. Cabin data (items 311 First, 312 Coach and 313 Middle) are reported only for international operations of Group III air carriers; in all other instances, item 310 Available seats, total is reported on Form 41 Schedule T-100 in column B-4, as follows.

Col.		Group III International Entity
B-4	311	Available seats-first cabin.
B-5	313	Available seats-middle cabin.
B-6	312	Available seats-coach cabin.
		All Other Carrier Groups and Entities
B-4	310	Available seats, total.

(19) *320 Available seat-miles.* The aircraft miles flown on each flight stage multiplied by the seat capacity available for sale.

(20) *410 Revenue aircraft miles flown.* Revenue aircraft miles flown are computed in accordance with the airport pairs between which service is actually performed; miles are generated from the data for scheduled aircraft departures (Code 520) times the interairport distances (Code 501).

(21) *430 Revenue aircraft miles scheduled.* The number of revenue aircraft miles scheduled. All such data shall be maintained in conformity with the airport pairs between which service is scheduled, whether or not in accordance with actual performance.

(22) *501 Interairport distance.* The great circle distance, in official statute miles as prescribed in Part 247 of this chapter, between airports served by each flight stage. Official interairport mileage may be obtained from the Office of Aviation Information Management at the address included in section 25 of this part.

(23) *510 Revenue aircraft departures performed.* The number of revenue aircraft departures performed in revenue scheduled service, including extra sections of scheduled flights.

(24) *520 Revenue aircraft departures scheduled.* The number of revenue aircraft departures scheduled, whether or not actually performed.

(25) *610 Revenue aircraft hours (airborne).* The elapsed time, computed from the moment the aircraft leaves the ground until its next landing.

(26) *630 Aircraft hours (ramp-to-ramp).* The elapsed time, computed from the moment the aircraft first moves under its own power from the boarding ramp at one airport to the time it comes to rest at the ramp for the next point of landing. This data element is also referred to as "block" and block-to-block aircraft hours.

(27) *650 Total aircraft hours (airborne).* The elapsed time, computed from the moment the aircraft leaves the ground until it touches down at the next landing. This includes flight training, testing, and ferry flights.

(28) *810 Aircraft days assigned to service—carrier's equipment.* The number of days that aircraft owned or

acquired through rental or lease (but not interchange) are in the possession of the reporting air carrier and are available for service on the reporting carrier's routes plus the number of days such aircraft are in service on routes of others under interchange agreements. Includes days in overhaul, or temporarily out of service due to schedule cancellations. Excludes days that newly acquired aircraft are on hand, but not available for productive use, days rented or leased to others (for other than interchange) and days in possession but formally withdrawn from air transportation service.

(29) *820 Aircraft days assigned to service—carrier's routes.* The same as "aircraft days assigned to service—carrier's equipment," but excluding the number of days that the reporting carrier's owned or rented equipment are in the possession of others under interchange agreements and including the number of days aircraft of others are in the possession of the reporting air carrier under interchange agreements.

(30) *921 Aircraft fuels issued (gallons).* The amount of aircraft fuels issued, in U.S. gallons, during the reporting period for both revenue and nonrevenue flights.

Section 19-6—Public disclosure of traffic data.

(a) Detailed air carrier on-flight market and nonstop segment data in Schedule T-100 and T-100(f) reports submitted to the Department shall not be publicly available for a period of 3 years, although industry and carrier summary data may be made public provided there are three or more carriers in the summary data disclosed. Further, at any time, the Department may publish T-100 international summary statistics without carrier detail. Further, the Department may release nonstop segment and on-flight market detail data by carrier before the end of the 3 years as follows:

(1) To foreign governments as provided in reciprocal arrangements between the foreign country and U.S. Government for exchange of on-flight market and/or nonstop segment data submitted by air carriers of that foreign country and U.S. carriers serving that foreign country;

(2) To parties to any proceeding before the Department under Title IV of the FAAct as required by the Administrative Law Judge or other decision-maker of the Department. Any data to which access is granted pursuant to this provision may be introduced into evidence, subject to the normal rules of admissibility of evidence.

(3) To agencies and other components of the U.S. Government for their internal use only.

(4) To such other persons and in such other circumstances as the Department determines to be in the public interest, consistent with regulatory functions and responsibilities, upon submission by the requesting party of a written statement of significant need.

(b) Before it makes a decision on requests for access to detail carrier information under section (a)(4), the Department shall contact the carrier whose data have been requested, and determine whether the carrier will consent to the release of its data. The Department's determination regarding confidential information will be made in writing, and a copy of this written determination will be made publicly available. The Department intends to give considerable weight to the reporting carrier's views in making determinations whether to release its data before the end of the 3 year restricted release period.

(c) Where access to restricted data is approved, the Department may release the requested nonstop segment and on-flight market data through firms of data service providers who agree to abide by these disclosure restrictions. There are established procedures for accessing restricted data in the pamphlet "Access to Restricted Release Aviation Economic Data." Copies are available from the Office of Aviation Information Management (OAIM) at the address in the Appendix to section 25 of this part.

5. Section 22 is amended by revising the List of Schedules in CAB Form 41 Report and the Due Dates of Schedules in CAB Form 41 Report in paragraph (a) to read:

Section 22—General Reporting Instructions

(a) * * *

LIST OF SCHEDULES IN RSPA FORM 41 REPORT

[See footnotes at end of table]

Schedule No.	Title	Filing frequency	Applicability by carrier group		
			I	II	III
A	Certification	Q	(1)	X	X
B-1	Balance sheet	Q	(1)	X	X
B-1.1	Balance sheet	SA	(2)	NA	NA
B-7	Airframe and aircraft engine acquisitions and retirements	Q	NA	X	X
B-12	Statement of changes in financial position	Q	(1)	X	X
B-43	Inventory of airframes and aircraft engines	A	X	X	X
P-1.1	Statement of operations	SA	(2)	NA	NA
P-1.2	Statement of operations	Q	(1)	X	X
P-1(a)	Interim operations report	M	X	X	X
P-2	Notes to RSPA Form 41 report	Q	(1)	X	X
P-5.1	Aircraft operating expenses	Q(1), SA(2)	X	NA	NA
P-5.2	Aircraft operating expenses	Q	NA	X	X
P-6	Operating expenses by objective groupings	Q	(1)	X	X
P-7	Operating expenses by functional groupings—Group III air carriers	Q	NA	NA	X
P-10	Employment statistics by labor category	A	(1)	X	X
P-12(a)	Fuel consumption by type of service and entity	M	(1)	X	X
T-100	U.S. air carrier traffic and capacity data by nonstop segment and on-flight market	M	X	X	X
T-100(f)	Foreign air carrier traffic data by nonstop segment and on-flight market	M (see 14 CFR...217)			
T-1	U.S. air carrier traffic and capacity summary by service class	M	X	X	X
T-2	U.S. air carrier traffic and capacity by aircraft type	Q	X	X	X
T-3	U.S. air carrier airport activity statistics	Q	X	X	X

LIST OF SCHEDULES IN RSPA FORM 41 REPORT—Continued

[See footnotes at end of table]

Schedule No.	Title	Filing frequency	Applicability by carrier group		
			I	II	III
T-8	Report of all-cargo operations	A	(3)	(3)	(3)

M=Monthly, Q=Quarterly, SA=Semiannually, A=Annually, NA=Not Applicable, X=All Carriers.
(1) Applicable to Group I Air Carriers with annual operating revenues of $10 million or more.
(2) Applicable to Group I Air Carriers with annual operating revenues below $10 million.
(3) Applicable to Air Carriers conducting Section 418 all-cargo operations.

DUE DATES OF SCHEDULES IN RSPA FORM 41 REPORT

Due dates[1]	Financial data on schedule No.	Traffic and capacity data on schedule No.
January 20	P-12(a)	
January 30	P-1(a)	T-100, T-100(f), T-1, T-2, T-3
February 10[2]	A, B-1, B-1.1, B-7, B-12, P-1.1, P-1.2, P-2, P-5.1, P-5.2, P-6, P-7, P-10.	
February 20	P-12(a)	
March 1	P-1(a)	T-100, T-100(f), T-1
March 20	P-12(a)	
March 30	B-43, P-1(a).	T-100, T-100(f), T-1, T-8
April 20	P-12(a)	
April 30	P-1(a)	T-100, T-100(f), T-1, T-2, T-3
May 10	A, B-1, B-7, B-12, P-1.2, P-2, P-5.1, P-5.2, P-6, P-7.	
May 20	P-12(a)	
May 30	P-1(a)	T-100, T-100(f), T-1
June 20	P-12(a)	
June 30	P-1(a)	T-100, T-100(f), T-1
July 20	P-12(a)	
July 30	P-1(a)	T-100, T-100(f), T-1, T-2, T-3
August 10	A, B-1, B-1.1, B-7, B-12, P-1.1, P-1.2, P-2, P-5.1, P-5.2, P-6, P-7.	
August 20	P-12(a)	
August 30	P-1(a)	T-100, T-100(f), T-1
September 20	P-12(a)	
September 30	P-1(a)	T-100, T-100(f), T-1
October 20	P-12(a)	
October 30	P-1(a)	T-100, T-100(f), T-1, T-2, T-3
November 10	A, B-1, B-7, B-12, P-1.2, P-2, P-5.1, P-5.2, P-6, P-7.	
November 20	P-12(a)	

DUE DATES OF SCHEDULES IN RSPA FORM 41 REPORT—Continued

Due dates[1]	Financial data on schedule No.	Traffic and capacity data on schedule No.
November 30	P-1(a)	T-100, T-100(f), T-1
December 20	P-12(a)	
December 30	P-1(a)	T-100, T-100(f), T-1

[1] Due dates falling on a Saturday, Sunday or national holiday will become effective the first following work day.
[2] Reporting due dates on Form 41 Schedules B and P are extended to March 30 if preliminary schedules are filed at the Department by February 10

6. Section 24 is amended by renumbering paragraph (f) as paragraph (g) and adding (e) and (f) in Schedule P-1.2, to read as follows:

Section 24—Profit and loss elements

* * * * *

Schedule P-1.2—Statement of Operations

* * * * *

(e) Group III air carriers shall subdivide total Transport Revenues-Passenger (Account 3901) between Accounts 3901.1, Passenger-Flight Class and Account 3901.2 Passenger-Coach, only for operations that are reported in the international entity (Atlantic, Pacific and Latin American). First class and coach passenger revenues associated with transport operations reported in the domestic entity shall be reported as a combined total in Account 3901 Transport Revenues-Passenger.

(f) All Group I and Group II air carriers shall report first class and coach passenger revenues as a combined total in Account 3901 Transport Revenues-Passenger, for both domestic and international entity operations. However, U.S. air carriers in any carrier group that elect to do so may continue to report first class and coach revenue data, if they consider such voluntary reporting to be less burdensome than changing their existing financial reporting system.

(g) Any air carrier that does not file Schedule P-1(a) in accordance with the filing option described in section 22—General Reporting Instructions shall, for the third month of any calendar quarter during which the option is exercised, type in the bottom margin of the system statement of operations the total number of full-time and part-time employees to be labeled as such and calculated in accordance with paragraph (d) of the reporting instructions for Schedule P-1(a).

* * * * *

Section 25—[Amended]

7. Section 25 *Traffic and Capacity Elements* is amended by:

A. Revising paragraphs (a) and (b) of the *General Instructions* to read:

General Instructions. (a) All prescribed reporting for traffic and capacity elements shall conform with the data compilation standards set forth in section 19—Uniform Classification of Operating Statistics.

(b) Schedules T-1, T-2, T-3 and T-100 for U.S. air carriers shall be submitted in magnetic computer tape or floppy disc as provided in section 19-1(c) of this Part. As prescribed in section 1-02 of this part, air carriers may request a waiver from the Director, Office of Aviation Information Management, RSPA , to allow the submission of hardcopy reports.

B. Schedules T-1(a), T-1(b), T-1(c), T-2, T-3(a), T-3(b) and T-3(c) are removed and new Schedules T-1, T-2 and T-3 are added to read as follows:

Schedule T-1 U.S. Air Carrier Traffic and Capacity Summary-By Service Class

(a) Schedule T-1 collects summary statistics to supplement the detail Schedule T-100 data. This schedule shall be filed monthly by each large certificated U.S. air carrier conducting domestic charter, or domestic cargo operations, or military charters in each applicable entity. Traffic and capacity data are reported on this schedule for the following service classes.

(1) G—Scheduled All-Cargo.

(2) L—Nonscheduled Civilian Passenger/Cargo.

(3) P—Nonscheduled Civilian Cargo.

(4) N—Nonscheduled Military Passenger/Cargo.

(5) R—Nonscheduled Military Cargo.

(b) Separate schedules shall be filed for each operating entity.

(c) Detailed instructions for preparing Schedule T-1 are included in the Appendix to this section.

(d) The reported data shall be compiled as aggregates of the basic data prescribed in section 19, Uniform Classification of Operating Statistics.

(e) The schedule shall include the following items:

Code	Service/class	Elements
		Air carrier.
		Operating entity.
		Report date (month ended).
	G,L,N,P,R	Service class code.
	N, R	Aircraft type code.
110	L,N	Revenue passengers enplaned.
140	L,N	Revenue passenger-miles (000).
240	G,L,N,P,R	Revenue ton-miles.
241	L,N	Revenue ton-miles passenger.
247	G,L,N,P,R	Revenue ton-miles freight.
249	G.L, P	Revenue ton-miles mail.
280	G,L,N,P,R	Available ton-miles.
320	L,N	Available seat-miles.
410	G,L,N,P,R	Revenue aircraft miles flown.
430	G	Revenue aircraft miles scheduled.
510	G,L,N,P,R	Revenue aircraft departures performed.
610	G,L,N,P,R	Revenue aircraft hours (airborne).
630	G,L,N,P,R	Revenue aircraft hours (ramp-to-ramp).

Schedule T-2 U.S. Air Carrier Traffic and Capacity Statistics-By Aircraft Type

(a) Schedule T-2 collects summary statistics to supplement the detail Schedule T-100 data. This schedule shall be filed for each calendar quarter by each large certificated U.S. air carrier.

(b) Separate schedules shall be filed for each operating entity of the air carrier.

(c) Detailed instructions for preparing Schedule T-2 are included in the Appendix to this section.

(d) The reported data shall be compiled as aggregates of the data prescribed in section 19, Uniform Classification of Operating Statistics.

(e) This schedule shall include the following items:

Code	Service class	Elements
		Air carrier.
		Operating entity.
		Report date (quarter ended).
	G,Z	Aircraft type code.
	G,Z	Service class code.
140	Z	Revenue passenger-miles (000).
240	G,Z	Revenue ton-miles.
247	Z	Revenue ton-miles freight.
249	Z	Revenue ton-miles mail.
280	G,Z	Available ton-miles.
320	Z	Available seat-miles.
410	G,Z	Revenue aircraft miles flown.
510	V,G,Z	Revenue aircraft departures performed.
610	Z	Revenue aircraft hours (airborne).
630	Z	Revenue aircraft hours (ramp-to-ramp).
650	Z	Total aircraft hours airborne.
810	Z	Aircraft days assigned to service—carrier's equipment.
820	Z	Aircraft days assigned to service—carrier's routes.
921	Z	Aircraft fuels issued (gallons).

Schedule T-3 U.S. Air Carrier Airport Activity Statistics

(a) This schedule supplements the detail Schedule T-100 data. Schedule T-3 collects supplementary airport activity statistics as follows: The domestic entity report covers summary statistics on domestic all-cargo operations and both civilian and military charters. The international entity report covers summary information on military charter operations only. Further, only the U.S. airport is identified for international military charter operations, and airports outside the U.S. are summarized as a one-line total, coded "NON" in lieu of the airport code; these data are collected only on this schedule, not in the detail Schedule T-100.

(b) Separate schedules shall be filed for each air carrier entity, as prescribed under section 19-5(c)(2) of this part.

(c) In addition to the following general information, more detailed instructions for completing schedule T-3 are included in the Appendix to this section.

(d) The data shall be compiled as aggregates of the basic data prescribed in section 19, Uniform Classification of Operating Statistics.

(e) This schedule shall include the following items:

Code	Service class	Elements
		Air carrier.
		Operating entity.
		Report date (quarter ended).
	G,V	Aircraft type code.
	G,V	Service class code (G or V).
	G,V	Airport code.
110	V	Revenue passengers enplaned.
217	G,V	Revenue cargo tons enplaned—freight.
219	G,V	Revenue cargo tons enplaned—mail.
510	G,V	Revenue departures performed, by aircraft type.
520	G	Revenue aircraft departures, scheduled, by aircraft type.

C. Removing Schedule T-9 *Nonstop Market Report.*

D. Adding new Schedules T-100 and T-100(f) to read as follows:

Schedule T-100 U.S. Air Carrier Traffic and Capacity Data By Nonstop Segment and On-Flight Market.

(a) This Schedule T-100 collects detail on-flight market and nonstop segment data. This schedule shall be filed monthly by each large certificated U.S. air carrier except for a charter air carrier or an all-cargo carrier with only domestic operations. Separate data shall be reported on Schedule T-100 for each operating entity (Latin America, Atlantic, Pacific, International or Domestic) of the air carrier in the five digit entity code prescribed under section 19-5(c)(2) of this part. Domestic scheduled passenger/cargo operations and all international operations of scheduled and nonscheduled passenger/cargo and all cargo services shall be reported on Schedule T-100, except that international military charters shall not be reported on Schedule T-100.

(b) Guidelines for reporting the automated monthly Schedule T-100 are included in the Appendix to this section.

(c) Reported data shall be compiled as aggregates of the basic data elements and service classes contained in sections 19-4 and 19-5 of this part.

Schedule T-100(f) Foreign Air Carrier Traffic Data by Nonstop Segment and On-Flight Market

(a) This Schedule T-100(f) collects detail on-flight market and nonstop segment data. This schedule shall be filed monthly by each foreign (non-U.S.) air carrier conducting operations to or from the United States with large aircraft pursuant to 402 permits or exemption authority. Reported traffic data shall include all services affecting the United States, as prescribed in this part.

(b) Guidelines for reporting the monthly Schedule T-100(f) are included in the Appendix to § 217.10 of this chapter. Copies of these instructions are provided to each foreign air carrier submitting the traffic data. Copies are also available from the Office of Aviation Information Management,

DAI-1, Research and Special Programs Administration, Department of Transportation, 400 Seventh Street SW., Washington, DC 20590.

(c) The reported data shall be compiled as aggregates of the basic data elements and service classes prescribed in sections 19-4 and 19-5 of this part.

E. A new Appendix is added to § 241.25 to read as follows:

Appendix to Section 241.25 of CFR Part 241—Instructions to U.S. Air Carriers for Reporting Traffic and Capacity Data on Form 41 Schedules T-100, T-1, T-2, and T-3

(a) Applicability. Each large U.S. air carrier that holds a 401 certificate and operates aircraft designed with a maximum capacity of more than 60 seats or a maximum payload capacity of more than 18,000 pounds must file these schedules. A carrier that conducts all of its operations under section 418 of the Act (all-cargo certificates) does not file. Each air carrier will be advised of its reporting requirements by letters of instruction from the Office of Aviation Information Management (OAIM).

(b) Schedules, frequency, and entity:

(1) Schedule T-100, Monthly. Schedule T-100 collects summarized flight stage data by reporting entity as follows: International entity reports cover scheduled and nonscheduled passenger/cargo and all cargo services. Domestic entity reports cover passenger/cargo operations in scheduled services only. The term entity refers to the geographic location designator prescribed by the Department in section 19-5(c)(2) of this part, such as, for instance, domestic entity air transport operations as distinguished from international entity air transport operations.

(2) Schedule T-1, Monthly. For the domestic entity, Schedule T-1 collects summary statistics on domestic all-cargo operations, and on both civilian and military charters. For international entities, it collects summary information on military charter operations only.

(3) Schedule T-2, Quarterly. Schedule T-2 collects summary information for all reporting entities. It contains data elements for which there are no corresponding details in T-100 reports. It is submitted for each operating entity prescribed by the Department for each air carrier.

(4) Schedule T-3, Quarterly. For the domestic entity, Schedule T-3 collects summary statistics on all-cargo operations and on both civilian and military charters; and for international entities, it collects summary information on military charter operations only. Further, only the U.S. airport must be identified for international military charter operations, and airports outside the U.S. are summarized as a one-line total, coded "NON" in lieu of the airport code, since international military charters are not reported in the detail international Schedule T-100 data.

(c) Format of reports:

(1) Automatic Data Processing (ADP) magnetic tape. Refer to paragraph (f) below for instructions pertaining to mainframe and minicomputer reporting. The Department will issue "Reporting Directives" to make necessary technical changes to these T-100 instructions, where no policy issues are involved that would require a new rulemaking, or where only a few air carriers are affected.

(2) Microcomputer diskette.

(i) Optional specification. If an air carrier desires to use its personal computers (PC's), rather than mainframe or minicomputers to prepare its data submissions, the following specifications for filing data on diskette media apply:

(ii) Reporting medium. Microcomputer ADP data submission of T-100 information must be on IBM compatible floppy disk, including diskettes, floppy disks, or flexible disks. The particular type of acceptable minidisk is on 5¼ inch, double-sided/double-density, with a capacity of approximately 360,000 characters of data (360K). Carriers wishing to use a different ADP procedure must obtain written approval to do so from the Director, OAIM, under the waiver provisions in section 1-2 of this part. Requests for approval to use alternate methods must disclose the proposed data transmission methodology. Refer to paragraph (k) for microcomputer record layouts.

(iii) Microcomputer file characteristics. The files will be created in ASCII delimited format, sometimes called Data Interchange Format (DIF). This form of recording data provides for variable length fields (data elements) which, in the case of alphabetic data, are enclosed by quotation marks (" ") and separated by a comma (,) and numeric data elements that are recorded without editing symbols are also separated by a comma. The data is identified by its juxtaposition within a given record. Therefore, each record must contain the exact number of data elements, all of which must be juxtapositionally correct. Personal computer software including most spreadsheets, data base management programs, and BASIC are capable of producing files in this format.

(d) Filing data for reports. The reports must be received at DOT within 30 days following the end of each reporting period. Refer to § 241.22 of this part for more information on date requirements.

(e) Address for filing: Data Administration Division, DAI-20, Room 4125, Office of Aviation Information Management, Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh Street SW., Washington, DC 20590.

(f) ADP format for magnetic tape:

(1) Magnetic tape specifications. IBM compatible 9-track EBCDIC recording. Recording density of 6250 or 1600 bpi. The order of recorded information is:

Volume label.
Header label.
Data records.
Trailer label.

(g) External tape label information.

Carrier name.
Report date.
File identification.
Carrier address for return of tape reel.

(h) Standards. It is the policy of the Department to be consistent with the American National Standards Institute and the Federal Standards activity in all data processing and telecommunications matters. It is our intention that all specifications in this application are in compliance with standards promulgated by these organizations.

(i) Volume, header, and trailer label formats:

(1) Use standard IBM label formats. The file identifier field of the header labels should be "T-100.SYSTEM".

(j) Magnetic tape record layouts for T-100, T-1, T-2, and T-3.

(1) Nonstop segment record layout:

Field No.	Positions	Mode	Description
1	1	1A	Record type code (S=nonstop segment).
2	2-6	5A/N	Carrier entity code.
3	7-10	4N	Report date (YYMM).
4	11-13	3A	Origin airport code.
5	14-16	3A	Destination airport code.
6	17	1A	Service class code (F,G,L, or P).
7	18-21	4N	Aircraft type code.
8	22-26	5N	Revenue aircraft departures performed (F,G,L,P510).
9	27-36	10N	Available capacity payload (pounds) (F,G,L,P270).
10 [1]	37-43	7N	Available seats—first cabin (F310, F311, L310).
11 [1]	44-50	7N	Available seats—middle cabin (F313).
12 [1]	51-57	7N	Available seats—coach cabin (F312).
13 [1]	58-64	7N	Passengers transported—first cabin (F130, F131, L130).
14 [1]	65-71	7N	Passengers transported-middle cabin (F133).
15 [1]	72-78	7N	Passengers transported—coach cabin (F132).
16	79-88	10N	Revenue freight transported (F,G,L,P237) (in pounds).
17	89-98	10N	Revenue mail transported (F,G,L,P239) (in pounds).
18	99-103	5N	Revenue aircraft departures scheduled (F,G,L,P520).
19	104-113	10N	Revenue aircraft ramp hours, ramp-to-ramp (F,G,L,P630) (in minutes).

Field No.	Positions	Mode	Description
20	114–123	10N	Revenue aircraft hours, airborne (F,G,L,P610) (in minutes).

[1] Cabin data (First, Coach and Middle) are not reported by any carrier group in the domestic entity, where total available seats are reported in 310 and total passengers transported are included in 130; these totals are also used for the international operations of Group I and II carriers; cabin data are reported only for Group III international operations. All carrier groups will report total nonscheduled passengers in the summary data item L130, and nonscheduled available seats in L310.

(2) On-flight market record layout:

Field No.	Positions	Mode	Description
1	1	1A	Record type indicator: M = on-flight market record.
2	2–6	5A	Carrier entity code.
3	7–10	4N	Report data (YYMM).
4	11–13	3A	Origin airport code.
5	14–16	3A	Destination airport code.
6	17	1A	Service class code (F,G,L or P).
7 [1]	18–24	7N	Total passengers in market—first cabin (F110 F111 L110).
8 [1]	25–31	7N	Total passengers in market—middle cabin (F113).
9 [1]	32–38	7N	Total passagers in market—coach cabin (F112).
10	39–48	10N	Revenue freight in market (F,G,L, P217) (in pounds).
11	49–58	10N	Revenue mail in market (F,G,L, P219) (in pounds).

[1] Cabin data (First, Coach and Middle) are not reported by any carrier Group in the domestic entity, where total passengers enplaned in a market are included in F110; cabin data are reported only for international operations of Group III air carriers; in international entity operations of Group I and Group II air carriers, total passengers enplaned are included in 110. All carrier groups will include nonscheduled passengers enplaned in L110.

(3) T–1, T–2, and T–3 Summary record layout:

Field No.	Positions	Mode	Description
1	1	1A	Record Type Code: 1 = T–1 data 2 = T–2 data 3 = T–3 data.
2	2–6	5A	Air Carrier Entity Code.
3	7–10	4N	Report Date (YYMM).
4	11–14	4A	Data Element Code (T–1, T–2, and T–3).
5	15–18	4A	Aircraft Type Code (T–1, T–2, and T–3).
6	19–21	3A	Airport Code (T–3).
7	22–31	10N	Data Value—Right justified with leading zeros.

(4) T–1 data elements:

1. Revenue passengers enplaned	L110	N110			
2. Revenue passenger-miles (000)	L140	N140			
3. Revenue ton-miles total	G240	L240	P240	N240	R240
4. Revenue ton-miles passenger	L241	N241			
5. Revenue ton-miles mail	G249	L249	P249		
6. Revenue ton-miles freight	G249	L247	P247	N247	R247
7. Available ton-miles	G280	L280	P280	N280	R280
8. Available seat-miles (000)	L320	N320			
9. Revenue aircraft miles flown	G410	L410	P410	N410	R410
10. Revenue departures performed	G510	L510	P510	N510	R510
11. Revenue aircraft miles scheduled	G430				
12. Revenue aircraft hours airborne	G610	L610	P610	N610	R610
13. Revenue aircraft hours ramp-to-ramp	G630	L30	P630	N630	R630
14. Revenue aircraft miles scheduled	G430				
15. Carrier code			.....		
16. Report date			.....		
17. Operating entity			.....		
18. Aircraft type code (Military charters)			.....		

(5) T-2 Data elements (by aircraft type):

1. Revenue ton-miles	G240	
2. Available ton-miles	G280	
3. Revenue aircraft miles flown	G410	
4. Revenue aircraft departures performed	G510	
5. Revenue aircraft departures performed	V510	
6. Revenue passenger-miles (000)		Z140
7. Available seat-miles (000)		Z320
8. Revenue ton-miles total		Z240
9. Revenue ton-miles mail		Z249
10. Revenue ton-miles freight		Z247
11. Available ton-miles		Z280
12. Revenue aircraft miles flown		Z410
13. Revenue aircraft departures performed		Z510
14. Revenue aircraft hours airborne		Z610
15. Revenue aircraft hours ramp-to-ramp		Z630
16. Total aircraft hours (airborne)		Z650
17. Aircraft days assigned to service equipment		Z810
18. Aircraft days assigned to service routes		Z820
19. Aircraft fuels issued		Z921
20. Aircraft type code		
21. Carrier code		
22. Report date		
23. Operating entity		

(6) T-3 Data elements (by origin airport):

1. Airport code		.....
2. Revenue passengers enplaned		V110
3. Revenue tons enplaned mail	G219	V219
4. Revenue tons enplaned freight	G217	V217
5. Revenue aircraft departures performed	G510	V510
6. Revenue aircraft departures scheduled	G520	
7. Aircraft type code		.....
8. Carrier code		.....
9. Report date		.....
10. Operating entity		.....

(k) Record layouts for microcomputer diskettes. The record layouts for diskette are generally identical to those shown for magnetic tape, with the exception that delimiters (quotation marks and commas) are used to separate fields. It is necessary that the order of fields be maintained in all records.

(1) File characteristics. The files will be created in ASCII delimited format, sometimes called Data Interchange Format (DIF). This form of recording data provides for variable length fields (data elements) which, in the case of alphabetic data, are enclosed by quotation marks (") and separated by a comma (,) and numeric data elements that are recorded without editing symbols are also separated by a comma. The data is identified by its juxtaposition within a given record. Therefore it is critical that each record contain the exact number of data elements, all of which data must be juxtapositionally correct. PC software including most spreadsheets, data base management programs, and BASIC produce minidisks files in this format.

(2) File naming conventions for diskettes. For microcomputer reports, each record type should be contained in a separate DOS file on the same physical diskette. The following DOS naming conventions should be followed:

Record type S = SEGMENT.DAT
Record type M =MARKET.DAT
Record type 1 = T-1.DAT
Record type 2 = T-2.DAT
Record type 3 = T-3.DAT

(l) Discussion of reporting concept.

(1) The detail T-100 data shall be maintained in such a manner as to permit monthly summarization and organization into two basic groupings. First, the nonstop segment information which is to be summarized by equipment type, within class of service, within pair-of-points, without regard to individual flight number. The second grouping requires that the enplanement/deplanement information be broken out into separate units called on-flight market records, which shall be summarized by class of service, within pair-of-points, without regard for equipment type of flight number.

(2) The Schedules T-1 and T-3 information is applicable only to operations that are not required in the detail T-100 report. The Department will derive other necessary summary data directly from the detail T-100. The T-1 and T-3 data pertaining to domestic entities is for scheduled all-cargo service and charter operations. The T-1 for international entities contains data on military charter operations only.

(3) The Schedule T-2 information is required from each carrier and for each reporting entity. It contains some data elements for which there is no corresponding detail in T-100.

(4) A single tape file shall be submitted containing nonstop segment and on-flight market records for all applicable entities. The summary data pertaining to schedules T-1, T-2, and T-3 should be submitted on a second tape reel. A carrier reporting on diskette should create separate files for each record type, using DOS file naming conventions to identify them.

(5) An air carrier who submits middle cabin data may be confronted by a situation resulting from a change of gauge or other considerations wherein a given leg of a flight may not offer the same classes of service that is available on the remainder of the legs. When preparing on-flight market records applicable to this situation, the carrier should consider passengers transported as though the entire trip was configured as the first segment. The passenger cabin where the passenger is seated at the beginning of the flight determines the classification for the whole trip.

(m) Joint Service.

(1) The Department may authorize joint service operations between two direct air carriers. Examples of these joint service operations are: blocked-space agreements; part-character agreements; code-sharing agreements; Wet-lease agreements, and similar arrangements.

(2) Joint service operations shall be reported in Form 41 Schedule T-100 and T-100(f) within the following guidelines:

(i) Blocked space, part-charters and code-sharing arrangements shall be reported by the carrier in operational control of the flight. The traffic moving under those agreements is reported the same as any other traffic on board the aircraft.

(ii) Wet lease agreements shall be reported by the lessee as though the leased aircraft and crew were a part of the lessee's own fleet.

(iii) If there are questions about reporting a joint service operation, contact the Director, Office of Aviation Information Management at the address in paragraph (d) of this Appendix.

(iv) The Department may require information pertaining to joint service operations in addition to that reported by in Schedules T-100 and T-100(f) by U.S. and foreign air carriers. If additional information is needed, *ad hoc* reporting will be used by the Director, Office of Aviation Information Management (OAIM), under authority delegated in §§ 385.27 (b) and (d) of this chapter. *Ad hoc* reporting requirements will be communicated to the applicable carriers by letter.

(m) Glossary of data elements. Sections 19-5 and 03 of 14 CFR Part 241.

(n) Schedules.

BILLING CODE 4910-62-M

FORM 41 SCHEDULE T-100
U. S. AIR CARRIER
TRAFFIC AND CAPACITY DATA BY NONSTOP SEGMENT AND ON-FLIGHT MARKET

A. SERVICE PATTERN							B. NONSTOP SEGMENT INFORMATION								
Line No.	A-3 Airport Code	A-4 Airport Code	A-5 Service Class Code				B-1 Aircraft Type Code	B-2 Revenue Aircraft Depart. Performed F,L510 G,P510	B-3 Avail. Capacity Payload F,L270 G,P270	B-4 * Avail. Seats TOTAL/ First F,L310 F311	B-5 Avail. Seats Middle F313	B-6 Avail. Seats Coach F312	B-7 * Revenue Psgrs. Transp. TOTAL/ First F,L130 F131	B-8 Revenue Psgrs. Transp. Middle F133	B-9 Revenue Psgrs. Transp. Coach F132
	Origin	Destin.	F	G	L	P		By aircraft type							
1.															
2.															
3.															
4.															
5.															
6.															
7.															
8.															
9.															
10.															
11.															
12.															
13.															
14.															
15.															
16.															
17.															
18.															
19.															
20.															

* Note: The multiple cabin (First, Middle and Coach Class) data for Available Seats, Revenue Passengers Transported and Revenue Passengers Enplaned are reported only for the International entity operations of Group III U.S. air carriers. In all other instances, air carriers will report total Available Seats, Revenue Passengers Transported and Revenue Passengers Enplaned.

RSPA Form 41 Schedule T-100

A-1. Air Carrier Name: _____ Code _____

A-2. Report Date: (Year) _____ (Month) _____

					C. ON-FLIGHT MARKET				
B-10 Revenue Freight Transp. (Pounds) F,L270 G,P270	B-11 Revenue Mail Transp. (Pounds) F,L239 G,P239	B-12 Revenue Acft. Dept. Sched. F,L520 G,P520	B-13 Revenue Aircraft Hours Ramp F,L630 G,P630	B-14 Revenue Aircraft Hours Airborne F,L610 G,P610	C-1 * Revenue Psgrs. Enplaned TOTAL/ First F,L110 F111	C-2 Revenue Psgrs. Enplaned Middle F113	C-3 Revenue Psgrs. Enplaned Coach F112	C-4 Revenue Freight Enplaned (Pounds) F,L217 G,P217	C-5 Revenue Mail Enplaned (Pounds) F,L219 G,P219
----------					-- Total for all aircraft types in market---				

FORM 41 SCHEDULE T-1
TRAFFIC AND CAPACITY SUMMARY
BY SERVICE CLASS

Air Carrier Name: _____ Code: ____

Entity Code: _____

Report Date: (Year) _____ (Month) _____

This schedule is used to report only: 1. Domestic all cargo scheduled service. 2. Domestic civilian charters. 3. International and domestic military charters.		Scheduled	Nonscheduled Civilian		Nonscheduled Military	
		All Cargo Service (G)	Passenger/ Cargo (L)	All Cargo (P)	Passenger/ Cargo By Aircraft Type (N)	All Cargo By Aircraft Type (R)
TRAFFIC ON REVENUE FLIGHTS					Aircraft Type Code _____	Aircraft Type Code _____
Revenue passengers enplaned	110	xxxxxx		xxxxxx		xxxxxx
Revenue passenger-miles (000)	140	xxxxxx		xxxxxx		xxxxxx
Revenue ton-miles	240					
Passenger	241	xxxxxx		xxxxxx		xxxxxx
Freight	247					
Mail	249				xxxxxx	xxxxxx
AIRCRAFT CAPACITY OPERATED						
Available ton-miles	280					
Available seat-miles	320	xxxxxx		xxxxxx		xxxxxx
Revenue aircraft-miles flown	410					
Revenue aircraft miles scheduled	430		xxxxxx	xxxxxx	xxxxxxx	xxxxxx
Revenue aircraft departures performed	510					
Revenue aircraft hours (airborne)	610					
Revenue aircraft hours (ramp-to-ramp)	630					

RSPA Form 41 Schedule T-1

FORM 41 SCHEDULE T-2

U.S. AIR CARRIER

TRAFFIC AND CAPACITY BY AIRCRAFT TYPE

Air Carrier Name:_____ Code:_____

Entity Code: _____

Report date: (Year)_____ (Month)_____

		Aircraft Type Code: _____	Aircraft Type Code: _____	Aircraft Type Code: _____	Aircraft Type Code: _____
SCHEDULED ALL-CARGO SERVICES:					
Revenue ton-miles	G240				
Available ton-miles	G280				
Revenue aircraft miles flown	G410				
Aircraft departures performed	G510				
NONSCHEDULED SERVICES:					
Aircraft departures performed	V510				
ALL SERVICES:					
Revenue passenger-miles (000)	Z140				
Available seat-miles (000)	Z320				
Revenue ton-miles	Z240				
Mail revenue ton-miles	Z249				
Freight revenue ton-miles	Z247				
Available ton-miles	Z288				
Revenue aircraft miles flown	Z410				
Aircraft departures performed	Z510				
Revenue aircraft hours (airborne)	Z610				
Revenue aircraft hours (ramp)	Z630				
Total aircraft hours (airborne)	Z650				
Aircraft days - equipment	Z810				
Aircraft days - routes	Z820				
Aircraft fuels issued	Z921				

RSPA Form 41 Schedule T-2

FORM 41 SCHEDULE T-3

U.S. AIR CARRIER

AIRPORT ACTIVITY STATISTICS

Air Carrier Name:_____Code_____

Report Date: (Year)_____ (Month)_____ _____ (Entity Code)

Line No.	Airport Code	Revenue Passengers Enplaned V110	Mail Tons Enplaned V219	Freight Tons Enpl. V217	Mail Tons Enpl. G219	Freight Tons Enpl. G217	Aircraft Departures Scheduled G520	Acft. Departures Performed — G510 — — Aircraft Type Code —			Acft. Departures Performed — V510 — — Aircraft Type Code —		
								____	____	____	____	____	____
1.													
2.													
3.													
4.													
5.													
6.													
7.													
8.													
9.													
10.													
11.													
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16.													
17.													
18.													
19.													
20.													

RSPA Form 41 Schedule T-3

Included as Exhibit A to this final rule is a revised Form 41 Schedule P-1.2 Statement of Operations which includes a category combining first class and coach passenger revenues into Account 3901 Transport Revenues-Passenger in all instances except for international operations of Group III air carriers.

Issued in Washington, DC, on November 7, 1988.

M. Cynthia Douglass,

Administrator, Research and Special Programs Administration, DOT.

Editorial note: This exhibit will not appear in the Code of Federal Regulations.

BILLING CODE 4910-62-M

Exhibit A

US Department of Transportation
Research and Special Programs
Administration

Air Carrier _____

Operation _____

STATEMENT OF OPERATIONS

	Account No.	Quarter Ended _____ , 19 __	12 Months Ended _____ , 19 __
OPERATING REVENUES			
Passenger-First Class	3901.1		
Passenger-Coach	3901.2		
Transport Revenues-Passenger	3901		
Mail	3905		
Property-freight	3906.1		
Property-excess passenger baggage	3906.2		
Charter-passenger	3907.1		
Charter-property	3907.2		
Reservation cancellation fees	3919.1		
Miscellaneous operating revenues	3919.2		
Public service revenues (subsidy)	4808		
Transport related revenues	4898		
Total Operating Revenues	4999		
OPERATING EXPENSES			
Flying operations	5100		
Maintenance	5400		
Passenger Service o	5500		
Aircraft and traffic servicing o	6400		
Promotion and sales o	6700		
General and administrative o	6800		
Depreciation and amortization +	6900		
Transport related expenses	7100		
Total Operating Expenses	7199		
Operating Profit or Loss	7999		
NONOPERATING INCOME AND EXPENSE			
Interest on long-term debt and capital leases	8181		
Other interest expense	8182		
Foreign exchange gains and losses	8185		
	8188.5		
Capital gains and losses	8188.6		
Other income and expenses-net	8189		
Nonoperating income and expense	8199		
Income before Income Taxes	8999		
INCOME TAXES FOR CURRENT PERIOD	9100		
Income before discontinued operations, extraordinary items and accounting changes	9199		
DISCONTINUED OPERATIONS	9600		
EXTRAORDINARY ITEMS	9796		
Income taxes applicable to extraordinary items	9797		
ACCOUNTING CHANGES	9800		
Net Income	9899		

▸ Denotes inverse amount; in accounts 8100, 9600, 9700, and 9800 denoted debit amount.

+ Group I Air Carriers Only

o Group II and Group III Air Carriers Only

RSPA Form 41 Schedule P-1.2

[FR Doc. 88-26322 Filed 11-15-88; 8:45 am]
BILLING CODE 4910-62-C

federal register

Wednesday
November 16, 1988

Part VII

Department of Defense

Department of the Army

32 CFR Part 651

Environmental Effects of Army Actions; Notice of Adoption of Final Rule

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 651

[Army Reg. 200-2]

Environmental Effects of Army Actions

AGENCY: Department of the Army, DOD.

ACTION: Notice of adoption of final rule.

SUMMARY: The Department of Army hereby gives notice that it is adopting revised policy and procedures for implementing the National Environmental Policy Act (NEPA) and Council on Environmental Quality (CEQ) regulations. These guidelines replace policy and procedures found in current Army Regulation 200-2 (32 CFR Part 651), Environmental Effects of Army Actions. The revision is necessary to clarify and update the current regulation. The revision clarifies organizational responsibilities, revises the list of actions which are categorically excluded from environmental impact analyses, clarifies public involvement procedures, and provides new guidance on mitigation and monitoring of environmental impacts. The final rule provides new guidance on the Army policy of integrating NEPA procedures into the Remedial investigation/Feasibility Study (RI/FS) stages of hazardous substance cleanup actions required under the Comprehensive Environmental Response, Compensation and Liability Act, as amended by the Superfund Amendments and Reauthorization Act (SARA). The final rule provides Army policy relative to compliance with NEPA in airspace proposals. The revised regulation incorporates field and other experiences since the publication of the last publication of the regulation.

EFFECTIVE DATE: These procedures are effective December 16, 1988.

ADDRESS: Office of the Assistant Chief of Engineers, Army Environmental Office, Room 1E671, Pentagon, Washington, DC 20310-1000. Comments or request for changes may be submitted on a Department of Defense Form 2028, Recommended Changes to Publications and Blank Forms.

FOR FURTHER INFORMATION CONTACT: Mr. Tim Julius, Army Environmental Office, (202) 272-0596 or Mr. Ray Clark, Office of the Assistant Secretary of the Army (I&L), (202) 695-7824.

SUPPLEMENTARY INFORMATION:

Classification

The Secretary of the Army has determined that this revision is not a "major" rule within the meaning of Executive Order 12291. The effect on the economy will be less than $100 million. The rule will not cause a major increase in costs or prices for consumers, individual industries, geographic regions, or Federal, State, or local governmental agencies. The rule will not have a significant adverse effect on competition, employment, investment productivity, innovation, or on the ability of a United States-based enterprise to compete with foreign-based enterprises in domestic or export markets.

Paperwork Reduction

This rule does not contain reporting or recordkeeping requirements subject to approval by the Office of Management and Budget under the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Costs and Benefits

This rule has been reviewed under E.O. 12291 and the Secretary of the Army has classified the action as non-major. The effect of the rule on the economy will be less than $100 million. Therefore, neither a regulatory impact analysis nor a full regulatory evaluation was required.

Small Business Impact

This rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act of 1980 and the Secretary of the Army has certified that this section does not have a significant impact on a substantial number of small entities.

Background

On 17 February, 1988, a notice of proposed rule 32 CFR Part 651, Environmental Effects of Army Actions, was published in the **Federal Register** (53 FR 4647-4671). A 30 day comment period for public review was provided. During that period seven (7) letters were received. Two letters were from state agencies, three were from federal agencies, and two letters were from Army field agencies. The seven letters provided 53 comments. The largest category of comments were related to administrative processing of environmental documentation through Army channels (16). The comments generally were from the Army field agencies who chose to respond to the proposed rule. A second category dealt with the inclusiveness of regulation, i.e.; the regulation should cover broader categories of actions which require environmental impact analysis (13). A third category also received 13 comments, that the regulation required clarification. Five comments were in the category of typographical/grammatical errors. Three comments suggested changes in terminology to ensure Army is using proper criteria for determining the level of environmental documentation required for Army actions.

The following discusses the comments and Army's responses to the general and specific concerns expressed on the proposed rules. Copies of all written comments have been provided to CEQ and are available for public review at the Army Environmental Office, Room 1E671, Pentagon, Washington, DC.

Specific Comments on the Rule

1. *Section 651.4 Policy.* One commenter suggested the rule cite other environmental laws and where they can be found. This comment was not adopted because this rule is not the appropriate place to cite all environmental regulations. The scope of this rule is confined to implementing NEPA. The Army has a regulation (AR 200-1) concerning compliance with other environmental laws and regulations.

2. *Section 651.5 Responsibilities.* One commenter suggested sentence structure change to enhance clarity and that suggestion was adopted (§ 651.5(b)). The same commenter suggested the responsibilities of the Program Executive Officer's responsibilities be defined in this section. This is an inappropriate place to define the PEO responsibilities. All the Army organizations which appear in this section have a special responsibility in the environmental program. The PEO has responsibilities which mirror those of HQDA staff agencies and those responsibilities are defined in § 651.5(c).

3. *Section 651.6 Records and Documents.* One commenter suggested that the regulation should specifically note that using a Categorical Exclusion does not exclude compliance with other environmental laws. This suggestion was not adopted because there is no instance in this rule that intimates that the rule repeals or usurps any other environmental law or regulation. In fact, many of the Categorical Exclusions (CX) are predicated upon compliance with other environmental laws and regulations. It is inherent that a CX does not exclude compliance with other environmental laws. Likewise, even though one prepares an environmental assessment or environmental impact statement, the proponent is not exempt from other environmental laws and

regulations. A second comment on this part refuted the need for Army to require a Record of Environmental Consideration (REC) for actions that are CXs. this suggestion is not adopted because CXs are broad, by design, to cover many Army actions that have no potential for environmental impact. The RECs are for those CXs that must be rigidly defined to be properly excluded. There is very little paperwork associated with a CX, yet the REC provides the proponent a vehicle to document his/her consideration of the potential environmental impacts. The Army finds these RECs useful.

4. *Section 651.7 Definitions.* One commenter requested clarification of the sentence "major federal action is not a determinate in a decision to prepare or not prepare environmental documentation". While it is true that a "major federal action significantly affecting the quality of the human environment" clearly requires an EIS, a major federal action with merely "potential" may not have significant effects on the environment, and therefore may require only an EA. It is conceivable that even a "major federal action" could be excluded because of its category. Another commenter suggested that the definition of "significantly affecting the environment" should also include that positive impacts, as well as negative environmental impacts, require environmental impact analysis. This is true and has been incorporated in the final rule.

5. *Section 651.8 Responsibilities.* Several commenters recommended additional Army agencies be added to this section. One state military agency pointed out that the National Guard Bureau (NGB) responsibilities are not incorporated, nor is the relationship between the NGB and the state Adjutant Generals (AG) clearly defined. The NGB responsibilities are the same as any other Headquarters, Department of Army (HQDA) staff agency and are therefore defined in § 651.5(c) 1–9. No change to the rule is required. The relationship of the NGB and the State AGs has been clarified in several sections of the rule.

6. *Section 651.9 (a). Applicability.* One respondent expressed concern that installation restoration projects pursuant to the Comprehensive Environmental Response, Compensation and Liability Act, as amended by the Superfund Amendments and Reauthorization Act (SARA) would not be adequately assessed under the Army's proposed rule. As a matter of policy, the Army will comply with the 40 CFR Parts 1500–1508 and the final rule has incorporated this revision. Another commenter suggested that applicability of the regulation should extend to Section 802 housing projects, as well as Section 801 housing. This suggestion has been adopted and incorporated in the final rule.

7. *Section 651.10 Categories of Actions.* One commenter suggested that paragraph (b) of this section, which deals with emergencies, did not provide relief for those emergency actions where the impacts may not be significant, but require preparation of an EA and publication of a FNSI. The intent of the proposed rule was to note that *even* projects with significant impacts may be undertaken without the benefit of an EIS. It was intended to be inclusive. However, the final rule clarifies this point.

8. *Section 651.11 Classified Actions.* One federal agency offered to participate in review of classified actions at the Army's request and noted the agency had reviewers with appropriate security clearances for such review. The Army appreciates the offer and will consider it for use in the future.

9. *Section 651.12 Integration with Army Planning.* One commenter noted that while the Army requires publication of a Finding of No Significant Impact (FNSI), it fails to mention the circulation of the EA which is the basis of the FNSI. It has always been Army policy and practice that the EA is available for public review. However, the sentence in § 651.12(b)(2) has been changed to amplify this policy. A federal agency noted that the proposed rule stated that EPA accepts Notices of Availability until noon on Friday, when the EPA actually accepts NOAs until the close of business each Friday. This information will be incorporated into the final rule. One respondent asked for criteria to understand what triggers a 30 day waiting period described in § 651.12(b)(2)(ii). It is Army policy that there is a 30 day waiting period after a FNSI is published before a decision is made. It should be noted that although CEQ does not require a 30 day waiting period, it is Army policy. There may be peculiar circumstances where the 30 day comment period is not followed, but those are rare. To clarify, this final rule states the Army policy to wait 30 days for comments. Another comment suggested that Historic Preservation Plans were mentioned twice in the same section for the same purposes and that one reference should be deleted. This suggestion was adopted.

10. *Section 651.13 Mitigation and Monitoring.* One respondent requested the rule incorporate guidance on the types of mitigation measures that should be included as line items in the budget. This suggestion was adopted and the wording has been revised. The final rule clarifies the responsibility of the proponent with respect to funding mitigations.

11. *Section 651.16 Categorical Exclusions (Procedures).* Respondent suggests the final rule explain why some CXs require RECs and others do not. The final rule states the rationale for this requirement in § 651.16(a). Another commenter suggested that § 651.16(b)(5) does not include other safety regulations with which Army agencies will comply besides AR 385–10. This suggestion is adopted and the final rule adds the phrase "* * * and all other applicable Army safety and preventive medicine regulations", in order to be more inclusive.

12. *Section 651.22 Components of the EA.* One commenter stated that the Army should not require both the EA and the FNSI to be signed. If the EA and the FNSI are integrated and never separated, only the FNSI would need to be signed. However, there are cases where the two are separated and requires that reviewers are aware that both have been reviewed and approved by the decisionmaker. It is Army policy that both will be signed.

13. *Section 651.23 Decision Process.* One commenter suggested that the preface to this section should include provisions for the proponent to go directly to a decision to prepare an EIS without first preparing an EA. Although Army believes this has not been a point of confusion within the agency, explicit wording has been incorporated in the final rule to reflect that a proponent may determine to prepare an EIS at any point in the decision process.

14. *Section 651.27 Criteria.* Two commenters pointed out that the criteria to prepare an EIS should not be based solely on "degradation" of the environment, but may also include "beneficial" impacts. It is true that a more appropriate term is "significantly affect" and the final rule has adopted this comment. Another commenter pointed out that paragraph (b) in this subsection needed a rewrite to create a complete second sentence. This was adopted. One respondent suggested the Army will prepare an EIS when an action "affects the environment, or parts of it, in ways or by means found by other federal agencies to be significant and to require an EIS." This suggestion was not adopted. The Army is responsible for its actions and must decide when an EIS is appropriate.

15. *Section 651.28 Actions Normally Requiring an EIS.* One respondent urged a rewrite of the provision dealing with Life Cycle Environmental Documentation (LCED) of weapon systems to incorporate the broader concept of "research and development systems". It is not clear that all research and development systems require an EIS. However, the point the respondent makes is well taken, i.e.; that not just weapon systems will be subject to EISs. Therefore, the final rule incorporates the phrase "materiel, such as weapon systems", to broaden the concept. It remains the responsibility of the proponent to determine the level of environmental documentation required to comply with NEPA and CEQ regulations.

16. *Section 651.30 Steps on Preparing and Processing an EIS.* Six comments were received regarding this section. One commenter suggested Army provide more information on internal processing of EISs through Army channels. This comment was adopted and guidelines were expanded in § 651.30(a). However, it is anticipated that a Department of Army pamphlet will be initiated in 1989 which will contain more how-to instructions than a policy rule can accommodate. A state military agency requested that the final rule indicate how lead agency is determined for an action initiated by the State Adjutant General. This regulation is meant for Department of Army Actions. The National Guard Bureau is always the proponent, and lead agency, when the action is accomplished with federal dollars. The state may be either a joint lead or cooperating agency. Language has been incorporated to clarify this point. Another commenter suggested the rule should not discuss the Final Environmental Impact Statement (FEIS) in the section on public review of the Draft EIS (DEIS). Army agrees with this comment and will move this paragraph to § 651.30(g). Another commenter suggested Army point out that Final EISs should be mailed to the commenters on the Draft EIS before filing the NOA with EPA. This was a shortcoming in the proposed rule and new language is incorporated in the final rule. The last comment is this section suggested that a paragraph should be added to provide guidance on preparation and coordination procedures for Supplemental EISs. This has been added in this section.

17. *Section 651.31 Existing EISs.* Commenter recommends that the final rule add a paragraph that will facilitate adoption of other agencies NEPA documents when appropriate. This language is included in the final rule.

18. *Appendix A—Categorical Exclusions.* Two comments were received on the Appendix. One respondent suggested the Army change the "Screening Questions" to "Screening Criteria". Since the 10 statements in the screen do represent criteria for using a CX, this suggestion was adopted. CEQ requested the Army delete CX A-28 because of its broadness and the potential for abuse. The proposed rule had incorporated stricter measures and provided a greater internal control on the use of A-28. The Army believes the elimination of A-28 will require additional specific CXs and therefore the list will be expanding periodically in the first one-two years after the final rule. However, the Army has removed CX A-28.

19. As a result of comments regarding the presentation of the material, Subpart A—Introduction was reorganized and Subpart B—Records and Documents was transposed with Subpart C—NEPA and the Decision Process to ensure logical presentation of the material. In addition, the CFR section numbers have been revised for format consistency.

List of Subjects in 32 CFR Part 651

Environmental protection, Environmental impact statements, Natural resources, Ecology.

Lewis D. Walker,

Deputy for Environment, Safety and Occupational Health OASA (I&L).

For the reasons set forth in the preamble, 32 CFR Part 651 is revised as follows:

PART 651—ENVIRONMENTAL EFFECTS OF ARMY ACTIONS (AR200-2)

Subpart A—Introduction

651.1 Purpose.
651.2 References.
651.3 Explanation of abbreviations and terms.
651.4 Responsibilities.
651.5 Policies.
651.6 Procedures.

Subpart B—National Environmental Policy Act (NEPA) and the Decision Process

651.7 Introduction.
651.8 Actions requiring evaluation.
651.9 Environmental review categories.
651.10 Determining appropriate environmental documentation.
651.11 Classified actions.
651.12 Integration with Army planning.
651.13 Mitigation and monitoring.

Subpart C—Required Records and Documents

651.14 Introduction.
651.15 Optional documents.

Subpart D—Categorical Exclusions (CX)

651.16 Introduction.
651.17 Determining when to use a CX.
651.18 CX actions.
651.19 Modification of the CX list.

Subpart E—Environmental Assessment (EA)

651.20 Introduction.
651.21 Conditions requiring an EA.
651.22 Actions normally requiring an EA.
651.23 EA Components.
651.24 Decision process.
651.25 Public involvement.
651.26 Public availability.
651.27 Existing environmental assessments (EAs).

Subpart F—Environmental Impact Statement (EIS)

651.28 Introduction.
651.29 Conditions requiring an EIS.
651.30 Actions normally requiring an EIS.
651.31 Format of the EIS.
651.32 Steps in preparing and processing an EIS.
651.33 Existing EISs.
651.34 Major Army command (MACOM) processing of an EIS.

Subpart G—Public Involvement and the Scoping Process

651.35 Public involvement.
651.36 Scoping process.
651.37 Preliminary phase.
651.38 Public interaction phase.
651.39 The final phase.
651.40 Aids to information gathering.
651.41 Modifications of the scoping process.

Subpart H—Environmental Effects of Major Army Actions Abroad

651.42 Introduction.
651.43 Global commons.
651.44 Army policy on global commons and foreign nations.
651.45 Responsibilities.
651.46 Implementation guidance.

Appendix A—List of Categorical Exclusions (CX)

Appendix B—References

Appendix C—National Environmental Policy Act

Appendix D—Contents of the Environmental Impact Statement (EIS)

Appendix E—Council for Environmental Quality (CEQ) Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act (NEPA)

Appendix F—Implementing a Monitoring and Methodology Program

Appendix G—Requirements for Environmental Considerations—Global Commons

Appendix H—Requirements for Environmental Considerations—Foreign Nations and Protected Global Resources

Appendix I—Glossary

Authority: National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.*

Council on Environmental Quality Regulations, 40 CFR Parts 1500–1508, 43 FR 55978–56007, November 29, 1978, as amended at 51 FR 15625, April 25, 1986, and E.O. 12114.

Subpart A—Introduction

§ 651.1 Purpose.

This regulation sets forth policy, responsibilities, and procedures for integrating environmental considerations into Army planning and decisionmaking. It establishes a criteria for determining what Army actions are categorically excluded from requirements to prepare an Environmental Impact Statement (EIS) and lists applicable categorical exclusions (CX) in Appendix A.

§ 651.2 References.

Required and related publications and referenced forms are listed in Appendix B.

§ 651.3 Explanation of abbreviations and terms.

Abbreviations and special terms used in this regulation are explained in the Glossary.

§ 651.4 Responsibilities.

(a) The Secretary of the Army (SA) has designated the Assistant Secretary of the Army (Installations and Logistics (ASA (I&L)) to serve as the Army's responsible official for National Environmental Policy Act (NEPA) matters.

(b) The Chief of Engineers (COE) has the responsibility for coordinating and monitoring NEPA activities within the Army. Through the Assistant Chief of Engineers (DAEN–ZC), the Army Environmental Office is the Army Staff (ARSTAF) point of contact (POC) for environmental matters.

(c) The Assistant Chief of Engineers (ACE) will—

(1) Provide assistance to Army agencies in completing environmental analysis and documentation through identifying and quantifying environmental impacts and selecting impact mitigation techniques.

(2) In cases of multiple Army agency involvement, designate a single agency or lead office with responsibility for preparing and processing environmental documentation; assign Army lead agency responsibility in cases of non-Army agency involvement.

(3) Review and comment on Environmental Impact Statements (EISs) submitted by Army, other Department of Defense (DOD) components, and other Federal agencies.

(4) Monitor proposed Army policy and program documents that have environmental implications to determine compliance with NEPA requirements and to ensure integration of environmental considerations into the decisionmaking process.

(5) Maintain liaison with the Office of Management and Budget, Council on Environmental Quality (CEQ), Environmental Protection Agency (EPA), and other Federal, State, and local agencies on environmental policies that may affect the Army. This liaison assists in identifying and evaluating applicable regulatory policies for proposed actions.

(6) Maintain a current record from which access to EISs may be obtained from the proponent. Also, maintain a record of actions of national concern that resulted in a Finding of No Significant Impact (FNSI).

(7) Establish procedures for retention of EISs prepared by the Department of the Army (DA).

(8) Require the revision or preparation of environmental documents, as appropriate, to ensure adequate consideration of environmental impacts when a proponent has failed to do so.

(9) Comment on EISs within those areas of assigned staff responsibility and technical capability.

(10) Resolve issues in determining if a public hearing or public scoping meeting is appropriate for the proposed action and assign the responsibility to an appropriate office.

(d) Heads of Headquarters, Department of Army (HQDA) agencies will—

(1) Apply policies and procedures herein to programs and actions within their staff responsibility except for State funded operations of the Army National Guard (ARNG).

(2) Task the appropriate component with preparation of environmental assessments (EAs) and/or EISs. Proponents (defined in the Glossary) may conduct their preparation in-house, through contract, or pursue indirect preparation with the assistance of supporting U.S. Army Corps of Engineers (USACE) Districts.

(3) Initiate the preparation of necessary environmental documentation, assess proposed programs and projects to determine their environmental consequences, and initiate environmental documents for circulation and review along with other planning or decisionmaking documents. These documents include a completed DD Form 1391 (Military Construction Project Data), Case Study and Justification Folder, Integrated Program Summary, and other documents proposing or supporting proposed programs or projects.

(4) Coordinate appropriate environmental documents with ARSTAF agencies.

(5) Designate, record, and report the identity of the agency's single POC for NEPA considerations to the Army Environmental Office.

(6) Assist in the review of environmental documents prepared by DOD and other Army or Federal agencies, as requested.

(7) Coordinate proposed directives, instructions, regulations, and major policy publications that have environmental implications with the Army Environmental Office.

(8) Maintain the capability (personnel and other resources) to comply with the requirements of this regulation.

(9) Prepare and maintain a record of decision (ROD) on each EIS for which they are the staff proponent.

(e) The Assistant Secretary of the Army (Financial Management) will establish procedures to ensure compliance with requirements for environmental exhibits and displays of data in support of annual authorization requests.

(f) The Judge Advocate General will provide legal advice and assistance in interpreting NEPA and CEQ regulations. The Judge Advocate General will interface with the Army General Counsel, Corps of Engineers General Counsel, and the Department of Justice on NEPA related litigation.

(g) The Surgeon General is responsible for environmental review related to the health and welfare aspects of proposed EISs submitted to HQDA.

(h) The Chief of Public Affairs is the POC for media inquiries of national significance. The Chief will—

(1) Provide guidance on issuing public announcements such as FNSI, Notices of Intent (NOI), scoping procedures, Notices of Availability (NOA), and other public involvement activities.

(2) Review and coordinate planned announcements on actions of local or national interest with appropriate ARSTAF elements and the Assistant Secretary of Defense for Public Affairs (OASD (PA)).

(3) Provide public affairs guidance in conducting environmental programs.

(4) Be POC for media inquiries that are of national significance.

(5) Issue press releases that coincide with the publication of FNSIs, NOIs, and NOAs.

(i) The Chief of Legislative Liaison will notify members of Congress of impending EISs and EAs of national concern.

(j) Major Army command (MACOM) commanders, Chief, National Guard Bureau, and heads of agencies will—

(1) Monitor proposed actions and programs within their commands.

(2) Task the appropriate component with preparation of EAs and EISs and development of public involvement activities. Proponents may delegate authority to conduct their preparation in-house, through contract, or pursue indirect preparation with the assistance of supporting U.S. Army Corps Engineers Districts.

(3) Assure that appropriate environmental documentation is prepared and forwarded to the appropriate proponent.

(4) Apply policies and procedures set forth in this regulation to programs and actions within their command and staff responsibility.

(5) Initiate the preparation of necessary environmental documentation and assess the environmental consequences of proposed programs and projects.

(6) Circulate and review environmental documents at the same time with other planning or decisionmaking documents. These related documents include a completed DD Form 1391, Case Study and Justification Folder, Integrated Program Summary, and other documents proposing or supporting proposed programs or projects.

(7) Coordinate appropriate environmental documents and public affairs initiatives with HQDA agencies and the Army Environmental Office.

(8) Designate, record, and report the identity of the agency's single POC for NEPA considerations to the Army Environmental Office.

(9) Assist in the review of environmental documents prepared by DOD and other Army or Federal agencies, as requested.

(10) Coordinate proposed directives, instructions, regulations, and major policy publications that have environmental implications with the Army Environmental Office.

(11) Maintain the capability (personnel and other resources) to comply with the requirements of this regulation (See 40 CFR 1507.2.)

(12) Prepare and maintain a ROD on EISs for which they are the staff proponent.

(13) Develop public affairs initiatives, when appropriate, for actions requiring EAs and EISs.

(k) Installation, activity, and unit commanders will accomplish responsibilities listed in paragraphs (j) (1) through (3), (5), (7), and (9) of this section.

§ 651.5 Policies.

(a) The DA will endeavor to ensure the wise use of natural resources on Army land. The DA will match military mission activities with the ecological compatibility of the land and natural resources in order to maintain resources for realistic training, while minimizing the adverse impact on the human and natural environment. Decisionmakers will be cognizant of, and responsible for, the impact of their decisions on cultural resources; soils, forests, rangelands, water and air quality, and fish and wildlife; as well as other natural resources under their stewardship. The DA will identify significant environmental effects of proposed programs and projects in adequate detail. These effects will be considered in the decision process along with technical, economic, and other necessary factors. DA will carry out the mission of national security in a manner consistent with NEPA and other applicable environmental standards, laws, and policies. DA will employ all practicable means consistent with other essential considerations of national policy to minimize or avoid adverse environmental consequences and attain the goals and objectives stated in sections 101 and 102 of NEPA. (See Appendix C.)

(b) Environmental considerations will be integrated into the decisionmaking process to ensure that—

(1) Major decision points are designated for principal programs and proposals likely to have a significant effect on the quality of the human environment, while providing for the NEPA process to coincide with these decision points.

(2) Relevant environmental documents, comments, and responses accompany the proposal through the existing Army review and the decisionmaking process. The Army will integrate NEPA requirements with other planning and environmental review procedures required by law or Army practice so that review of environmental considerations is concurrent rather than consecutive.

(3) The alternatives considered are within the range of alternatives discussed in relevant environmental documents.

(c) Worldwide and long-range character of environmental problems will be recognized, and where consistent with national security requirements and United States (U.S.) foreign policy, appropriate support will be given to initiatives, resolutions, and programs designed to maximize international cooperation in protecting the quality of the world human environment. In accordance with Executive Order 12114, DOD Directive 6050.7, and Subpart H of this regulation, an environmental planning and evaluation process will be incorporated into Army actions that may significantly affect global commons, environments of other nations, or any protected natural or ecological resources of global importance. (See Subpart H.)

(d) Laws, other than NEPA, that require the Army to gain approval of other Federal, State, or local Government agencies before taking actions that may have environmental consequences will be obeyed. However, compliance does not relieve the responsible official from preparing environmental impact analyses and processing necessary environmental documents. NEPA compliance is required unless existing law, applicable to a specific action or activity, prohibits, exempts, or makes compliance impossible.

(e) When appropriate, environmental documentation to consider operations security principles and procedures described in AR 530-1 will be reviewed and documented on the cover sheet or signature page.

§ 651.6 Procedures.

(a) The Assistant Chief of Engineers retains a copy of each draft and final EIS (Draft Environmental Impact Statement (DEIS) and Final Environmental Impact Statement (FEIS)) prepared by the Army. The EIS will be retained until the proposed action and any mitigation program is complete or the information therein is no longer valid. The EIS is then deposited in the National Archives and Records Administration.

(b) DA agencies are encouraged to draw upon the special expertise that is available within the medical department, including the U.S. Army Environmental Hygiene Agency (AEHA), to identify and evaluate environmental health impacts.

(c) Military Construction Army/Military Construction ARNG (MCA/MCAR) funds may not be used for preparation of environmental documents. Operations and Maintenance/Operation and Maintenance, ARNG (OMA/OMAR) or other operating funds are the proper sources of funds for environmental document preparation.

(d) The proponent for federally funded ARNG actions is the National Guard Bureau (NGB) division in whose area of responsibility the action rests. For instance, National Guard Bureau-Installations Division (NGB-ARI) would

be the proponent for proposed training activities. The NGB division proponent performs the actions described in this section with the States or territories affected by the proposed action.

(e) In specific cases, such as the construction of a water treatment facility or a flood control plan, the engineer could be the proponent. The engineer and/or his environmental management staff should advise proponents as to the format and technical data that must be considered in the environmental document. The engineer's environmental management staff is, however, responsible for reviewing each environmental document for compliance with NEPA and appropriate Army and/or ARNG regulations. No matter who prepares the environmental document, the proponent remains responsible for its content and conclusions.

(f) The decisionmaking process often subjects proposal decisions to review and/or approval by higher level authorities including HQDA proponent (defined in the Glossary); therefore, the review and approval of the environmental document follows the same channel of review and approval as that of the proposed action. This does not apply to federally funded ARNG actions since the NGB division, which is the proponent for such actions, is also the HQDA proponent.

Subpart B—National Environmental Policy Act (NEPA) and the Decision Process

§ 651.7 Introduction.

(a) NEPA establishes policies and goals for the protection of the environment. Section 102(2) of NEPA contains certain procedural requirements directed toward the attainment of such goals. (See Appendix C for a copy of NEPA.) The CEQ issued regulations to implement the procedural provisions of NEPA and they are provided in Appendix E. Implementing procedures to CEQ regulations are contained in DOD Directive 6050.1 (applicable in the continental United States (CONUS)) and DOD Directive 6050.7 (applicable outside the continental United States (OCONUS)).

(b) The NEPA process includes the systematic examination of possible and probable environmental consequences of implementing a proposed action. To be effective, integration of the NEPA process with other Army project planning will occur at the earliest possible time to ensure—

(1) Planning and decisionmaking reflect environmental values.

(2) Policies and goals of § 651.4 are implemented.

(3) Delays and potential conflicts later in the process are minimized.

(c) To achieve these actions, all Army decisionmaking that may have an impact on the human environment will use a systematic, interdisciplinary approach that ensures the integrated use of the natural and social sciences, planning, and the environmental design arts. (Pub. L. 91-190; sec. 102(2)(A)). This approach allows timely identification of environmental effects and values in sufficient detail for evaluation concurrently with economic, techical, and mission-related analyses at the earliest possible step in the decision process. When EAs or EISs are undertaken, the economic and social impacts will be included in the analysis of total environmental impacts. However, these secondary impacts, unaccompanied by physical environmental impacts, should not determine whether or not to prepare an environmental document.

(d) NEPA also requires the proponent of an action or project to identify and describe all reasonable alternatives to the proposed action or project. To assist in identifying reasonable alternatives, the proponent must consult appropriate Federal, State, and local agencies, and the general public.

(e) These procedures will assist the decisionmaker in selecting a preferred couse of action. They provide the relevant background information and subsequent analyses of the proposal's positive and negative environmental effects. The decisionmaker's written environmental evaluation is either a CX with a record of consideration (REC), an EA with a FNSI, or an EIS with a ROD. (See Subpart C.)

§ 651.8 Action requiring evaluation.

(a) The types of projects or actions to evaluate for environmental impact include—

(1) Policies, regulations, and procedures (for example, Army regulations and circulars).

(2) New management and operational concepts and programs in areas such as logistics, research, development, test and evaluation, procurement, and personnel assignment.

(3) Projects (for example, facilities construction, research and development for weapons, vehicles, and other equipment).

(4) Activities (for example, individual and unit training, flight operations, overall operation of installation, or facility test and evaluation programs).

(5) Requests for a Nuclear Regulatory Commission license (new, renewal, or amendment) or an Army radiation authorization.

(6) Materiel development, acquisition, and/or transition.

(7) Research and development in areas such as genetic engineering, laser testing, and electromagnetic pulse generation.

(8) Installation restoration projects undertaken pursuant to section 104 of the Comprehensive Environmental Response Compensation and Liability Act (CERCLA), as amended by the Superfund Amendments and Reauthorization Act (SARA). The National Oil and Hazardous Substances Contingency Plan (40 CFR Part 300), implements the requirements of CERCLA/SARA, and describes a formal process, the feasibility study (FS).

(i) The FS provides substantive and procedural standards to ensure full consideration of environmental issues and alternatives, and an opportunity for the public to participate in evaluating environmental factors and alternatives before a final decision is made.

(ii) In most cases, when a FS is prepared in accordance with 40 CFR Part 300, a second NEPA document is not required. As a matter of policy, the organization preparing the FS will ensure the document also complies with 40 CFR Parts 1500-1508. The cover of the FS document and the subsequent ROD will contain the legend "This document is intended to comply with the National Environmental Policy Act of 1969." All public notices announcing the availability of the FS will also note this intent. Installation Restoration Program actions in which an FS is not prepared in accordance with 40 CFR 300 will require appropriate environmental documentation.

(9) Requests for special use airspace in accordance with AR 95-50 that require Federal Aviation Administration approval (new, renewal, or amendment).

(b) In addition to the above, certain activities supported by the Army through the following actions require proper environmental documentation:

(1) Federal contracts, grants, subsidies, loans, or other forms of funding such as Government owned contractor operated industrial plants and section 801/802 Housing, Military Appropriations Act of 1984, construction, (via third-party contracting).

(2) Leases, easements, permits, licenses, certificates, or other entitlement for use (for example, grazing lease and grants of easement for highway right-of-way).

(3) Request for approval to use or store materials, radiation sources,

hazardous and toxic material, or wastes on Army land. If the requester is non-Army, the responsibility to prepare the proper environmental documentation is that of the non-Army requester. If required, the requester will provide information needed for the Army review. The Army reviews and approves all environmental documentation before approving the request.

§ 651.9 Environmental review categories.

The following are the five broad categories into which a proposed action may fall for environmental review:

(a) *Exemption by law.* The law must apply to DOD and/or Army and must prohibit, exempt, or make impossible full compliance with NEPA (40 CFR 1500.6). (See § 651.11 for security exemptions).

(b) *Emergencies.* (1) In the event of an emergency, the Army may need to take immediate actions that have environmental impacts, that may include immediate actions to promote national defense or security and actions necessary for the protection of life or property. In such cases the HQDA proponent will notify the Army Environmental Office, which in turn will notify the Office of the Assistant Secretary of the Army, Installations and Logistics (OASA (I&L)) who will coordinate with the Assistant Secretary of Defense for Production and Logistics (ASD (P&L) regarding the emergency action. Time is of the essence so that OASA (I&L) may consult with the CEQ if necessary. A public affairs plan should be developed as soon as possible so that channels of communication remain open between the media, public, and the installation. In no event will Army delay an emergency action necessary for national defense, security, or preservation of human life or property to comply with this regulation or the CEQ regulations. State call-ups of ARNG during a natural disaster are excluded from this consultation requirement.

(2) These notifications apply only to actions necessary to control immediate effects of the emergency; other actions remain subject to NEPA review. (40 CFR 1506.11)

(3) After action reports may be required at the discretion of the OASA (I&L).

(c) *Categorical exclusions (CX).* These actions (Subpart D and Appendix A) normally do not require an EA or an EIS. The Army has determined that they do not individually or cumulatively have a significant effect on the human environment. Qualification for a CX is described in Subpart D of this regulation.

(d) *Environmental assessment (EA).* (See section for actions normally requiring an EA.)

(1) If the proposed action is adequately covered within an existing EA or EIS, prepare a REC to that effect. (See Figure 1).

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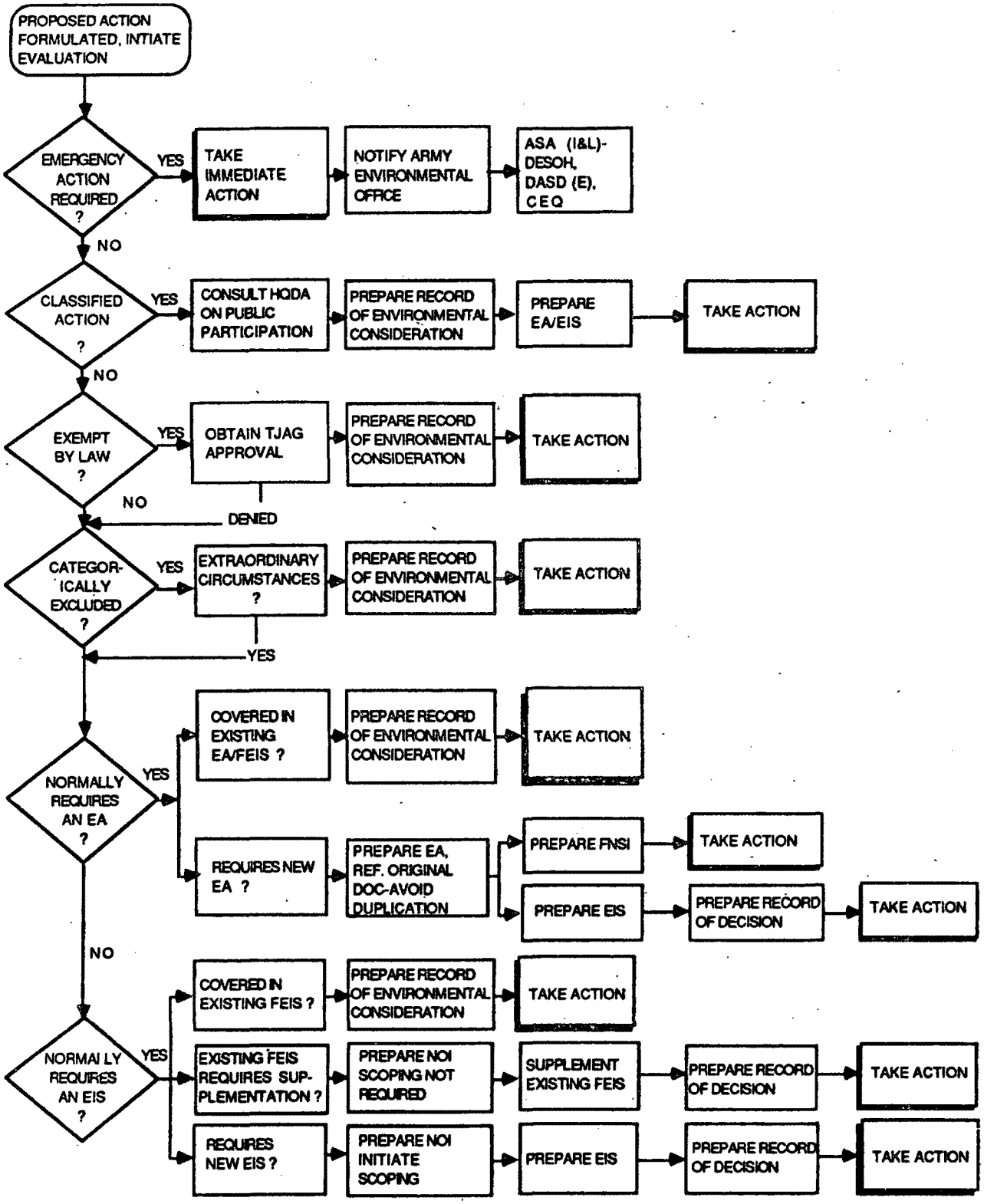

Figure 1. Flow chart summarizing process for determination of document requirements

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(2) If the proposed action is within the general scope of an existing EA or EIS, but requires additional information, prepare a new environmental document that considers the new, modified, or missing information. Incorporate by reference, existing documents and publish the conclusion (FNSI or NOI).

(3) If the proposed action is not covered adequately in any existing EA or EIS, or is of significantly larger scope than that described in the existing document, then prepare an EA followed by either a FNSI or a new EIS.

(e) *Environmental Impact Statement (EIS).* (See § 651.30 for actions normally requiring an EIS.)

(1) If it is determined that the action is covered adequately in a previously filed FEIS, the REC must so state, citing the applicable FEIS by name and date. The REC is then attached to the proponent's record copy of that FEIS. As a general rule, a FEIS older than 3 years cannot be used in this manner, but must be supplemented.

(2) If the proposed action is within the scope of an existing FEIS, but was not covered in that document or not covered adequately, then the proponent must prepared supplemental documentation to that FEIS.

(3) If the proposed action is not within the scope of any existing EIS, then the proponent must begin the preparation of a new EIS.

§ 651.10 Determining appropriate environmental documentation.

(a) The flowchart shown in Figure 1 summarizes the process for determining documentation requirements.

(b) The proponent of a proposed action may adopt appropriate environmental documents (EAs or EISs) prepared by another agency (40 CFR 1500.4(n) and 1506.3). In such cases, the proponent will retain its own record keeping for RECs and RODs. (See 40 CFR 1506.3 for procedures to follow when adopting other documents.)

(c) When an existing adequate EA or EIS is used in lieu of preparation of a new document, the REC should state the document title, date, and where it may be reviewed.

§ 651.11 Classified actions.

(a) For public dissemination of environmental documents containing classified information, AR 380–5 will be followed.

(b) Classified facts will be separated from unclassified facts and conclusions related to the proposed action. Unclassified portions of the action may then be processed routinely in accordance with this regulation. Classified portions will be kept separate for reviewers and decisionmakers with need-to-know as defined in AR 380–5 and (c) of this section.

(c) Classification does not relieve a proponent of the necessity to assess and document the environmental effects of the proposed action. The HQDA proponent, in coordination with the Army Environmental Office and the Deputy Chief of Staff for Intelligence, Security Division (DAMI–CIS), may select a review team. The team may be drawn from the Army agency or office not connected with the proponent agency, or from agencies outside the Army. The review team's purpose is to provide an external review of classified environmental documents.

§ 651.12 Integration with Army planning.

(a) *Early integration.* The Army goal to integrate environmental reviews concurrently with other Army planning and decisionmaking actions avoids delays in mission accomplishments. To achieve this goal, proponents should provide complete environmental documents for early inclusion with any recommendation or report to decisionmakers (Master Plan, Natural Resource Management Plan, Remedial Investigation, FS, etc.).

The same documents will be forwarded to the planners, designers, and/or implementers so that recommendations and mitigations on which the decision was based may be carried out.

(b) *Time limits.* The timing of the preparation, circulation, submission, and public availability of environmental documents is of great importance in ensuring that environmental values are integrated in the planning and decision processes. It is important to remember that next to the project itself, a properly prepared EIS may require the longest time to complete.

(1) Categorical exclusions (CX). When a proposed action is categorically excluded from further environmental review (Subpart D and Appendix A), the proponent may proceed immediately with that action.

(2) Findings of no significant impact (FNSI).

(i) If the proposed action is one of national concern, is unprecedented, or normally requires an EIS, the proponent will make the EA and FNSI available for public review 30 or more days prior to making a final decision. A news release is required to publicize the availability of the FNSI. If the action is of national significance, a simultaneous announcement that includes publication in the **Federal Register** (FR) must be made by HQDA.

(ii) For proposed actions referred to in paragraph (b)(2)(i) of this section, the proponent must allow a 30-day period for public comment between the time that the FNSI is publicized (40 CFR 1506.6(b)) and the time the proposed action begins. In those cases where the 30 day wait jeopardizes the project, the additional comment period provides no public benefit, and none of the conditions of paragraph (b)(2)(i) apply, the period may be shortened with MACOM approval. In no circumstances should the public comment period for an EA/FNSI be less than 15 days.

(iii) A deadline and POC must be included for receipt of comments in the FNSI and the news release.

(3) Environmental Impact Statements (EIS). The EPA publishes a weekly notice in the FR of the EISs filed during the preceding week. This notice usually occurs each Friday. A NOA reaching EPA on a Friday will be published in the following Friday issue of the FR. (Failure to deliver a NOA to EPA by close of business on Friday will result in an additional one week delay.) A news release publicizing the action will be made in conjunction with the notice in the FR. The following time periods calculated from the publication date of the EPA notice will be observed:

(i) Not less than 45 days for public comment on DEISs (40 CFR 1506.10(c)).

(ii) Not less than 15 days for public availability of DEISs prior to any public hearing on the DEISs (40 CFR 1506.(c)(2)).

(iii) Not less than 90 days total for public availability of the DEIS and FEIS prior to any decision on the proposed action. These periods may run concurrently (40 CFR 1506.10 (b) and (c)).

(iv) The time periods prescribed here may be extended or reduced in accordance with 40 CFR 1506.10(b)(2) and 1506.10(d).

(v) When variations to these time limits are set, the Army agency should consider the factors in 40 CFR 1501.8(b)(1).

(vi) The proponent may also set time limits for other procedures or decisions related to DEISs and FEISs as listed in 40 CFR 1501.8(b)(2).

(vii) The entire EIS process could require more than 1 year. (See Figure 2.) Thus, it is important that the process begin as soon as the project is conceptualized and that the proponent coordinate with all staff elements who may have a role to play in the NEPA process. Most of this time is taken by the preparation of the DEIS and the revision and response to comments to prepare the FEIS.

(viii) A public affairs plan should be developed that provides for periodic interaction with the community. There is a minimum public review time of 90 days between the publication of the DEIS and the announcement of the ROD. Army EISs are not normally processed in so short a time due to the internal staffing required for this type of action. After the availability of the ROD is announced, the action may proceed. Figure 2 indicates typical and required time periods for EISs.

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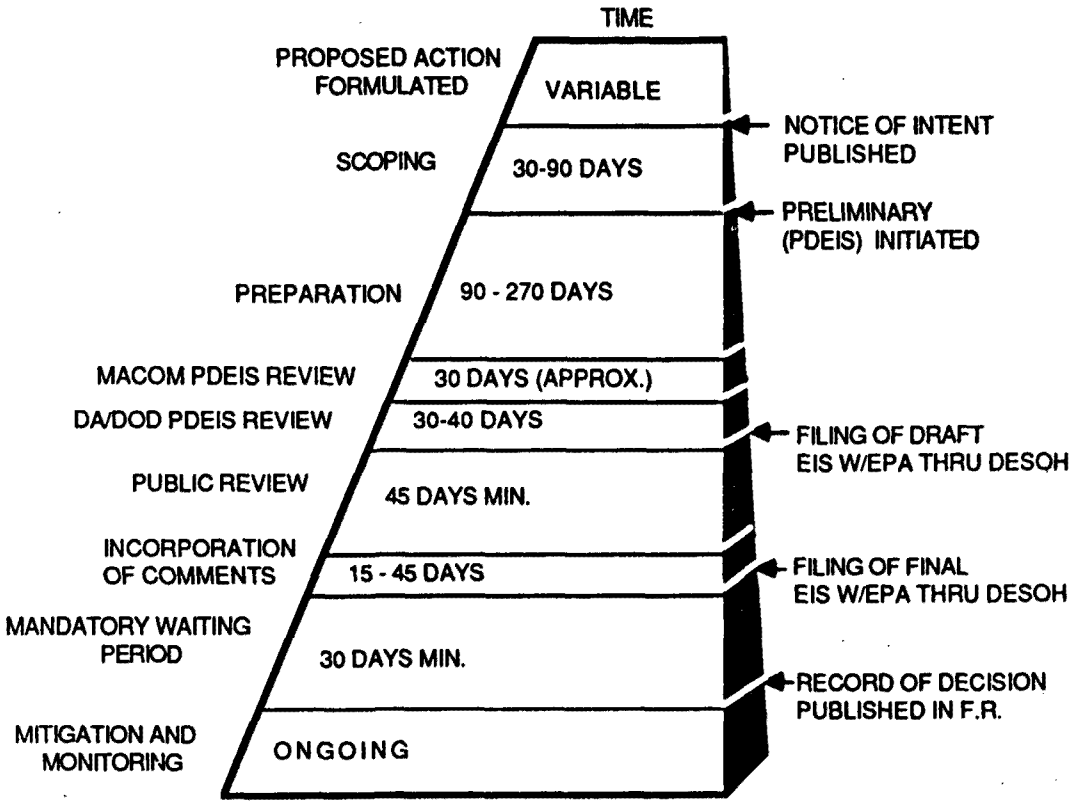

Figure 2. Time involved for preparing and processing an Environmental Impact Statement (EIS)

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(c) *Programmatic environmental review (tiering).* (1) Army agencies are encouraged to write programmatic environmental analyses when such programs are being considered for general application (40 CFR 1502.4(c), 1502.20 and 1508.23). This will eliminate repetitive discussions of the same issues and focus on the key issues at each appropriate level of project review. When a broad EIS or EA has been prepared and a subsequent EIS or EA is then prepared on an action included within the entire program or policy (particularly a site-specific action), it need only summarize issues discussed in the broader statement and concentrate on the issues specific to the subsequent action. This subsequent document will state where the earlier document is available.

(2) An example would be the assessment of a proposed major weapon system program. Development of an overall programmatic EIS or EA for the life cycle of the system is recommended. Tiered EAs and EISs, as appropriate, would evaluate specific subphases such as testing, production, development, use, and ultimate disposal.

(d) *Scoping.* (1) When the planning for an Army project or action indicates a need for an EIS preparation, the proponent initiates the scoping process. (See Subpart G for procedures and actions to be taken during the scoping process.) This process determines the scope of issues to address in the EIS and identifies the significant issues related to the proposed action. During the scoping process the participants identify the range of actions, alternatives, and impacts to consider in the EIS (40 CFR 1508.25). For an individual action, the scope may depend on the relationship of the proposed action to other environmental documents.

(2) The extent of the scoping process, including public involvement, will depend on several factors. These factors include—

(i) The size and type of the proposed action.

(ii) Whether the proposed action is of regional or national interest.

(iii) Degree of any associated environmental controversy.

(iv) Size of the affected environmental parameters.

(v) Significance of any effects on them.

(vi) Extent of prior environmental review.

(vii) Involvement of any substantive time limits.

(viii) Requirements by other laws for environmental review.

(3) The proponent may incorporate scoping in the public involvement or environmental review process other than that required for an EIS. If so, a significant reduction in the extent of scoping incorporated is at the proponent's discretion.

(e) *Analyses and documentation.* Environmental analyses and documentation required by this regulation will be integrated as much as practical with other environmental reviews, laws, and executive orders (40 CFR 1502.25) and—

(1) Environmental analysis and documentation required by various State laws.

(2) Any cost-benefit analyses prepared in relation to a proposed action (40 CFR 1502.23).

(3) Permitting and licensing procedures required by Federal and State law. For instance, the Clean Air Act, as amended (42 U.S.C. 57401 *et seq.*) and the Clean Water Act, as amended (33 U.S.C. 125 *et seq.*).

(4) Installation and Army Master Planning functions and plans.

(5) Installation management plans, particularly those that deal directly with the environment. These include the Natural Resource Management Plans (Fish and Wildlife Management Plan, Forest Management Plan, and Range Improvement or Maintenance Plan).

(6) Stationing and installation planning, force development planning, and materiel acquisition planning.

(7) Installation Compatible Use Zone (ICUZ) program.

(8) Hazardous waste management plans.

(9) Historic Preservation Plan as required by AR 420–40.

(10) Intergovernmental coordination as required by AR 210–10.

(11) Asbestos Management Plans.

(f) *Relations with local and regional agencies.* (1) Installation, agency, or activity environmental officers or planners should establish planning relations with other agencies. These agencies include the staffs of adjacent local governments and State agencies. This will promote cooperation and resolution of mutual land use and environment-related problems.

(2) Preparation of a Memorandum of Understanding is desirable for promoting cooperation and coordination. This memorandum will identify areas of mutual interest, establish POCs, identify lines of communication between agencies, and specify procedures to follow in conflict resolution. Additional coordination is available from State and area-wide planning and development agencies, including those designated by AR 210–10. Thus, the proponent may gain insights on other agencies' approaches to EAs, surveys, and studies of the current proposal. These other agencies would also be able to assist in identifying possible participants in scoping procedures for projects requiring an EIS.

§ 651.13 Mitigation and monitoring.

(a) Identification in environmental documents. Only those mitigation measures that can reasonably be accomplished as part of a proposed alternative will be identified in environmental documentation (EA, FNSI, or EIS). Measures that the proponent implements as part of the selected action will be included in the environmental documentation. Mitigation measures that appear practicable, but unobtainable within expected resources or that some other agency (including non-Army agencies) should perform, will be identified as such in the environmental document. "Practicable" measures include, among others, actions that appear capable of being accomplished. Complete development or testing of the exact means of performing the action may not have occurred.

(b) Consideration throughout the National Environmental Policy Act (NEPA) process. Consider mitigation throughout the NEPA process. When an EIS or EIS Supplement is prepared, the ROD will state specific mitigation measures taken to reduce or avoid the selected action's adverse environmental effects. For EAs, the FNSI will state, when applicable, the appropriate mitigation measures that will be implemented. The proponent must ensure such mitigation measures become a project line item in the proposal budget. Mitigations that are committed to in an EA, but that are eventually not funded, must lead to reevaluation of the project and the significance of its impacts. In addition, the FNSI will state those practicable mitigation measures that have not been adopted. (40 CFR 1505.2(c)).

(c) Assistance from cooperating non-Army agencies. Proponents may request assistance with mitigation when appropriate. Whether it is appropriate to request assistance is determined by whether the requesting agency—

(1) Was a cooperating agency during preparation of an environmental document, or

(2) Has the technology, expertise, time, funds, or familiarity with project or local ecology necessary to implement the mitigation measure more effectively than the lead agency.

(d) Implementing the decision.

(1) The proponent agency or other appropriate cooperating agency will implement mitigation and other conditions established in the EA or EIS or during its review, and committed as part of the FNSI or the ROD.

(2) Legal documents implementing the action (contracts, permits, grants, and so forth) will specify mitigation measures to be performed. Penalties against the contractor for noncompliance may also be specified as appropriate. Specification of penalties should be fully coordinated with the appropriate legal advisor.

(3) A monitoring and enforcement program will be adopted and summarized in the ROD where applicable for any mitigation. (See Appendix F for guidelines on implementing such a program.) Whether adoption of a monitoring and enforcement program is applicable (40 CFR 1505.2(c)) and whether the specific adopted action is an important case (40 CFR 1505.3) may depend on such factors as the following:

(i) A change in environmental conditions or project activities assumed in the EIS (such that original predictions of the extent of adverse environmental impacts may be too limited).

(ii) Cases when the outcome of the mitigation measure is uncertain (for example, new technology).

(iii) Projects in which major environmental controversy remains associated with the selected alternative.

(iv) Cases when failure of a mitigation measure, or other unforeseen circumstances, could result in serious harm to Federal or State listed endangered or threatened species; important historic or archaeological sites that are either on, or meet eligibility requirements for nomination to the National Register of Historic Places; wilderness areas, wild and scenic rivers, or other public or private protected resources. Evaluation and determination of what constitutes serious harm in coordination with the appropriate Federal, State or local agency responsible for each particular program must be made.

(v) The proponent will respond to inquiries from the public or other agencies regarding the status of mitigation measures adopted.

Subpart C—Required Records and Documents

§ 651.14 Introduction.

The following records and documents are required:

(a) Record of Environmental Consideration (REC). The REC describes the proposed action and anticipated timeframe, identifies the proponent, and explains why further environmental analysis and documentation is not required. It is a signed statement to be submitted with project documentation. It is used when the proposed action is exempt from the requirements of NEPA, or has been adequately assessed in existing documents and determined not to be environmentally significant. A REC is also used to document the use of those CX that require such records. (See Figure 3 for format.)

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Record of Environmental Consideration (REC)

To: (Environmental Officer)

From: (Proponent)

Project title:

Brief description:

Anticipated date and/or duration of proposed action: (Month/year)

Reason for using record of environmental consideration (choose one):

a. Adequately covered in an (EA, EIS) entitled _____, dated _____.
The EA/EIS may be reviewed at _____ _____. (location)

OR,

b. Is categorically excluded under the provisions of CX _____, AR 200-2, appendix A, (and no extraordinary circumstances exist as defined in paragraph 4-3), because _____
_____
_____.

_____
Date Project Proponent

_____
Date Installation Environmental Coordinator

Variation from this format is acceptable provided basic information and approvals are included in any modified document.

Figure 3. Format for record of environmental consideration (REC)

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(b) Environmental assessment (EA). An EA is a document that—

(1) Briefly provides the decisionmaker with sufficient evidence and analysis for determining whether a FNSI or an EIS should be prepared.

(2) Assures compliance with NEPA, if an EIS is not required and a CX is inappropriate.

(3) Facilitates preparation of a required EIS.

(4) Includes brief discussions of the need for the proposed action, alternatives to the proposed actions (NEPA, sec. 102(2)(e)) (see Appendix C), proposed and alternative actions environmental impacts, and a listing of persons and agencies consulted. (See Suppart E for requirements.)

(c) *Finding of no significant impact (FNSI).* A FNSI is a document that briefly states why an action will not significantly affect the environment, thus voiding the requirement for an EIS. The FNSI will include a summary of the conclusions of the EA and will note any environmental documents related to it. If the EA is attached, the FNSI need not repeat any of the EA's discussion, but may incorporate it by reference. A FNSI is always signed by the decisionmaker. (See § 651.24 for processing.)

(d) *Notice of intent (NOI).* An NOI is a public notice that an EIS will be prepared and considered. The NOI will briefly—

(1) Describe the proposed and alternative actions.

(2) Describe the proposed scoping process, including whether, when, and where any public meetings will be held.

(3) State the name and address of the POC who can answer questions on the proposed action and its EIS. (See §§ 651.32(a), 651.34(a), and 651.37 for application.)

(e) *Environmental impact statement (EIS).* An EIS is a detailed written statement required by NEPA for major Federal actions with significant environmental effects (42 U.S.C. 4321, sec. 102(2)(c). (See Appendix C.) (See Subpart F for requirements.)

(f) *Life cycle environmental document (LCED).* The LCED is intended to be a programmatic assessment that addresses the known and reasonably foreseeable environmental impacts of a proposed item/system during all phases of development, production, use, and ultimate disposal of the item/system. The LCED may be in the form of an EA or an EIS, and must be supplemental to address additional significant environmental impacts as conditions change. The LCED will be prepared by the DA proponent/developer (or program manager) and is most frequently used within the materiel research, development, and acquisition community.

(g) *Record of Decision (ROD).* A public ROD is required under the provisions of 40 CFR 1505.2 after completion of an EIS. Nevertheless, the ROD is not considered to be an environmental document since the decision considers other factors in addition to environmental issues. (See § 651.32(i) for application.)

§ 651.15 Optional documents.

The following additional documents may assist in the implementation of this regulation. These documents are optional, but their use is encouraged.

(a) *Environmental planning guide.* Prepared prior to or at the outset of a major program concept exploration. It is a concise (for example, 10-page) document intended for use by the program planners and designers. It provides guidelines and supporting rationale by which planners and designers could prevent, avoid, or minimize adverse environmental effects through environmentally sensitive design and planning. Through appropriate language in the scope of work, contractors can be encouraged or required to use such an environmental planning guide.

(b) *Environmental planning record.* This records the progress and process of environmental considerations throughout a given program's development. Ideally, it is a document that is written when the program commences. There is no set form; it may be a journal with periodic entries, a file of memoranda, trip reports, and so forth. This document is a visible track record of how environmental factors have actually been considered and incorporated throughout the planning process. Through appropriate language in the scope of work, contractors can be encouraged or required to prepare an environmental planning record, or parts thereof.

(c) *Environmental monitoring report.* This report is prepared at one or more points after program or action execution. Its purpose is to determine the accuracy of impact predictions. It can serve as the basis for adjustments in mitigation programs and to adjust impact predictions in future projects.

Subpart D—Categorical Exclusions (CX)

§ 651.16 Introduction.

(a) The use of CX is intended to reduce paperwork and delay and eliminate unnecessary EA and EIS preparation. CX is defined in the Glossary.

(b) The following criteria will be used to determine those categories of actions that normally do not require either an EIS or EA:

(1) Minimal or no individual or cumulative effect on environmental quality.

(2) No environmentally controversial change to existing environmental conditions.

(3) Similarity to actions previously examined and found to meet the above criteria.

§ 651.17 Determining when to use a CX.

In order to use the CX provision, the proponent must take the following actions:

(a) Determine whether the proposal is encompassed by one of the categories not normally requiring the preparation of an EA or EIS. (See Appendix A.)

(b) Determine if there are any extraordinary circumstances that may result in the proposed action having an impact on the human environment that would require an EA or EIS. These circumstances include—

(1) Greater scope or size than normally experienced for a particular category of action.

(2) Potential for degradation, even though slight, of already existing poor environmental conditions. Also, initiation of degrading influence, activity, or effect in areas not already significantly modified from their natural condition.

(3) Employment of unproven technology.

(4) Presence of threatened or endangered species and their habitats, archaeological materials, historical places, or other protected resources.

(5) Use of hazardous or toxic substances that may come in contact with the surrounding natural environment. Nevertheless, a categorical exclusion exists for use of hazardous and toxic substances under adequately controlled conditions within established laboratory buildings that are designed for, and in compliance with, regulatory standards. Adequately controlled conditions includes complying with AR 385–10 and all other applicable Army safety and preventive medicine regulations for the processing of hazardous and toxic substances, and complying with the Resource Conservation and Recovery Act (RCRA) for their disposal.

(6) Proposed actions affecting areas of critical environmental concern. These include, but are not limited to, prime or unique agricultural lands, wetlands, coastal zones, wilderness areas,

aquifers, floodplains, or wild and scenic river areas.

(c) Determine whether all the screening criteria in Appendix A are true for the proposal.

(d) If the proposed action qualifies for one of the CX, no analytical environmental document is necessary. However, if a REC (Figure 3) is required by the CX listing in Appendix A, a REC will be completed and signed by the proponent. Consultation between the proponent and the installation environmental coordinator is required.

§ 651.18 CX actions.

Types of actions that normally qualify for CX are listed in Appendix A.

§ 651.19 Modification of the CX list.

The Army list of CXs is subject to continual review and modification. Send, for review, requested additional modifications to the Army Environmental Office. Subordinate Army headquarters may not modify the CX list through supplements to this regulation. Upon approval, proposed modifications to the list of CXs will be published in the **Federal Register** by the Army Environmental Office. This provides an opportunity for public review and comment.

Subpart E—Environmental Assessment (EA)

§ 651.20 Introduction.

An EA is made to determine the extent of environmental impacts of a project and decide whether or not those impacts are significant. It is not required for actions that are subject to categorical exclusion or exclusion from environmental review by law. (See 40 CFR 1508.9.) The EA is described in § 651.14(b).

§ 651.21 Conditions requiring an EA.

An EA is required when the proposed action has the potential for—

(a) Cumulative impact on environmental quality when combining effects of other actions or when the proposed action is of lengthy duration.

(b) Release of harmful radiation or hazardous/toxic chemicals into the environment.

(c) Violation of pollution abatement Standards.

(d) Some harm to culturally or ecologically sensitive areas.

§ 651.22 Actions normally requiring an EA.

The following actions normally require an EA:

(a) Special field training exercise or test activity on Army land of a nature or magnitude not within the annual installation training cycle.

(b) Military construction, including contracts for off-post construction.

(c) An installation pesticide, fungicide, herbicide, insecticide, and rodenticide-use program.

(d) Changes to established installation land use that generates impacts on the environment.

(e) Proposed changes in doctrine or policy that may have a potential environmental impact.

(40 CFR 1508.18 (*b*) (1)).

(f) Repair or alteration projects affecting historically significant structures, archaeological sites, or places on, or meeting, the criteria for nomination to the National Register of Historic Places.

(g) Acquisition or alteration of, or space for, a laboratory that will use hazardous chemicals, drugs, or biological or radioactive materials.

(h) Actions that could potentially cause soil erosion, affect prime or unique farmland, wetlands, floodplains, coastal zones, wilderness areas, aquifers or other water supplies, or wild and scenic rivers.

(i) New weapon systems development and acquisition, including the materiel acquisition, transition, and release processess.

(j) Development of installation master plan.

(k) Development of natural resource management plans (land, forest, fish, and wildlife).

(l) Proposals that may lead to the excessing of Army real property.

(m) Actions that take place in, or adversely affect, wildlife refuges.

(n) Proposals for energy conversion through forest harvest.

(o) Field activities on land not controlled by the military. This includes firing of weapons, missiles, or lasers over navigable waters of the United States, or extending 45 meters or more above ground level into the national airspace. It also includes joint air attack training that may require participating aircraft to exceed 250 knots at altitudes below 3000 feet above ground level.

(p) An action with local or regional effects on energy availability.

(q) An activity that affects any species on, or proposed for, the U.S. Fish and Wildlife Service list of Threatened and Endangered Plant and Animal Species. Also, activities affecting any species on an applicable State or territorial list of threatened or endangered species.

(r) Production of hazardous or toxic materials.

(s) Installation restoration projects undertaken in response to the CERCLA. (See § 651.8(a)(8) for a full discussion of the integration of NEPA and CERCLA/SARA.)

(t) Operations and Maintenance/Army National Guard projects that will impact environmental quality.

(u) Site specific deployment of life cycle systems meeting the threshold criteria for requiring an EA.

(v) Special field training excercises or test activities off Army or DOD property that extend into the national airspace (45 meters above ground level).

(w) Changes to established airspace use that generates impacts on the environment or socioeconomic systems, or creates a hazard to nonparticipants.

§ 651.23 EA components.

(a) The EA will be the responsibility of the proponent. The Army Environmental Office will advise and assist in the preparation of the EA. In the case of United States Army Reserve (USAR) environmental documentation, the supporting installation facility engineer is responsible for ensuring proper environmental documentation is prepared and will comply with the provisions of AR 140–475. The EA will include brief discussions of—

(1) Purpose and need for the proposed action.

(2) Description of the proposed action.

(3) The alternatives considered (always including the "no action" alternative).

(4) Affected environment (baseline conditions).

(5) Environmental consequences of the proposed action and the alternatives.

(6) Listing of agencies and persons consulted.

(7) The conclusion, or finding, on whether the environmental impacts are significant. If the finding is that there are no significant impacts, a FNSI will be published. If the finding is that impacts are potentially significant, the EA should state that a NOI will be published leading to preparation of an EIS.

(b) The EA, the FNSI, and all other appropriate planning documents will be provided to the appropriate decisionmaker for review and consideration. The signature page for the EA and FNSI package will be signed by the decisionmaker to indicate his or her review and approval.

§ 651.24 Decision process.

Every EA results in a FNSI or a NOI to prepare an EIS. Initiation of a NOI to prepare an EIS should occur at any time in the decision process when significant effects are determined.

(a) The FNSI is a separate document (40 CFR 1508.13) that briefly presents reasons why an action will not have a

significant effect on the human environment and, thus, will not be the subject of an EIS. The FNSI will contain a summary of the EA or have the EA attached. If the EA is attached, the FNSI may incorporate it by reference, thus avoiding duplication of discussion. The FNSI will reference other relevant environmental documents that are being or have been prepared. The FNSI must contain the following:

(1) The name of the action.

(2) A brief description of the action (including any alternatives considered).

(3) A short discussion of the anticipated environmental effects.

(4) The facts and conclusions that have led to the FNSI.

(5) A deadline and POC for further information or receipt of public comments. (See § 651.35.)

(b) The FNSI should not exceed two typewritten pages in length.

(c) The FNSI will be made available to the public prior to initiation of the proposed action, unless it is excluded on a security basis. (See § 651.11 for security exclusions.) FNSIs that have national interest should be submitted with the proposed press release through command channels to Deputy of Environment, Safety, and Occupational Health (DESOH) for approval and subsequent publication in the FR. FNSIs having national interest will be coordinated with Office of the Chief of Public Affairs (OCPA). Local publication of the FNSI will not precede the FR publication. The text of the publication should be identical to the FR publication.

(d) For actions of only regional or local interest, the FNSI will be publicized in accordance with 40 CFR 1506.6(b) and § 651.12(b)(2) of this regulation. Distribution of the FNSI (30 days prior to intitiation of the proposed action) should include any agencies, organizations, and individuals who have expressed interest in the project and others whom the proponent and preparers (defined in the Glossary) deem appropriate.

§ 651.25 Public involvement.

(a) Environmental agencies, applicants, and the public should be involved to the extent practical in the preparation of an EA. When considering the extent practicable of public interaction (40 CFR 1501.4(*b*)), some of the factors to be weighed are—

(1) Magnitude of the proposed project/action.

(2) Extent of anticipated public interest.

(3) Urgency of the proposal.

(4) Any relevant questions of national security classification.

(b) See § 651.35 for additional public involvement information.

§ 651.26 Public availability.

Documents incorporated into the EA or FNSI by reference will be available for public review. Where possible, use of public libraries is encouraged. Operating hours of the chosen depository should extend beyond normal business hours.

§ 651.27 Existing environmental assessments (EAs).

EAs are dynamic documents. To ensure that the setting, actions, and effects described remain substantially accurate, the proponent or installation environmental officer will periodically review existing documentation (environmental impact assessment (EIA) or (EA)) as an action continues. Preparation of a new environmental document is necessary if substantive changes have occurred.

Subpart E—Environmental Impact Statement (EIS)

§ 651.28 Introduction.

An EIS is a public document with a primary purpose of ensuring that NEPA policies and goals are incorporated early into the programs and actions of Federal agencies. An EIS is required to provide a full and fair discussion of significant environmental impacts. Along with other project documentation, the EIS provides a basis for informed decisionmaking. Further, it allows public review and comment on the proposal.

§ 651.29 Conditions requiring an EIS.

An EIS is required when a proponent, preparer, or approving authority determines that the proposed action has the potential to—

(a) Significantly affect environmental quality or public health or safety.

(b) Significantly affect historic or archaeological resources, public parks and recreation areas, wildlife refuge or wilderness areas, wild and scenic rivers, or aquifers.

(c) Have significant adverse effect on properties listed or meeting the criteria for listing in the National Register of Historic Places, or the National Register of Natural Landmarks. (The National Park Service, U.S. Department of the Interior maintains the National Register.)

(d) Cause a significant impact to prime and unique farm lands, wetlands, floodplains, coastal zones, or ecologically or culturally important areas or other areas of unique or critical environmental concern.

(e) Result in potentially significant and uncertain environmental effects or unique or unknown environmental risks.

(f) Significantly affect a species or habitat listed or proposed for listing on the Federal list of endangered or threatened species.

(g) Either establish a precedent for future action or represent a decision in principle about a future consideration with significant environmental effects.

(h) Adversely interact with other actions with individually insignificant effects so that cumulatively significant environmental effects result.

(i) Involve the production, storage, transportation, use, treatment, and disposal of hazardous or toxic materials that may have significant environmental impact.

§ 651.30 Actions normally requiring an EIS.

The following actions normally require an EIS:

(a) Significant expansion of a military facility, such as a depot, munitions plant, or major training installation.

(b) Construction of facilities that have a significant effect on wetlands, coastal zones, or other areas of critical environmental concern.

(c) The disposal of nuclear materials, munitions, explosives, industrial and military chemicals, and other hazardous or toxic substances that have the potential to cause significant environmental impact.

(d) The life cycle development of new material such as weapon systems that requires the construction and operation of new fixed facilities or the significant commitment of natural resources.

(e) Land acquisition, leasing or other actions that may lead to significant changes in land use.

(f) Continental United States (CONUS) realignment or stationing of a brigade or larger table of organization and equipment (TOE) unit during peacetime (except where the only significant impacts are socioeconomic with no significant biophysical environmental impact).

(g) Training exercises conducted outside the boundaries of an existing military reservation where significant environmental damage might occur.

(h) Major changes in the mission of facilities either affecting areas of critical environmental concern or causing significant environmental impact.

§ 651.31 Format of the EIS.

(a) The EIS must contain the following:

(1) Cover sheet.

(2) Summary.

(3) Table of contents.

(4) Purpose of and need for the action.

(5) Alternatives considered, including proposed action.

(6) Affected environmental (baseline conditions).

(7) Environmental and socioeconomic consequences.

(8) List of preparers.

(9) Distribution list.

(10) Index.

(11) Appendixes (if any).

(b) The content of each section is discussed in greater detail in Appendix D.

§ 651.32 Steps in preparing and processing an EIS.

(a) *Notice of intent (NOI).* (1) Prior to preparing an EIS (see Figure 4), a NOI will be published in the FR and in newspapers with appropriate or general circulation in the areas potentially affected by the proposed action. The Office of Legislative Liaison (OCLL) will be notified by the ARSTAF proponent of pending EISs so that congressional coordination may be effected. After the NOI is published in the FR, copies of the notice may also be distributed to agencies, organizations, and individuals, as the responsible official deems appropriate.

(2) Forward the NOI and the proposed press release to the HQDA proponent for coordination prior to publication. The ARSTAF proponent will coordinate the NOI with HQDA (Army Environmental Office, OCLL, and OCPA). The DESOH is the only person authorized to release an NOI to the FR for publication. A cover letter similar to Figure 5 will accompany the NOI. An example NOI is at Figure 6. The NOI initiates the scoping process; therefore, provide adequate response time for those wishing to comment on the NOI or participate in the scoping process. Subpart G discusses public participation requirements and options.

BILLING CODE 3710-08-M

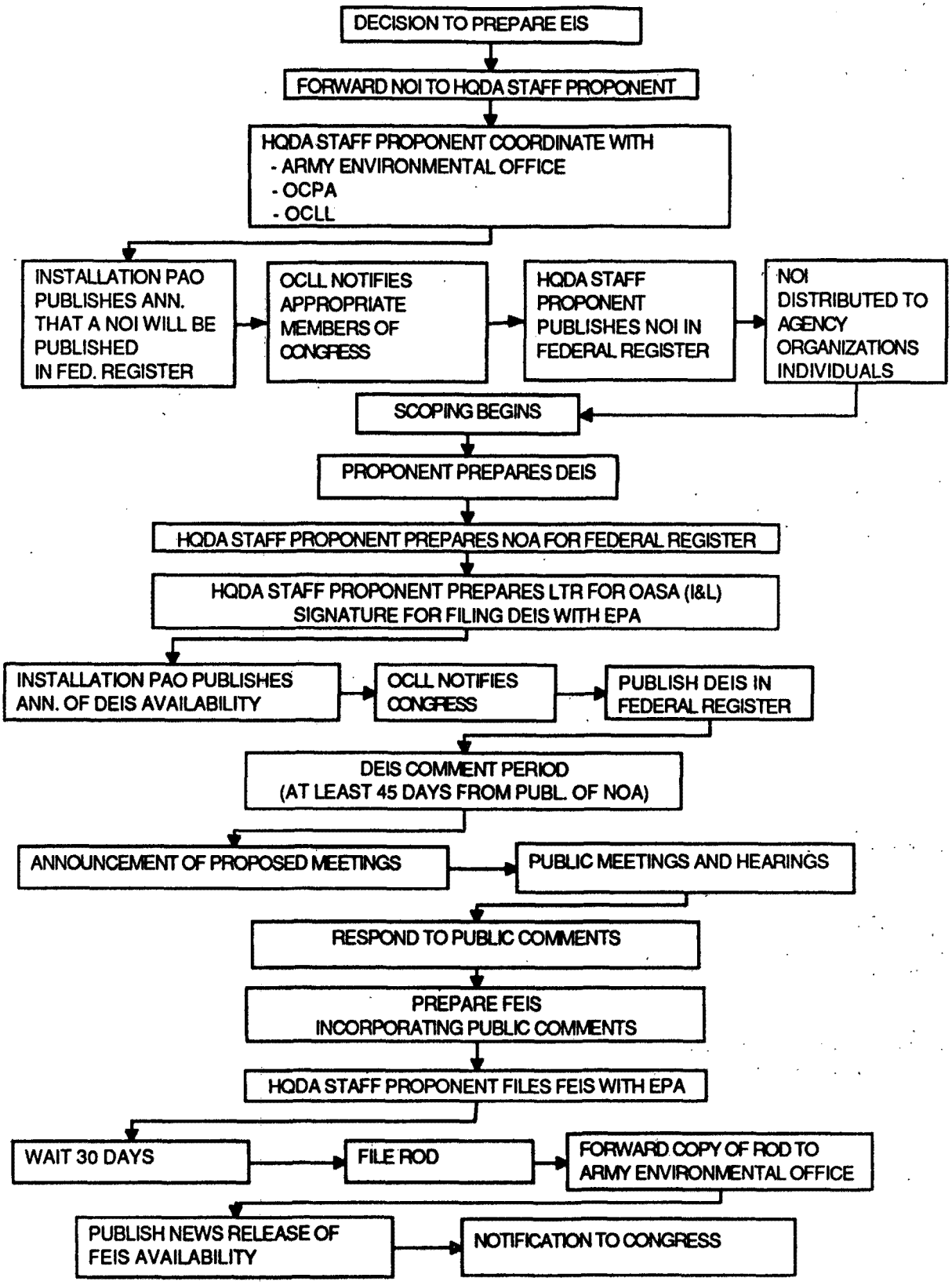

Figure 4. Steps in preparing and processing an Environmental Impact Statement (EIS)

Director
Office of the Federal Register
National Archives and Records ~~Service~~ Administration
~~1100 L Street, NW~~
Washington, DC 20408

Dear Sir:

The attached Notice of Intent is submitted for publication in the Notice Section of the Federal Register.

Please publish this Notice of Intent in the earliest edition of the Federal Register possible. This notice is required for the Department of Army to perform its military mission and comply with the National Environmental Policy Act and the President's Council on Environmental Quality regulations.

Please bill this to charge code 3710-08-M.

Sincerely,

Lewis D. Walker
Deputy for Environment, Safety
and Occupational Health
OASA (I&L)

1 encl. (3 copies)

CC: HQDA (SAIL-DESOH)
HQDA ()
HQDA (Staff Proponent)

---

3 Originals must be signed
The charge code 3710-08-M must appear in the letter.

Figure 5. Sample Notice of Intent (NOI) transmittal letter.

3710-08-M

Department of Army
Notice of Intent (NOI)

To prepare a Draft Environmental Impact Statement (DEIS) for proposed barracks construction, at Ft. Jefferson, CA.

Agency: DOD, U.S. Army, Ft. Jefferson, California.

Summary: Proposed Action: A series of three barracks are proposed for construction at Ft. Jefferson, California in order to provide adequate housing for bachelor enlisted personnel assigned to the installation. These facilities are proposed to replace existing substandard facilities for personnel who currently live in expensive rental units within the community or in inadequate quarters on the installation. The inadequate quarters are deficient in seismic design and do not meet DOD standards for privacy, space, or security. The requirements for these projects are not the result of new or expanded missions. The location of the proposed barracks is between M and N Streets on Wisconsin Avenue. Alternatives:

a. No Action
b. Rehabilitation of existing facilities
c. Alternate site locations

Scoping Process: Comments received as a result of this notice will be used to assist the Army in identifying potential impacts to the quality of the environment. Individuals or organizations may participate in the scoping process by written comment or by attending a scoping meeting to be held on May 23, 1989, 8 PM, at the Norwood Avenue Elementary School, 123 Norwood Avenue. Written comments may be forwarded to: Commander, U.S. Army Engineer School, Attention: Director of Facilities Engineering, Fort Jefferson, California. Comments and suggestions should be received not later than 15 days following the public scoping meeting to be considered in the DEIS. Questions regarding this proposal may contact Ms. Jane McIntyre, (900) 555-9876.

Lewis D. Walker
Deputy for Environment, Safety
and Occupational Health
OASA (I&L)

Figure 6. Sample Notice of Intent (NOI)

BILLING CODE 3710-08-C

(b) *Lead and cooperating agency determination.* As soon as possible after the decision is made to prepare an EIS, the proponent, if necessary, will contact appropriate Federal, State, and local agencies to identify lead or cooperating agency responsibilities concerning EIS preparation. At this point, a public affairs plan must be developed. In State ARNG actions that have any Federal funding, the National Guard Bureau (NGB) will be the lead agency for the purpose of Federal compliance with NEPA. The State may be either a joint lead or a cooperating agency, as determined by NGB.

(c) *Scoping.* If determined that Army is the lead agency, the proponent will begin the scoping process described in § 651.36. Portions of the scoping process may take place prior to publication of the NOI.

(d) *Draft Environmental Impact Statement (DEIS) preparation and processing.*

(1) Preliminary DEIS (PDEIS). Based on information obtained and decisions made during the scoping process, the proponent will prepare the PDEIS. Forward 15 copies of the PDEIS to the HQDA proponent for circulation to OASA (I&L), Office of the Assistant Chief of Engineers (OACE), Office of the Judge Advocate General (OTJAG), Office of the Surgeon General (OTSG), Office of the Chief of Public Affairs (OCPA), and other interested offices for review and comment. The PDEIS is then returned to the preparer for revision as required and printing of the DEIS for filing.

(2) DEIS. The Army proponent will advise the DEIS preparer of the number of copies to be forwarded for final HQDA review (see paragraph (d)(1) of this section for distribution list) and those for filing with EPA. Distribution may include interested Congressional delegations and committees, governors, national environmental organizations, the DOD and Federal agency headquarters, and other selected entities. The Army proponent will prepare the FR NOA, the proposed news release, and the EPA filing letter for signature of the DESOH. When the DEIS has been formally approved by the DESOH, the HQDA proponent will notify the preparer to distribute the DEIS to the remainder of the distribution list. The DEIS must be distributed prior to, or simultaneous to, filing with EPA. The list includes Federal, State, regional, and local agencies, private citizens, and local organizations. The EPA will publish the NOA in the FR. The 45-day comment period begins on the date of the EPA notice in the FR.

(e) *Public review of DEIS.* (1) The length of the DEIS public comment period will normally be no less than 45 days from publication of the NOA in the FR. If the statement is unusually long, circulate a summary with an attached list of locations where review of the entire DEIS may take place (for example, local public libraries).

(2) However, EIS distribution must include the following:

(i) Any Federal agency that has jurisdiction by law or special expertise with respect to any environmental impact involved and any appropriate Federal, State, or local agency authorized to develop and enforce environmental standards.

(ii) The applicant, if any.

(iii) Any person, organization, or agency requesting the entire environmental impact statement.

(3) Hold public meetings or hearings on the DEIS in accordance with the criteria established in 40 CFR 1506.6 (c) and (d) or for any other reason the proponent deems appropriate. News releases should be prepared and issued to publicize the meetings or hearings.

(f) *Response to comments.* Incorporate responses to comments in the DEIS by modification of the text and/or written explanation. Where possible, group similar comments for a common response. The preparer or a higher authority may make individual response, if considered desirable.

(g) *Prepare Final Environmental Impact Statement (FEIS).* If the changes in the DEIS are exclusively factual corrections, prepare and circulate only an errata sheet containing DEIS comments, responses, and changes. Nevertheless, the entire document and new cover sheet will be filed with EPA (40 CFR 1503.4(c)). If broader modifications are necessary, the proponent will prepare a preliminary FEIS incorporating these modifications. Processing the FEIS is essentially the same as the process outlined for the DEIS transmittal. The FEIS distribution must include any person, organization, or agency that submitted substantive comments on the EIS. Also, distribution to commenting agencies and the public must occur prior to, or simultaneously with, filing the NOA for the EIS with EPA. There is no need to invite public comment during the 30 day post-filing waiting period. (40 CFR 1503.1(b).)

(h) *Decision.* Make no decision on a proposed action until 30 days after EPA has published the NOA of the FEIS in the FR, or 90 days after the NOA of the DEIS, whichever is later. EPA publishes NOAs weekly. Those NOAs ready for EPA by close of business Friday are published in the next Friday's issue of the FR.

(i) *Record of decision (ROD).* When a decision is made, the decisionmaker will prepare a ROD (40 CFR 1505.2 and 1505.3) which will become a part of the environmental documentation presented for the final decision. Forward a copy of the signed ROD to the Army Environmental Office. The ROD will—

(1) State the decision.

(2) Identify all alternatives considered by the Army in reaching its decision, specifying the preferred alternatives as well as the environmental alternatives, if they are not the same. The Army may discuss preferences among alternatives based on relevant factors including economic and technical considerations and agency statutory missions.

(3) Identify and discuss all such factors, including any essential considerations of national policy that were balanced by the Army in making its decision. Because economic and technical analyses are balanced with environmental analysis, the agency preferred alternative will not necessarily be the environmentally preferred alternative.

(4) State how those considerations entered into the final decision.

(5) State whether all practicable means to avoid or minimize environmental harm from the selected alternative have been adopted, and if not, why they were not. A monitoring and enforcement program will be adopted and summarized for any mitigation. (See Appendix F.)

(j) *Pre-decision referrals.* 40 CFR Part 1504 specifies procedures to resolve Federal agency disagreements on the environmental effects of a proposed action. Pre-decision referrals apply to interagency disagreement on a proposed action's potential unsatisfactory effects.

(k) *Changes during preparation.* If there are substantial changes in the proposed action, or significant new information relevant to environmental concerns during the proposed action's planning process, the proponent will prepare revisions or a supplement to any environmental document or prepare new documentation as necessary.

(l) *Mitigation.* All measures planned to minimize or mitigate expected significant environmental impacts will be identified in the EIS. Implementation of the mitigation plan is the responsibility of the proponent (See Appendix F.) The proponent will make available to the public, upon request, the status and results of mitigation measures associated with the proposed action.

(m) *Implementing the decision.* The Army may provide for monitoring to assure that its decisions are carried out and should do so in controversial cases or environmentally sensitive areas. (See Appendix F.) Mitigation and other conditions established in the EIS or during its review, and comment as part of the decision, will be implemented by the lead agency or other appropriate consenting agency. The proponent will—

(1) Include appropriate conditions in grants, permits, or other approvals.

(2) Condition funding of actions on mitigation.

(3) Upon request, inform cooperating or commenting agencies on the progress in carrying out adopted mitigation measures that they have proposed and that were adopted by the agency making the decision.

(4) Upon request, make the results of relevant monitoring available to the public and Congress.

(n) *Supplemental EIS (SEIS).* SEISs (40 CFR 1502.9(c)) are processed in the same way as draft and final EISs. Scoping is not required for an SEIS.

§ 651.33 Existing EISs.

A newly proposed action must be the subject of a separate EIS. The proponent may extract and revise the existing environmental documents in such a way as to bring them completely up to date, in light of the new proposals. Such a revised EIS will be prepared and processed entirely under the provisions of this regulation. If an EIS of another agency is adopted, it must be processed in accordance with 40 CFR 1506.3.

§ 651.34 Major Army command (MACOM) processing of an EIS.

In certain cases where the scope of the EIS is limited, the HQDA proponent may authorize a MACOM to process an EIS.

(a) *NOI.* When the NOI is forwarded to the HQDA proponent (§ 651.32(a)(2)), the proponent may determine that the MACOM should accomplish EIS processing. The HQDA proponent will consult with the Army Environmental Office, who will gain approval from DESOH. Proponent will return the NOI with any comments and a letter authorizing the MACOM to process the EIS in accordance with the guidance in this chapter. The MACOM is responsible for preparing the NOI, proposed news release, and a transmittal letter as described in Figure 5, and for forwarding that material to the Army Environmental Office. After a review to ensure acceptability of the document, the OASA (I&L) will forward the NOI to the FR.

(b) *PDEIS.* When the PDEIS is staffed at the unit Headquarters, copies will be provided for concurrent review to the following HQDA elements to ensure that HQDA interposes no objection: JALS-RL, OGC, OCPA, OCLL, DASG-PSP-E, the Army Environmental Office, and the HQDA proponent.

(c) *Filing the EIS.* The unclassified portions of the DEIS and FEIS will be filed with the EPA Federal Activities Office by forwarding five copies with a transmittal letter as described in Figure 7. An additional five copies will be sent to the applicable EPA regional office for its review of the proposed action. One copy will be forwarded to Office of the Secretary of Defense (OSD) (Figure 8). Distribution of HQDA EIS copies will follow that of the PDEIS list. (See paragraph (b) of this section.) Copies will be coordinated for Congressional delegations and committees with the HQDA (OCLL) to meet Congressional notification procedures. Remaining distribution is for interested governors, Federal agency headquarters, national environmental organizations, regional, State and local agencies and organizations, and interested private citizens. The proponent is responsible for developing the distribution list; advice is available from the Army Environmental Office. A NOA may be published in the FR by forwarding the notice, a proposed news release, and a transmittal letter by the same method used for the NOI (See paragraph (a) of this section.)

(d) *ROD.* At the time of decision, a ROD will be prepared. (40 CFR 1505.2 and 1505.3.) A copy of the ROD will be provided to the Army Environmental Office.

BILLING CODE 3710-08-M

Director
Office of Federal Activities
U.S. Environmental Protection Agency
Room 2119, West Tower
Waterside Mall
Washington, DC 20460

Dear Sir:

Enclosed are five copies of the Draft Environmental Impact Statement (DEIS), Proposal to Construct Barracks at Fort Jefferson, California.

These copies are forwarded for filing in accordance with the Council on Environmental Quality regulations for implement the provisions of the National Environmental Policy Act (40 CFR Part 1500-1508).

Lewis D. Walker
Deputy for Environment, Safety
and Occupational Health
OASA (I&L)

1 Enclosure (5 copies)

DEISs and the accompanying NOA reaching EPA by noon Friday will be published in the Federal Register the following Friday. Failure to deliver documents to EPA by Friday noon will result in an additional 1 week delay.

Figure 7. Sample letter of transmittal of draft Environmental Impact Statement (DEIS) to Environmental Protection Agency (EPA)

MEMORANDUM FOR: Secretary of Defense, Production and Logistics (P&L), Washington, DC 20301

SUBJECT: Availability of Draft Environmental Impact Statement

In accordance with Department of Defense Directive 6050.1, Environmental Considerations in DOD Actions, attached is one (1) copy of the Draft Environmental Impact Statement (DEIS), Proposal to Construct Barracks at Fort Jefferson, California.

Lewis D. Walker
Deputy for Environment, Safety
and Occupational Health
OASA (I&L)

1 Enclosure
as

Figure 8. Sample letter of transmittal of draft Environmental Impact Statement (DEIS) to Office of the Secretary of Defense (OSD)

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Subpart G—Public Involvement and the Scoping Process

§ 651.35 Public involvement.

(a) The requirement (40 CFR 1506.6) for public involvement recognizes that all potentially affected parties will be involved, when practical, whenever developing environmental documentation. This requirement can be met at the very beginning of the environmental analysis and documentation process by developing a plan to include all affected parties. (See also AR 360–5.) The plan will include the following:

(1) Information disseminated to local and installation communities through such means as news releases to local media, announcements to local citizens groups, and Commander's letters at each phase or milestone (more frequently if needed) of the project. Such information may be subject to Freedom of Information Act and operations security review.

(2) Each phase or milestone (more frequently if needed) of the project will be coordinated with representatives of local, State, and Federal Government agencies.

(3) Public comments will be invited and two-way communication channels will be kept open through various means as stated above.

(4) Public affairs officers at all levels will be kept informed.

(b) When an EIS is being prepared, public involvement is a requisite element of the scoping process (40 CFR 1501.7(a)(1)).

(c) Preparation of EAs will incorporate public involvement processes whenever appropriate (40 CFR 1506.6).

(d) Persons and agencies to be consulted include the following:

(1) Municipal, township, and county elected and appointed officials.

(2) State, county, and local government officials and administrative personnel whose official duties include responsibility for activities or components of the affected environment related to the proposed Army action.

(3) Local and regional administrators of other Federal agencies or commissions that may either control resources potentially affected by the proposed action (for example, the U.S. Fish and Wildlife Service); or who may be aware of other actions by different Federal agencies whose effects must be considered with the proposed Army action (for example, the U.S. General Services Administration (GSA)).

(4) Members of identifiable population segments within the potentially affected environments, whether or not they have clearly identifiable leaders or an established organization such as farmers and ranchers, homeowners, small business owners, and Indian tribes.

(5) Members and officials of those identifiable interest groups of local or national scope that may have interest in the environmental effects of the proposed action or activity (for example, hunters and fishermen, Isaak Walton League, Sierra Club, and the Audubon Society).

(6) Any person or group that has specifically requested involvement in the specific action or similar actions.

(e) The public involvement processes and procedures by which participation may be solicited include the following:

(1) The direct individual contact process identifies persons expected to express an opinion and participate in later public meetings. Direct contact may also identify the preliminary positions of such persons on the scope of issues that the EIS will address. Such limited contact may suffice for all required public involvement, when the expected environmental effect is of very limited scope.

(2) Small workshops or discussion groups.

(3) Larger public gatherings that are held after some formulation of the potential issues. The public is invited to express its views on the proposed courses of action. Public suggestions or alternative courses of action not already identified may be expressed at these gatherings that need not be formal public hearings.

(4) Identifying and applying other processes and procedures to accomplish the appropriate level of public involvement.

(f) The meetings described in paragraph (e) of this section should not be public hearings in the early stages of evaluating a proposed action. Public hearings do not substitute for the full range of public involvement procedures under the purposes and intent of a above.

(g) Public surveys or polls to identify public opinion of a proposed action will be performed. (AR 335–15, chapter 10).

§ 651.36 Scoping process.

(a) Introduction. The scoping process, required for EIS preparation (40 CFR 1501.7), should aid the proponent in determining the scope and significant issues related to the proposed action. The process requires appropriate public participation immediately following publishing the NOI in the FR. The Army policy is that EISs for legislative proposals significantly affecting the environment will go through scoping unless extenuating circumstances make it impractical.

(b) Scoping procedures. Scoping procedures fall into preliminary, public interaction, and final phases. These phases are discussed in §§ 651.37, 651.38, and 651.39, respectively.

§ 651.37 Preliminary phase.

In the preliminary phase, the proponent agency or office identifies as early as possible, how it will accomplish scoping and with whose involvement. Key points will be identified or briefly summarized as appropriate in the NOIs. The proponent will—

(a) In the NOI, identify the significant issues to be analyzed in the EIS.

(b) In the NOI, identify the office or person responsible for matters related to the scoping process. If they are not the same as the proponent of the action, make that distinction.

(c) Identify the lead and cooperating agency, if already determined (40 CFR 1501.5–6).

(d) Identify the method by which the agency will invite participation of affected parties and identify a tentative list of the affected parties to be notified.

(e) Identify the proposed method for accomplishing the scoping procedure.

(f) Indicate the relationship between the timing of the preparation of environmental analyses and the tentative planning and decisionmaking schedule including—

(1) The scoping process itself.

(2) Collecting or analyzing environmental data, including studies required of cooperating agencies.

(3) Preparation of DEISs and FEISs.

(4) Filing of the ROD.

(5) Taking the action.

(6) For a programmatic EIS, preparing a general expected schedule for future specific implementing actions that will involve separate environmental analysis.

(g) If applicable, in the NOI, identify the extent to which the EIS preparation process is exempt from any of the normal procedural requirements of this regulation, including scoping.

§ 651.38 Public interaction phase.

(a) During this portion of the process, the proponent will invite comments from all affected parties and respondents to the NOI to assist in developing issues for detailed discussion in the EIS. Assistance in identifying possible participants is available from the Army Environmental Office.

(b) In addition to the affected parties identified above, participants should include the following:

(1) Technical representatives of the proponent. Such persons must be able to describe the technical aspects of the proposed action and alternatives to other participants.

(2) One or more representatives of any Army-contracted consulting firm, if one has been retained to participate in writing the EIS or providing reports that the Army will directly use to create substantial portions of the EIS.

(3) Experts in various environmental disciplines, if any area where impacts are foreseen is not already represented among the other scoping participants.

(c) In all cases, provide the participants with information developed during the preliminary phase and with as much of the following information that may be available:

(1) A brief description of the environment at the affected location. When descriptions for a specific location are not available, use general descriptions of the probable environmental effect. Also include the extent to which the environment has been modified or affected in the past

(2) A description of the proposed alternatives. The description will be sufficiently detailed to enable evaluation of the range of impacts that may be caused by the proposed action and alternatives. The amount of detail that is sufficient will depend on the stage of the development of the proposal, its magnitude, and its similarity to other actions with which participants may be familiar.

(3) A tentative identification of "any public environmental assessments and other environmental impact statements that are being or will be prepared that are related to but are not part of the scope of the impact statement under consideration" (40 CFR 1501.7(a)(5)).

(4) Any additional scoping issues or limitations on the EIS, if not already described during the preliminary phase.

(d) The public involvement may begin with the NOI to publish an EIS. The NOI may indicate when and where a scoping meeting will take place and whom to contact to receive preliminary information. The purpose of the scoping meeting is to be an informal public meeting. It is a working session where the gathering and evaluation of information relating to potential environmental impacts can proceed.

(e) Starting with the above information, the person conducting the scoping process will use input from any of the involved or affected parties. This will aid in developing the conclusions. The proponent determines the final scope of the EIS. If the proponent chooses not to require detailed treatment of significant issues or factors in the EIS, in spite of relevant technical or scientific objections by any participant to the contrary, the proponent will clearly identify (in the environmental consequences section of the EIS) the criteria that were used to eliminate such factors from detailed consideration.

§ 651.39 The final phase.

(a) The scope used in the preparation of DEIS consists of the determinations made by the proponent during and after the public interaction phase of the process, as follows:

(1) The scope and the significant issues for detailed analysis in the EIS (40 CFR 1501.7(a)(2)). To determine the scope of EISs, the proponent will consider three types of actions, alternatives, and impacts.

(2) The three actions (other than unconnected single actions) are as follows:

(i) Connected actions, that are closely related and should be discussed in the same impact statement. Actions are connected if they automatically trigger other actions that may require EISs, cannot or will not proceed unless other actions are taken previously or simultaneously, are interdependent parts of a larger action, and depend on the larger action for their justification.

(ii) Cumulative actions, when viewed with other proposed actions, have cumulatively significant impacts and should be discussed in the same impact statement.

(iii) Similar actions, that have similarities that provide a basis for evaluating their environmental consequences together, such as common timing or geography, may be analyzed in the EIS. Agencies should do so when the best way to assess such actions is to treat them in a single EIS.

(3) The three alternatives are as follows:

(i) No action.

(ii) Other reasonable courses of action.

(iii) Mitigation measures (not in the proposed action).

(4) The three types of impacts are as follows:

(i) Direct.

(ii) Indirect.

(iii) Cumulative.

(5) Indentification and elimination from detailed study of issues that are not significant or have been covered by prior environmental review. This narrows the discussion of these issues to a brief presentation of why they will not have a significant effect on the human environment. It may also provide a reference to their coverage elsewhere. (40 CFR 1501.7(a)(3)).

(6) Allocation of assignments for preparation of the EIS among the lead and any cooperating agencies, with the lead agency retaining responsibility for the statement. (40 CFR 1501.7(a)(4)).

(7) Indication of any public EAs and other EISs, prepared by the Army or another Federal agency, related to, but not part of, the EIS under consideration. (40 CFR 1501.7(a)(5)).

(8) Identification of any other environmental review and consultation requirements so the lead and cooperating agencies may prepare other required analyses and studies concurrently with the EIS. (40 CFR 1501.7(a)(6)).

(b) As part of the scoping process the lead agency may—

(1) Set time limits, as provided in § 651.12(b), if they were not already indicated in the preliminary phase.

(2) Prescribe overall page limits to the EIS in accordance with the CEQ regulations that emphasize conciseness.

(c) All determinations reached by the proponent during the scoping process will be clearly conveyed to the preparers of the EIS in a Scope of Statement. The Scope of Statement will be made available to participants in the scoping process and to other interested parties on request. Any conflicts on issues of a scientific or technical nature that arise between the proponent and scoping participants, cooperating agencies, other Federal agencies, or preparers of the document will be identified during the scoping process and resolved or discussed by the proponent in the DEIS.

§ 651.40 Aids to information gathering.

The proponent may use or develop graphic or other innovative methods to aid information gathering, presentation, and transfer during the three scoping phases. These include methods for presenting preliminary information to scoping participants, obtaining and consolidating input from participants, and organizing its own determinations on scope for use during preparation of the DEIS.

§ 651.41 Modifications of the scoping process.

(a) If a lengthy period exists between a decision to prepare an EIS and the time of preparation, the proponent will initiate the NOI at a reasonable time in advance of preparation of the DEIS. The NOI will state any tentative conclusions regarding the scope of the EIS made prior to publication of the NOI. Reasonable time for public participation will be allowed before the proponent

makes any final decisions or commitments on the EIS.

(b) The proponent of a proposed action may use scoping during preparation of environmental review documents other than EIS, if desired. The proponent may use the above procedures or may develop modified procedures at his or her discretion.

Subpart H—Environmental Effects of Major Army Actions Abroad

§ 651.42 Introduction.

Protection of the environment is an Army priority, no matter where the installation is located. The Army is committed to pursuing an active role in addressing environmental quality issues in our relations with neighboring communities and assuring that consideration of the environment is an integral part of all decisions. This subpart assigns responsibilities for review of environmental effects abroad of major Army actions. It is a requirement of E. O. 12114, "Environmental Effects Abroad of Major Federal Actions," dated 4 January 1979. This chapter applies to HQDA and Army agencies' actions that would significantly affect the quality of the human environment outside the United States.

§ 651.43 Global commons.

Environmental effects of actions that affect the global commons require environmental analyses and documentation. (See enclosures 1 and 2 of DOD Directive 6050.7) (Appendices G and H.) These relate to environmental effects abroad of major military actions.

§ 651.44 Army policy in global commons and foreign nations.

(a) Act with care in the global commons. All the nations of the world share the stewardship of these areas. Take account of environmental considerations when acting in the global commons in accordance with the procedures set out in Appendix G.

(b) Act with care within the jurisdiction of a foreign nation. Respect treaty obligations and the sovereignty of other nations. Exercise restraint in applying U.S. laws within foreign nations unless Congress has expressly provided otherwise. Evaluate environmental considerations in accordance with Appendix H when the prepared action could affect the environment of a foreign nation.

(c) Coordinate with the Department of State on formal communications with foreign governments concerning environmental agreements and other formal arrangements with foreign governments. Consult with the Department of State regarding use of additional exemptions from this directive as specified in Appendix H. Coordinate and consult with the Department of State through the Assistant Secretary of Defense (International Security Affairs) (ASD (ISA)).

§ 651.45 Responsibilities.

(a) Army agencies that control actions abroad (as defined within the limitations of Status of Forces Agreements) will—

(1) Ensure that regulations and other major policy issuances receive a review by the Army Environmental Office for consistency with E.O. 12114, DOD Directive 6050.7, and this regulation.

(2) Consult with HQDA Strategy, Plans and Policy Directorate-Politico-Military Division (DAMO–SSM) on significant or sensitive actions or decisions affecting relations with other nations.

(3) Prepare and consider environmental documents for proposed actions required by this regulation.

(4) Ensure that regulations and other policies which affect global commons are subject to review for consistency with this regulation.

(5) Designate a single POC for matters regarding this regulation.

(b) The Assistant Secretary of the Army, Installation and Logistics (ASA (I&L)) will—

(1) Serve as the Secretary of the Army's responsible official for environmental matters abroad.

(2) Maintain liaison with the Assistant Secretary of Defense for Production and Logistics (ASD (P&L)) on matters concerning E.O. 12114, DOD Directive 6050.7, and this regulation.

(3) Coordinate actions with other Secretariat offices as appropriate.

(c) The Chief of Engineers will—

(1) Serve as ARSTAF proponent for implementation of E.O. 12114, DOD Directive 6050.7, and this regulation.

(2) Apply in planning and executing overseas construction activities where appropriate in light of applicable statutes and SOFAs.

(d) Deputy Chief of Staff for Organizations and Plans (DCSOPS) will—

(1) Serve as the focal point on the ARSTAF for integrating environmental considerations required by E.O. 12114 into Army plans and activities. Emphasis is on those reasonably expected to have widespread, long-term, and severe impacts on the global commons or the territories of foreign nations.

(2) Consult with the Office of Foreign Military Rights Affairs of Assistant Secretary of Defense (International Security Affairs) (ASD (ISA)) on significant or sensitive actions affecting relations with another nation.

(e) The Judge Advocate General (TJAG), in coordination with the Office of the General Counsel, will provide advice and assistance concerning the requirements of E.O. 12114 and DOD Directive 6050.7.

(f) The Chief of Public Affairs (CPA) will provide advice and assistance on public affairs as necessary.

§ 651.46 Implementation guidance.

(a) Environmental documents prepared under the provisions of this chapter should use the format for such documents found in Appendixes G and H. Otherwise, use a format appropriate in light of the applicable statutes and SOFAs.

(b) Submit nominations for inclusions in the list of CX through DAMO–SSM to the Army Environmental Office.

Appendix A—List of Categorical Exclusions (CX)

Section I: Categorical exclusions (CX)

A–1. Normal personnel, fiscal, and administrative activities involving military and civilian personnel (recruiting, processing, paying, and records keeping).

A–2. Law and order activities performed by military police and physical plant protection and security personnel, excluding formulation and/or enforcement of hunting and fishing policies or regulations that differ substantively from those in effect on surrounding non-Army lands.

A–3. Recreation and welfare activities not involving off-road recreational vehicle management.

A–4. Commissary and Post Exchange (PX) operations, except where hazardous material is stored or disposed.

A–5. Routine repair and maintenance of buildings, roads, airfields, grounds, equipment, and other facilities, to include the layaway of facilities, except when requiring application or disposal of hazardous or contaminated materials.

A–6. Routine procurement of goods and services, including rotine utility services.

A–7. Construction that does not significantly alter land use, provided the operation of the project when completed would not of itself have a significant environmental impact; this includes grants to private lessees for similar construction. (REC required.)

A–8. Simulated war games and other tactical and logistical exercises without troops.

A–9. Training entirely of an administrative or classroom nature.

A–10. Storage of materials, other than ammunition, explosives, pyrotechnics, nuclear, and other hazardous or toxic materials.

A-11. Operations conducted by established laboratories within enclosed facilities where—

a. All airborne emissions, waterborne effluents, external radiation levels, outdoor noise, and solid and bulk waste disposal practices are in compliance with existing Federal, State, local laws, and regulations.

b. No animals that must be captured from the wild are used as research subjects, excluding reintroduction projects. (REC required.)

A-12. Developmental and operational testing on a military installation, where the tests are conducted in conjunction with normal military training or maintenance activities so that the tests produce only incremental impacts, if any and provided that the training and maintenance activities have been adequately assessed, where required, in other Army environmental documents. (REC required.)

A-13. Routine movement of personnel; routine handling and distribution of nonhazardous and hazardous materials in conformance with DA, EPA, Department of Transportation, and State regulations.

A-14. Reduction and realignment of civilian and/or military personnel that fall below the thresholds for reportable actions as prescribed by statute or AR 5-10. (REC required).

A-15. Conversion of commercial activities (CA) to contract performance of services from in-house performance under the provisions of DOD Directive 4100.15.

A-16. Preparation of regulations, procedures, manuals, and other guidance documents that implement, without substantive change, the applicable HQDA or other federal agency regulations, procedures, manuals, and other guidance documents that have been environmentally evaluated.

A-17. Acquisition, installation, and operation of utility and communication systems, data processing, cable and similar electronic equipment that use existing rights of way, easements, distribution systems, and facilities.

A-18. Activities that identify or grant permits to identify, the state of the existing environment (for example, inspections, surveys, and investigations) without alteration of that environment or capture of wild animals.

A-19. Deployment of military units on a temporary duty (TDY) basis where existing facilities are used and the activities to be performed have no significant impact on the environment. (REC required.)

A-20. Grants of easements for the use of existing rights-of-way for use by vehicles; electrical, telephone, and other transmission and communication lines; transmitter and relay facilities; water, wastewater, stormwater, and irrigation pipelines, pumping stations, and facilities; and for similar public utility and transportation uses. (REC required.)

A-21 Grants of leases, licenses, and permits to use existing Army controlled property for non-Army activities, provided there is an existing land-use plan that has been environmentally assessed and the activity will be consistent with that plan. (REC required.)

A-22. Grants of consent agreements to use a Government-owned easement in a manner consistent with existing Army use of the easement; disposal of excess easement areas to the underlying fee owner. (REC required.)

A-23. Grants of licenses for the operation of telephone, gas, water, electricity, community television antenna, and other distribution systems normally considered as public utilities. (REC required.)

A-24. Transfer of real property administrative control within the Army, to another military department, or other Federal agency, including the return of public domain lands to the Department of Interior and reporting of property available for outgranting; and grants of leases, licenses, permits, and easements for use of excess or surplus property without significant changes in land use. (REC required.)

A-25. Disposal of uncontaminated buildings and other improvements for removal off-site. (REC required.)

A-26. Studies that involve no commitment of resources other than manpower. (REC required.)

A-27. Study and test activities within the procurement program for Military Adaptation of Commercial Items for items manufactured in the U.S. (REC required.)

A-28. Development of table organization and equipment documents, no fixed location or site.

A-29. Grants of leases, licenses, and permits to use DA property for or by another governmental entity when such permission is predicated upon compliance with the NEPA. (REC required.)

Section II: Screening Criteria

A-30. A CX is a category of actions that do not individually or cumulatively have a significant effect on the human environment and for which, therefore, neither an EA nor an EIS is required.

A-31. A CX may be used only when the criteria of paragraphs 4-1 and 4-2 have been applied and each of the following are true:

(a) This action is not a major federal action significantly affecting the quality of the human environment.

(b) There are minimal or no individual or cumulative effects on the environment as a result of this action.

(c) There is no environmentally controversial change to existing environmental conditions.

(d) There are no extraordinary conditions associated with this project.

(e) This project does not involve the use of unproven technology.

(f) This project involves no greater scope or size than is normal for this category of action.

(g) There is no potential of an already poor environment being further degraded.

(h) This action does not degrade an environment that remains close to its natural condition.

(i) There are no threatened or endangered species (or critical habitat), significant archaeological resources, National Registered or National Register eligible historical sites, or other statutorily protected resources.

(j) This action will not adversely affect prime or unique agricultural lands, wetlands, coastal zones, wilderness areas, aquifers floodplains, wild and scenic rivers, or other areas of critical environmental concern.

Appendix B—References

Section I

Required Publications

AR 360-5
Army Public Affairs, Public Information.

Section II

Related Publications

A related publication is merely a source of additional information. The user does not have to read it to understand the regulations.

AR 5-10
Reduction and Realignment Actions.
AR 11-27
Army Energy Program.
AR 95-50
Airspace and Special Military Operation Requirements.
AR 140-475
Real Estate Selection and Acquisition: Procedures and Criteria.
AR 200-1
Environmental Protection and Enhancement.
AR 210-10
Administration.
AR 210-20
Master Planning for Army Installations.
AR 335-15
Management Information Control System.
AR 380-5
Department of the Army Information Security Program.
AR 385-10
Army Safety Program.
AR 420-40
Historic Preservation.
AR 530-1
Operations Security (OPSEC).
DODD 4100.15
Commercial Activities Programs.
DODD 6050.1
Environmental Effects in the United States of Department of Defense Actions.
DODD 6050.7
Environmental Effects Abroad of Major Department of Defense Actions.

Section III

Related Form

DD Form 1391
Military Construction Project Data.

Appendix C—National Environmental Policy Act

(42 U.S.C. 4321 *et seq.*)

Appendix D—Contents of the Environmental Impact Statement (EIS)

D-1. Cover Sheet

The cover sheet will not exceed one page (40 CFR 1502.11) and will include—

(a) A cover sheet preceded by a protective cover sheet that contains the following statement: "The material contained in the attached (final or draft) Environmental Impact Statement is for internal coordination use only and may not be released to non-Department of Defense Agencies or

individuals until coordination has been completed and the material has been cleared for public release by appropriate authority." This sheet will be removed prior to filing the document with EPA.

(b) A list of responsible agencies including the lead agency and any cooperating agency.

(c) The title of the proposed action that is the subject of the statement and, if appropriate, the titles of related cooperating agency actions, together with State and county (or other jurisdiction as applicable) where the action is located.

(d) The name, address, and telephone number of the person at the agency who can supply further information, and, as appropriate, the name and title of the major approval authority in the command channel through HQDA staff proponent.

(e) A designation of the statement as a draft, final, or draft or final supplement.

(f) A one-paragraph abstract of the statement that should describe only the need for the proposed action, alternative actions, and the significant environmental consequences of the proposed action and alternatives.

(g) The date by which comments must be received, computed in cooperation with the EPA. (See example cover sheet, Figure D-1.)

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LEAD AGENCY: Department of the Army, TRADOC.

COOPERATING AGENCY(IES): (if any) U.S. Forest Service, U.S. Department of Agriculture.

TITLE OF THE PROPOSED ACTION: Development of training area, Fort Pleasant, Maryland.

AFFECTED JURISDICTION: State of Maryland; Smith, Taylor, and Jones Counties.

PREPARER/PROPONENT APPROVED (OR REVIEWED BY): Name, address and telephone number, name and title of proponent. (i.e., Installation Commander or program manager).

REVIEWED BY: Name and title of the environmental coordinator

APPROVED BY: Name and title of any intermediate proponent (i.e., MACOM commander); Name and title of Army Staff proponent (i.e., Director of program affected by EIS).

ABSTRACT: One paragraph summary.

REVIEW COMMENT DEADLINE: (Computed in cooperation with EPA guidance).

Figure D-1. Example cover sheet

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D-2. Summary

The summary will stress the major conclusions of environmental analysis, areas of controversy, and issues yet to be resolved. It should list all Federal permits, licenses, and other entitlements that must be obtained prior to proposal implementation. Further, a statement of compliance with the requirements of other Federal environmental protection laws will be included (40 CFR 1502.25).

In order to simplify consideration of complex relationships, every effort will be made to present the summary of alternatives and their impacts in a graphic format with the narrative. This summary should not exceed 10 pages.

D-3. Table of Contents

This section will provide for the table of contents, list of figures and tables, and a list of all referenced documents, including a bibliography of references within the body of the EIS. The table of contents should have enough detail so that searching for sections of text is not difficult.

D-4. The Purpose of and Need for the Action

This section should clearly state the nature of the problem and discuss how the proposed action or range of alternatives would solve the problem. This section is designed specifically to call attention to the benefits of the proposed action. If a cost-benefit analysis has been prepared for the proposed action, it may be included here, or attached as an appendix and referenced here. This section will briefly give the relevant background information on the proposed action and summarize its operational, social, economic, and environmental objectives.

D-5. Alternatives Considered

This section presents all reasonable alternatives and their environmental impacts. An examination of each specific proposal in clear terms is required. This section should be written in simple, nontechnical language for the lay reader. A no action alternative will be included (40 CFR 1502.14(d)). For actions other than construction, the term no action is often misleading because a continuation of the status quo is implicit. This section needs no examination of the status quo. A preferred alternative need not be identified in the DEIS; however, a preferred alternative generally must be included in the FEIS (40 CFR 1502.14(e)).

A simple title or a letter or numerical symbol may be used for each of the discussed alternatives (for example, alternative A). Reference to the title or designation will be continued uniformly throughout the document in the appropriate sections. The environmental impacts of the alternatives will be presented in comparative form, thus sharply defining the issues and providing a clear basis for choice among the options that are provided the decisionmaker and the public (40 CFR 1502.14). The information should be summarized in a brief, concise manner. The use of tabular or matrix format is encouraged to provide the reviewer with an at-a-glance review. In sum, the following points are required:

(a) A description of all reasonable alternatives including the preferred action, alternatives beyond DA jurisdiction (40 CFR 1502.14(c)), and the no action alternative.

(b) A comparative presentation of the environmental consequences of all reasonable alternative actions including the preferred alternative.

(c) A description of the mitigation measures nominated for incorporation into the proposed action and alternatives, as well as mitigation measures that are available but not incorporated.

(d) Listing of any alternatives that were eliminated from detailed study. A brief discussion of the reasons for which each alternative was eliminated.

D-6. Affected Environment

This section will contain information about existing conditions in the affected areas necessary to understand the potential effects of the alternatives under consideration (40 CFR 1502.15). Environments created by the implemented proposal will be included as appropriate. Affected elements could include, for example, biophysical characteristics (ecology and water quality); land use and land use plans; architectural, historical, and cultural amenities; utilities and services; and transportation. This section will not be encyclopedic. It will be written clearly and the degree of detail for all points covered will be related to the significance and magnitude of expected impacts. Elements not impacted by any of the alternatives need only be presented in summary form or referenced.

D-7. Environmental and Socioeconomic Consequences

This section of the EIS forms the scientific and analytic basis for the summary comparison of effects discussed in D-5. The following will be discussed (40 CFR 1502.16):

(a) Direct effects and their significance. Include in the discussion the direct impacts on human health and welfare and on other forms of life and related ecosystems. Examples of direct effect might include noise from military helicopter operations or the benefits derived from the installation of wet scrubbers to meet air quality control standards.

(b) Indirect effects and their significance. Include here socioeconomic impacts. Many Federal actions attract people to previously unpopulated areas and indirectly induce pollution, traffic congestion, and haphazard land development. Conversely, other actions may disperse the existing population. Aircraft noise often affects future development patterns, and air pollution abatement operations may result in secondary water pollution problems.

(c) Possible conflicts between the proposed actions and Federal, regional, State, and local (including indian tribe) land and airspace use plans, policies, and controls for the area concerned. Compare the land use aspects of the proposed action and discuss possible conflicts, such as siting an extremely noisy activity adjacent to a residential area, leasing land for purposes inconsistent with State wildlife management, or creating conflicts with prime and unique farmland policies.

(d) The environmental effects of alternatives, including the proposed action.

(1) Impacts of the alternatives, including a worst case analysis where there are gaps in relevant information or scientific uncertainty.

(2) Adverse environmental effects that cannot be avoided should the proposal be implemented. Include the relationship between short-term uses of the human environment and the maintenance and enhancement of long-term productivity. The section should discuss the extent to which the proposed action and its alternatives involve short-term vs. long-term environmental gains and losses. In this context, short-term and long-term do not refer to any rigid time period and should be viewed in terms of the environmentally significant consequences of the proposed action. Thus, short-term can range from a very short period of time during which an action takes place to the expected life of a facility.

(e) Energy requirements and conservation potential of various alternatives and mitigation measures. Consult the Energy Resource Impact Statement (AR 11-27), when applicable, to satisfy this requirement. Account for the energy consumption of each proposed alternative and associated economics. Discuss, where appropriate, the uses of renewable and nonrenewable energy resources. Conservation techniques that could attenuate energy consumption should also be discussed within this section; for example, the use of insulation for newly constructed family housing that would reduce the long-term consumption of fuel oil or natural gas.

(f) Natural or depletable resource requirements and conservation potential of various mitigation measures. Include discussion of any irreversible or irretrievable commitments of resources that would be involved in the proposal should it be implemented. The term resources should include—

(1) Materials. Discuss materials in short supply such as metals and wood, but do not include materials that are plentiful or have competitive alternatives (for example, aggregate or fill materials).

(2) Natural. Discuss the use of natural resources resulting in irrevocable effects such as ecosystem imbalance, destruction of wildlife, loss of prime and unique farmlands. Specifically include consumption of natural energy resources in short supply, such as oil or natural gas.

(3) Cultural. Discuss destruction of human interest sites, archaeological and historical, scenic views or vistas, or valued open space. Reiterate lasting socioeconomic effects the proposed action might have on the surrounding community.

(g) Urban quality, historic and cultural resources, and the design of the built environment, including reuse and conservation potential of various alternatives and mitigation measures. Discuss the effect on adjacent neighborhoods and the city at large. Examine the effects on physical design features (also known as the built environment) and resultant impacts on social interaction areas such as privacy, public opinion, personnel perceptions, and other aspects of the social environment. Review the

reuse potential of existing building space and its time-use allocation, usually referred to as time and spatial management. (Time and spatial management allows for conservation of energy and other resources by discouraging new construction and operation until all existing building and time allocations have been fully scrutinized for alternate reuse.)

(h) Means to mitigate adverse environmental effects. Include mitigation not already included as part of the various alternatives. Also, specify migitations that require action by other agencies or outside parties.

D-8. List of Preparers

The EIS will list the names of its preparers, together with their qualifications (expertise, experience, and professional disciplines.) (40 CFR 1502.17). Include those people who were primarily responsible for preparing (research, data collection, and writing) the EIS or significant background or support papers, and basic components of the statement. When possible, the people who are responsible for a particular analysis, as well as an analysis of background papers, will be identified. If some or all of the preparers are contractors' employees, they may be identified as such. Identification of the firm that prepared the EIS is not, by itself, adequate to meet the requirements of this point. Normally, the list will not exceed two pages.

D-9. Distribution List

For the DEIS, a list will be prepared indicating from whom review and comment is requested. The list will include public agencies and private parties or organizations. The FEIS will normally only list those who have commented or shown an interest in the proposed action.

D-10. Index

The index will be an alphabetical list of topics in the EIS, especially of the types of effects induced by the various alternative actions. Reference may be made to either page number or paragraph number.

D-11. Appendices

If an agency prepares an appendix to an EIS, the appendix will—

(a) Consist of material prepared in connection with an EIS (as distinct from material that is not so prepared and incorporated by reference).

(b) Consist only of material that substantiates any analysis fundamental to an impact statement.

(c) Be analytic and relevant to the decision to be made.

(d) Be circulated with the EIS or readily available upon request.

Appendix E—Council on Environmental Quality (CEQ) Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act (NEPA)

(40 CFR Parts 1500-1508)

Appendix F—Implementing a Monitoring and Methodology Program [1]

F-1. Mitigation

(a) The 1978 CEQ regulations for implementing NEPA recognizes the following five means of mitigating an environmental impact:

(1) Avoiding the impact altogether by not taking a certain action or parts of an action.

(2) Minimizing impacts by limiting the degree or magnitude of the action and its implementation.

(3) Rectifying the impact by repairing, rehabilitating, or restoring the effect on the environment.

(4) Reducing or eliminating the impact over time by preservation and maintenance operations during the life of the action.

(5) Compensating for the impact by replacing or providing substitute resources or environments (40 CFR 1508.20).

(b) The intention of mitigation is to reduce the effects of the action on the environment. The five means of mitigation (see (a), above) are discussed in (1) through (5) below.

(1) Avoidance. This method avoids environmental impact by not performing certain activities; for example, allowing tracked vehicles to cross only at designated improved stream crossings. This restriction would reduce the effects on a stream resulting from random access, such as increased turbidity caused by bank erosion and bottom disturbance caused by the tracks.

(2) Limitation of action. The extent of an impact can be reduced by limiting the degree or magnitude of the action; for example, changing the firing time or the number of rounds fired on artillery ranges to reduce the noise impact on nearby residents. In the example in (a) above, the number of authorized stream crossings would have been limited or minimized.

(3) Restoration of the environment. This method restores the environment to its previous condition or better. Movement of troops and vehicles across vegetated areas often destroys vegetation. This impact can be mitigated by either reseeding or replanting the areas with native plants after the exercise.

(4) Preservation and maintenance operations. This method designs the action so as to reduce adverse environmental effects. Examples include maintaining erosion control structures, using air pollution control devices, and encouraging car pools in order to reduce transporation effects such as air pollution, energy consumption, and traffic congestion.

(5) Replacement. This method replaces the resource or environment that will be impacted by the action. Replacement can occur in-kind or otherwise; for example, replace deer habitat in the project area with deer habitat in another area; or, replace fisheries habitat with deer habitat. This replacement can occur either on the site of impact or at another location. This type of mitigation is often used in water resources projects. For example, if an action were destroying some of the installation's best deer habitat, a potential mitigation would be developing another section of the installation into deer habitat. This is an example of an in-kind replacement at a different site.

F-2. Identification of Mitigation Techniques

(a) Introduction. Identifying and evaluating mitigation techniques involves using experts familiar with the predicted environmental impacts. A single mitigation measure will often alleviate several different impact.

(b) Sources of information. Many potential sources of information exist concerning the mitigation of various environmental effects. The following sources of information are available on post: Other sources are as follows:

(1) Within the DA, there are sources such as the Army Environmental Hygiene Agency (AEHA), the major Army command (MACOM) environmental office, the Army Environmental Office, U.S. Army Corps of Engineers (USACE) research laboratories (for example, U.S. Construction Engineering Research Laboratory [USA-CERL], U.S. Army Waterways Experiment Station, and U.S. Cold Regions Research Laboratory), USACE Huntsville Division, and the military assistance offices in certain districts.

(2) State agencies are another potential source of information. The appropriate POC within these agencies may be obtained from the installation environmental office.

(3) Another source is directories such as USA-CERL Technical Report N-40,[2] as discussed in Engineering Technical Note 79-6.[3]

(4) Another source on mitigation procedures is Ramifications/Mitigation statements from USA-CERL's Environmental Impact Computer System (EICS).[4]

(5) Local interest groups may also be able to help identify potential mitigation measures.

(c) Example mitigation techniques. Several different mitigation techniques have been used on military installations for a number of years. The following examples illustrate the variety of possible measures:

(1) There are maneuver restrictions in areas used extensively for tracked vehicle training. These restrictions are not designed to infringe on the military mission, but rather to reduce the amount of damage to the training area.

(2) Aerial seeding has been done on some installations to reduce erosion problems.

(3) Changing the time and/or frequency of operations has been used. This may involve changing the season of the year, the time of day, or even day of the week for various activities. This avoids noise impacts as well

[1] From: John Fittipaldi, et al., Handbook for Environmental Impact Analysis and Planning, Technical Report N-130, U.S. Army Construction Engineering Research Laboratory (USA-CERL), October 1982, pp. 133-143.

[2] R. Lacey, et al., Compendium of Administrators of Land Use and Related Programs, Technical Report N-40/ADA057226 (USA-CERL July 1978).

[3] Coordination with Federal and State Land Use Agencies, Engineer Technical Note 76-6 (Department of the Army (DA), 8 February 1979).

[4] L. V. Urban, et al., Computer-aided Environmental Impact Analysis for Construction Activities; User Manual, Technical Report E-50/ADA008988 (USA-CERL, March 1975).

as aesthetic, transportation, and some ecological problems.

(4) Reducing the effects of construction has involved using techniques that keep heavy equipment away from protected trees and quickly reseeding areas after construction.

(d) Mitigation alternatives. Consideration of all practical mitigation alternatives are considered. The emphasis is not on what can be theoretically accomplished, but on what can be accomplished for each alternative.

(1) Practical mitigations are those that the proponent can accomplish with the project's constraints such as manpower and money. Practical measures must be defined at the installation level; what may be practical on one post or at one time may not be practical on another. A number of items determine what is practical, including military mission, manpower restrictions, cost, institutional barriers, technical feasibility, and public acceptance. Practicality does not necessarily ensure resolution of conflicts among these items, rather it is the degree of conflict that determines practicality.

(2) The previous examples involved some amount of conflict in all these areas. Although mission conflicts are inevitable, they are not insurmountable. Therefore, the proponent should be cautious about declaring all mitigations impracticable and should carefully consider any manpower requirements. This may be a greater restriction than military mission conflicts.

(3) There is no standard rule of thumb applicable to mitigation activities. The key point concerning both the manpower and cost constraints is that unless money is actually budgeted and manpower assigned, the mitigation does not exist. This will require coordination by the proponent office early in the process to allow enough time to get the mitigation activities into the budget cycle. If the mitigation is not funded on schedule with the action, the action can be judicially stopped.

(4) Mitigations that do not fall directly within the definition of practical must still be considered, including those to be accomplished by other agencies. The proponent must coordinate with these agencies so that they can plan to obtain the necessary manpower and funds. Mitigations that were considered but rejected must be discussed, along with the reason for the rejection, within the EIS.

F-3. Monitoring

Monitoring is an integral part of any mitigation system and a way to examine an enviromental mitigation. The two basic types of monitoring are as follows:

(a) Enforcement monitoring. Enforcement monitoring ensures that mitigation is being performed as described in the environmental document and ensuring that mitigation requirements and penalty clauses are written into any contracts. It also includes ensuring that these provisions are enforced. Before mitigation can take place on-post, it must be budgeted, scheduled, and the necessary manpower must be assigned. Any changes required in post regulations must be completed and enforced. The actual mitigation (for example, aerial seeding of a training area) must be performed. Enforcement monitoring involves the monitoring of all these activities.

(b) Effectiveness monitoring. Effectiveness monitoring measures the success of the mitigation effort and/or the environmental effect. This must be a scientifically based quantitative investigation. Generally, qualitative measurements are not acceptable. However, it is not necessary to measure everything that may be affected by the action, only enough information to judge the method's effectiveness.

F-4. Establishing a Monitoring System

Establishment of a monitoring system must involve all appropriate offices that will be involved in its implementation. When evaluating several different potential monitoring systems, the ability to perform the monitoring is the most critical factor. This means that manpower—both on post and outside expertise—must be available. Sufficient funds must also be available for the monitoring process. Figures F-1 through F-3 illustrate the steps in establishing a monitoring system. Figure F-1 is designed to help select the type of monitoring system needed. Figure F-2 shows the responsibilities of the lead agency in establishing an enforcement monitoring program. Figure F-3 illustrates the steps necessary to establish an effectiveness monitoring program.

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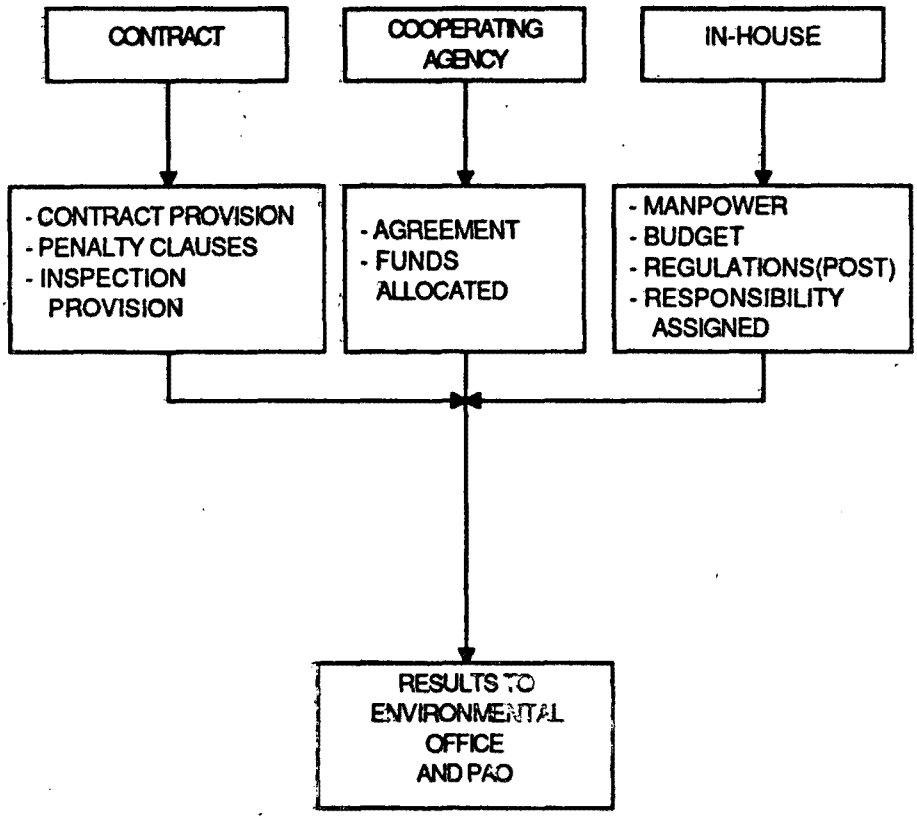

Figure F-1. Monitoring mitigations

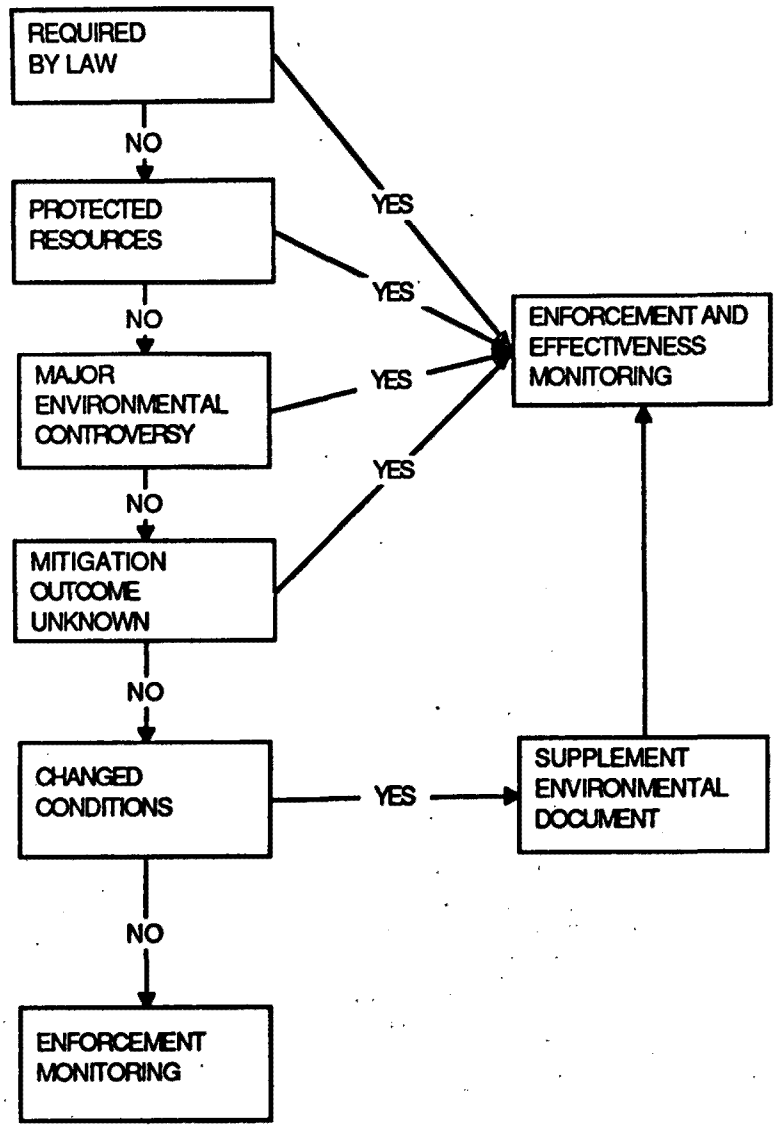

Figure F-2. Enforcement monitoring

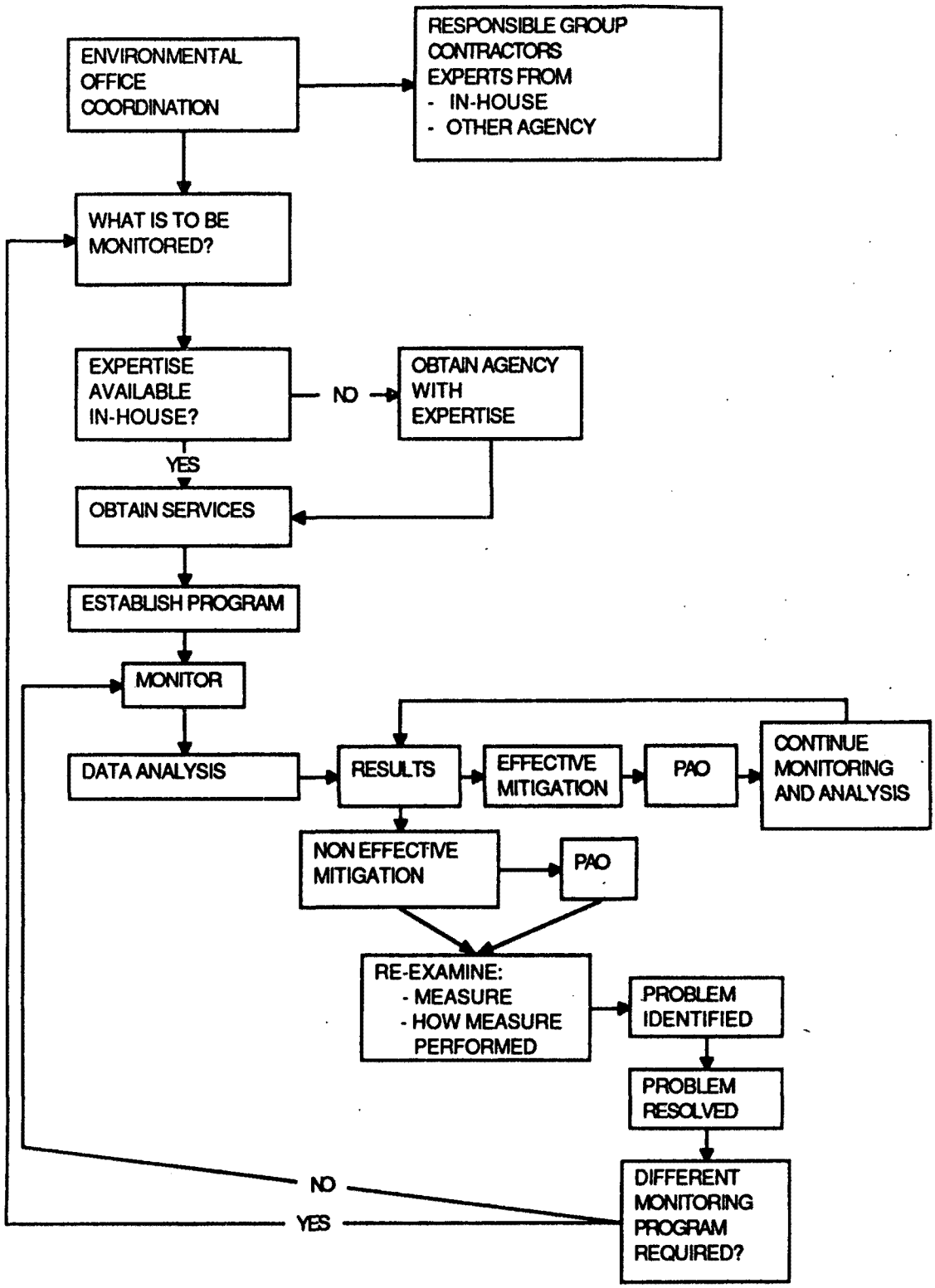

Figure F-3. Effectiveness monitoring

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F-5. Type of Monitoring Program

AR 200-1 and other laws and regulations help determine the types of monitoring program. There are five basic considerations for monitoring programs (Figure F-1):

(a) Legal requirements. Permits for some actions will require that a monitoring system be established, for example, dredge and fill permits from the Corps of Engineers. These will generally require both enforcement and effectiveness monitoring programs.

(b) Protected resources. These include Federal- or State-listed endangered or threatened species, important historic or archaeological sites (whether or not these are included on the National Register of Historic Places), wilderness areas, wild and scenic rivers, and other public or private protected resources. Private protected resources include areas such as Audubon Society Refuges, Nature Conservancy lands, or any other land that would be protected by law if it were under Government ownership, but is privately owned. If any of these resources are affected, an effectiveness and enforcement monitoring program must be undertaken in conjunction with the Federal, State, or local agency that manages the type of resource.

(c) Major environmental controversy. If a controversy remains regrading the effect of an action or the effectiveness of a mitigation, an enforcement and effectiveness monitoring program must be undertaken. Controversy includes not only scientific disagreement about the mitigation's effectiveness, but also public interest or debate.

(d) Mitigation outcome. The probability of the mitigation's success must be carefully considered. The proponent must know if the mitigation has been successful elsewhere. The validity of the outcome should be confirmed by expert opinion. However, the proponent should note that a certain technique, such as artificial seeding with the natural vegetation, that may have worked successfully in one area, may not work in another.

(e) Changed conditions. The final consideration is whether any condition, such as the environmental setting, have changed (for example, a change in local land use around the area, or a change in project activities, such as increased amount of acreage being used or an increased movement of troops). Such changes will require preparation of a supplemental impact evaluation and additional monitoring. If none of these conditions are met (that is, requirement by law, protected resources, no major controversy is involved, effectiveness of the mitigation is known, and the environmental or project conditions have not changed), then only an enforcement monitoring program is needed. Otherwise, both an enforcement and effectiveness monitoring program will be required.

F-6. Enforcement Monitoring Progam Development

The development of an enforcement monitoring program is governed by who will actually perform the mitigation (Figure F-2). The following three different groups may actually perform the work: a contractor, a cooperating agency, or a lead agency (in-house). However, the lead agency is ultimately responsible for performing any mitigation activities.

(a) Contract performance. Several provisions must be made in work to be performed by contract. The lead agency must ensure that contract provisions include the performance of the mitigation activity and that penalty clauses are written into the contracts. It must provide for timely inspection of the mitigation measures and is responsible for enforcing all contract provisions.

(b) Cooperating agency performance. The lead agency must ensure that if a cooperating agency performs the work, it understands its role in the mitigation. The lead agency must determine and agree upon how the mitigation measures will be funded. It must also ensure that any necessary formal paperwork such as cooperating agreements are complete.

(c) Lead agency performance. If the lead agency performs the mitigation, the proponent has several responsibilities to—

(1) Ensure that needed tasks are performed.

(2) Provide appropriate funding in the project budget.

(3) Make arrangements for necessary manpower allocations.

(4) Make any necessary changes in the agency (installation) regulations (such as, environmental or range regulations).

(d) Results. In any case, whether the mitigation is performed by contract, a cooperating agency, or the lead agency, all results will be sent to the Public Affairs Office and the Environmental Office on post.

F-7. Effectiveness Monitoring Program Development

Effectiveness monitoring is the most difficult to establish (Figure F-3). The responsible agent, such as the Director of Training, should coordinate the monitoring with the Environmental Office.

(a) Determination of what is to be monitored. The first step in this type of monitoring program is to determine what must be monitored. This determination should be based on criteria discussed during the establishment of the system; for example, the legal requirements, protected resources, area of controversy, known effectiveness, or changed conditions. Initially, this can be a very broad statement, such as reduction of impacts on a particular stream by a combination of replanting, erosion control devices, and range regulations.

(b) Finding expertise. The next step is finding the expertise necessary to establish the monitoring system. The expertise may be available on-post; Table F-1 lists potential sources on a military installation. If it is not available, it must be obtained from an outside source. Directories such as USA-CERL Technical Report N-40 [5] may provide the needed information. In addition, local universities may have specialists and local interest groups who can identify experts within a particular field. This may be particularly helpful if a mitigation is considered controversial.

(c) Establishment of a program. After a source of expertise is located, the program can be established, using the following five technical criteria:

(1) Any parameters used must be measurable; for example, the monitor must be quantitative and statistically sound.

(2) A baseline study must be completed before the monitoring begins in order to identify the actual state of the system prior to any disturbance.

(3) The monitoring system must have a control, so that it can isolate the effects of the mitigation procedures from effects originating outside the action.

(4) The system's parameters and means of measuring them must be replicable.

(5) Parameter results must be available in a timely manner so that the decisionmaker can take any necessary corrective action before the effects are irreversible.

Table F-1. Potential Monitoring and Mitigation Expertise

Ecology
- Installation Environment Specialist
- Installation Wildlife Officer
- Installation Forester
- Installation Natural Resource Committee
- Corps District Environmental Staff

Health and Safety
- Installation Preventive Medicine Officer
- Installation Safety Officer
- Installation Hospital
- Installation Mental Hygiene or Psychiatry Officer
- Chaplain's Office

Air Quality
- Installation Environmental Specialist
- Installation Preventive Medicine Officer

Water Quality
- Installation Environmental Specialist
- Installation Preventive Medicine Officer
- Corps District Environmental Staff

Socioeconomic
- Personnel Office
- Public Information Officer
- Corps District Economic Planning Staff

Earth Science
- Installation Environmental Specialist
- Corps District Geotechnical Staff

Land Use Impacts
- Installation Master Planner
- Corps District Community Planners

Noise
- Preventive Medicine Officer
- Directorate of Engineering and Housing
- Installation Master Planner

[5] R. Lacey, et al., Compendium of Administrators of Land Use and Related Programs, Technical Report N-40/ADA052226 (USA-CERL, 1978).

Table F-1. Potential Monitoring and Mitigation Expertise—Continued

Aesthetics
- Installation Landscape Architect
- Corps District Landscape Architects

Energy and Resource Conservation
- Installation Environmental Specialist

Historic and Archaeological Resources
- Installation Environmental Specialist
- Installation Historian or Architect
- Corps District Archaeologist

Airspace
- Installation Air Traffic and Airspace Officers
- Department of the Army Regional Representative to the Federal Aviation Administration
- Department of the Army Aeronautical Services Office
- Military Airspace Management System (MAMS)
- Installation Range Control Officer

(d) Program management. There are several program management considerations. First, not every mitigation has to be monitored separately. The effectiveness of several mitigation actions can be determined by one measurable parameter. For example, the turbidity measurement from a stream can include the combined effectiveness of mitigation actions such as reseeding, maneuver restrictions, and erosion control devices. However, if a method combines several parameters and a critical change is noted, each mitigation measurement must be examined to determine the problem.

(e) Initiation of program. The next step is to initiate the monitoring program. In most cases, a monitor should be established well before the action begins, particularly when biological variables are being measured and investigated. At this stage, any necessary contracts, funding, and manpower assignments must be initiated.

(f) Sample collection, data analysis, and coordination. The next step in the monitoring program is sample collection and data analysis. A nontechnical summary of the data analysis should be provided to the Public Affairs Office, which will handle routine information requests related to the program. Technical results from the analysis should be sent to the installation environmental office, which will coordinate them with the proponent. Other related coordination with the concerned public and other agencies, as arranged through development of the mitigation plan, will be handled through the environmental office.

(g) Continuation of program.

(1) If the mitigations are effective, the monitoring should be continued. However, even if a noneffective result is obtained, a nontechnical summary should still be sent to the Public Affairs Office. The Environmental Office and the responsible group should reexamine the mitigation measures with the experts. The problem may be either inadequacy of the mitigation measure, in the performance, or in the monitoring.

(2) Once the problem is identified, the responsible group and the experts should determine whether more detailed information is needed, whether the monitoring is being implemented incorrectly, or whether the mitigation is inadequate.

(3) After the problem is resolved, the group must determine whether a different monitoring system should be established. If the old program is adequate, it should be continued; however, if a different program is required, then a new system must be established.

Appendix G—Requirements for Environmental Considerations—Global Commons

(Refer to Department of Defense, Final Procedures, 32 CFR Part 197, Enclosure 1.)

Appendix H—Requirements for Environmental Considerations—Foreign Nations and Protected Global Resources

(Refer to Department of Defense, Final Procedures issued April 12, 1979 (44 FR 21786), 32 CFR Part 197, Enclosure 2. Adopted herewith except that references to the Assistant Secretary of Defense (Manpower, Reserve Affairs, and Logistics) are changed to Assistant Secretary of Defense (Production and Logistics).)

Appendix I—Glossary

Section I

Abbreviations

ARNG
Army National Guard
ARSTAF
Army Staff
ASA (I&L)
Assistant Secretary of the Army (Installations and Logistics)
CEQ
Council on Environmental Quality
CERCLA
Comprehensive Environmental Response Compensation and Liability Act
CX
Categorical exclusions
DA
Department of the Army
DEIS
Draft Environmental Impact Statement
DESOH
Deputy of Environment, Safety, and Occupational Health
DOD
Department of Defense
EA
Environmental assessment
EIS
Environmental Impact Statement
EPA
Environmental Protection Agency
FEIS
Final Environmental Impact Statement
FNSI
Finding of No Significant Impact
FR
Federal Register
FS
Feasibility study
HQDA
Headquarters, Department of Army
I&L
Installation and logistics
MACOM
Major Army command
NEPA
National Environmental Policy Act
NOA
Notice of availability
NOI
Notice of Intent
OASA (I&L)
Office of the Assistant Secretary of the Army, (Installation and Logistics)
OCLL
Office of the Chief of Legislative Liaison
OCPA
Office of the Chief of Public Affairs
OSD
Office of the Secretary of Defense
POC
Point of contact
REC
Record of environmental consideration
ROD
Record of decision
SARA
Superfund Amendments and Reauthorization Act
SOFA
Status of Forces Agreement

Section II

Terms

Categorical exclusion (CX)

A category of actions that do not require an EA or an EIS because DA has determined that the actions do not have an individual or cumulative impact on the environment. (Refer to Subpart D for further discussion.)

Closure of a majority installation

(Except where the only significant impacts are socioeconomic with no significant biophysical environmental impact). "Majority military installation" is defined in chapter 2 of "Department of Defense Base Structure Report" as "A contiguous parcel of land with facilities and improvements thereon having a command and control organization providing a full range of BASOPS (base operations) functions in support of assigned missions." Compare with the definition of a "minor installation," which is "under the command of and receives resources support from the commander of another installation which is geographically distant."

Foreign government

A government regardless of recognition by the United States, political factions, and organizations that exercises governmental power outside the United States.

Foreign nations

Any geographic area (land, water, and airspace) that is under the jurisdiction of one or more foreign governments. It also refers to any area under military occupation by the United States alone or jointly with any other foreign government. Includes any area that is the responsibility of an international organization of governments also includes contiguous zones and fisheries zones of foreign nations.

Global commons

Geographical areas outside the jurisdiction of any nation. They include the oceans outside territorial limits and Antarctica. They do not include contiguous zones and fisheries zones of foreign nations.

HQDA proponent

As the principal planner, implementer, and decision authority for a proposed action, the HQDA proponent is responsible for the substantive review of the environmental documentation and its thorough consideration in the decisionmaking process.

Major Federal action

Reinforces, but does not have a meaning independent of, "significantly affecting the environment," and will be interpreted in that context. A Federal proposal with "significant effects" requires an environmental impact statement, whether it is "major" or not. Conversely, a "major federal action" without "significant effects" does not necessarily require an EIS.

Preparers

Personnel from a variety of disciplines who write environmental documentation in clear and analytical prose. They are primarily responsible for the accuracy of the document.

Proponent

Proponent identification is dependent on the nature and scope of a proposed action as follows:

(1) Any Army structure may be a proponent. For instance, the installation/activity Facility Engineer (FE)/Director of Engineering and Housing becomes the proponent of installation-wide Military Construction Army (MCA) and Operations and Maintenance (O&M) Activity; Commanding General, U.S. Army Training and Doctrine Command (TRADOC) becomes the proponent of a change in initial entry training. The proponent may or may not be the preparer.

(2) In general, the proponent is the lowest level decisionmaker. It is the unit, element, or organization that is responsible for initiating and/or carrying out the proposed action. The proponent has the responsibility to prepare and/or secure funding for preparation of the environmental documentation.

Significantly affecting the environment

An action, program or project that would violate existing pollution standards; cause water, air, noise, soil or underground pollution; impair visibility for substantial periods of any day; cause interference with the reasonable peaceful enjoyment of property or use of property; create an interference with visual or auditory amenities; limit multiple use management programs for an area; cause danger to the health, safety, or welfare of human life; or cause irreparable harm to animal or plant life in an area. Significant beneficial effects also do occur and must be addressed if applicable. (See 40 CFR 1508.27.)

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federal register

Wednesday
November 16 1988

Part VIII

Environmental Protection Agency

Federal Agency Hazardous Waste Compliance Docket; First Six-Month Update of List of Federal Facilities and Revision to Initial List

ENVIRONMENTAL PROTECTION AGENCY

[FRL-3468-5]

Federal Agency Hazardous Waste Compliance Docket

AGENCY: Environmental Protection Agency.

ACTION: First six-month update of list of Federal facilities under CERCLA Section 120(c) and revisions to initial list.

SUMMARY: Section 120(c) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), requires the Environmental Protection Agency (EPA) to establish a Federal Agency Hazardous Waste Compliance Docket that contains certain information regarding Federal facilities that manage hazardous waste or have potential hazardous waste problems. CERCLA requires that the docket be updated every six months as new facilities are reported to EPA by Federal agencies. The following list identifies the Federal facilities to be included in the first six-month update of the docket. For each Federal facility that appears on the docket, the responsible Federal agency must complete, at a minimum, a Preliminary Assessment (PA) and, if warranted, a Site Inspection (SI) to determine if response actions are necessary. In addition to the update list, this notice includes a section comprising revisions to the initial list published earlier. At the time of publication of this notice, the new total number of Federal facilities listed on the docket is 1,170.

DATE: This list is current as of October 3, 1988.

FOR FURTHER INFORMATION CONTACT: Federal Facilities Docket Hotline, Telephone: (800) 548-1016 toll-free.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Revisions to the Initial Docket
III. Process for Compiling the Updated Docket
IV. Facilities Not Included
V. Information Contained on Docket Listing

I. Introduction

The Federal Agency Hazardous Waste Compliance Docket ("docket") was required to be established under Section 120(c) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), 42 U.S.C. 9620(c), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA). The docket contains information on Federal facilities that is submitted by Federal agencies to the U.S. Environmental Protection Agency ("EPA" or "the Agency") under sections 3005, 3010, and 3016 of the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6925, 6930, and 6937, and under Section 103 of CERCLA. The purpose of the docket is three-fold: (1) to identify the universe of Federal facilities that must be evaluated to determine if they pose risk to public health and the environment sufficient to warrant a response action and/or inclusion on the National Priorities List; (2) to compile and maintain the information submitted to EPA on these facilities under the provisions listed in Section 120(c) of CERCLA; and (3) to provide a mechanism to make this information available to the public.

The initial list of Federal facilities to be included in the docket was published on February 12, 1988 (53 FR 4280). This list must be updated every six months, beginning with the publication of the February notice, to include new facilities on the docket that are subsequently reported to EPA by Federal agencies. The first six month update of the docket is being published today. The definition of facility for docket purposes remains unchanged from that employed for the initial docket list (see 53 FR 4280 (1988)).

Today's notice is divided into two major sections: "Docket Revisions" and "Docket Update". The Docket Revisions section is a listing of corrections that are being made to the initial docket published on February 12, 1988. The Docket Update section is the list of newly identified facilities that have been reported to EPA since the compilation of the initial docket.

The information submitted to EPA on each Federal facility, as required by the above provisions, is contained in docket repositories located in the EPA Regional office where the facility is found. (See 53 FR 4280 (1988) for a description of the information required under these provisions.) All docket repositories are currently operational and available to the public. Each repository contains the documents submitted to EPA under the reporting provisions (and/or correspondence relevant to the reporting provisions) indicated for each facility. A complete national index of the information found in the Regional docket repositories will be maintained at EPA Headquarters in Washington, DC, and made available to the public. This index will also be available for public review at each Regional repository. Contact the Federal Facilities Docket Hotline for information on how to arrange for review and copying of specific documents.

II. Revisions to the Initial Docket

Revisions to the initial docket can be divided into three overall categories: (1) facilities being removed from the list; (2) facilities being added to the list; and (3) corrections. Each entry in the Revisions section has been labelled with a code indicating the reason for the change. A key to these codes is found below.

Necessary revisions to correct the initial docket were identified by both EPA and Federal agencies. These revisions vary from simple address and spelling changes to facility name changes and ownership corrections. Many are simply typographical or typesetting errors. The affected Federal agencies have been notified previously of the revisions being published today.

Facilities are being removed from the docket for a number of reasons, such as the facility is not Federally owned, incorrect reporting of hazardous waste activity, change in Federal ownership, exemption as a Small Quantity Generator (SQG), etc. Facilities being removed will no longer be required to conduct a Preliminary Assessment (PA) as required by CERCLA Section 120(d) for docket facilities.

Some facilities are being added to the docket now because they were inadvertently not included on the initial list. In most cases, the additions are the result of new information obtained by EPA indicating that a facility should have been listed in the February notice. For all facilities being added in this section, the responsible agency will have 18 months from the date of this publication to complete the required PA and Site Inspection (SI), if warranted.

EPA is today clarifying its policy of not listing SQGs under RCRA on the docket. The intent of the original policy was to exempt facilities from docket listing that were *solely* SQGs and had never produced more than 1,000 kg in any month. EPA did not include on the initial docket a number of SQGs that had also reported under RCRA Section 3016 or CERCLA Section 103. The Agency believes that if a facility reports a release under Section 103 or other hazardous waste activity, it is no longer considered to be solely a SQG. EPA believes that these facilities must be assessed to determine if cleanup actions are necessary. Therefore, today the Agency is adding to the docket SQGs that had previously reported to EPA under other reporting provisions. Again, these facilities will have 18 months to complete the appropriate assessment.

The corrections subsection is shown in a slightly different format due to the nature of the revisions, which include typographical errors, name and address changes, and changes in the reporting mechanisms. For each facility, the original entry as it appeared in the February notice is shown directly above the corrected entry for easy comparison. These entries are organized alphabetically by state instead of by Federal agency.

In the process of compiling the documents for the Regional repositories, EPA identified a number of facilities that had previously submitted a PA report, SI report, or in the case of some Defense facilities, an Installation Restoration Program (IRP) report, yet had not submitted a Section 103 notification form. Section 120(c)(3) of CERCLA requires that EPA include information submitted under Section 103 in the docket. In general, Section 103 requires any person who has knowledge of known, suspected, or likely releases of hazardous substances from a facility to notify EPA. Thus, the Agency believes that information it has received by means of the above-mentioned reports should be included in the docket regardless of the absence of formal Section 103 notification. Therefore, the docket record for each of these facilities is being corrected to indicate this reporting.

III. Process for Compiling the Updated Docket

In compiling the newly-reported facilities for the update being published today, EPA extracted the names, addresses, and identification numbers of facilities from the three EPA data bases (the RCRA Section 3016 inventory data base, the Hazardous Waste Data Management System, and the CERCLA data base) that contain Federal facility information submitted under the four provisions listed in Section 120(c).

Extensive computer checks compared the initial docket list with the information obtained from the above data bases to determine which facilities were, in fact, newly reported and qualified for inclusion on the update. The Agency has found it extremely difficult to reconcile the file structures and reporting differences in the various data bases for docket purposes. Consequently, it is possible that some individual sites were included in this update instead of, or in addition to, the overall facility as required. It is also possible that state-owned or privately-owned facilities have been included in spite of the quality assurance efforts that EPA has undertaken. These potential problems are the result of historical procedures used to report and track Federal facility data and the Agency is working to resolve them. Federal agencies are requested to contact EPA's Docket Coordinator in writing at the following address if revisions to the update information being published are necessary:

Federal Facilities Docket Coordinator, US EPA, 401 M Street SW. (OS-503), Washington, DC 20460.

IV. Facilities Not Included

EPA is not including the following categories of facilities in the docket at this time:

1. Facilities formerly owned by a Federal agency and now privately owned. However, facilities that are now owned by another Federal agency will remain on the docket with the responsibility resting with the current owner. The agency is still considering listing formerly-owned DOD facilities on the docket at a later time. However, a number of related policy issues have not yet been resolved. Therefore, formerly-owned facilities will not be listed on this update.

2. Any facilities not currently owned by a Federal agency. For example, facilities that are *operated* by the Federal government under state or private ownership will not be listed on the docket.

3. Small Quantity Generators that have never produced more than 1,000 kg in any month and have not reported spills under Section 103 or other hazardous waste activities under Section 3016.

4. Facilities that are solely transporters as reported under RCRA Section 3010.

5. Any facilities not reported by a Federal agency.

The agency will be collecting additional information in the coming months on whether or not to include one or more of these categories in future updates to the docket, and may solicit public comment on the issues at a later date.

V. Information Contained on Docket Listing

As discussed above, the information below is divided into two separate sections. The first section is comprised of revisions to the list published on February 12, 1988. The revisions Section is broken into the following categories: facility removals, facility additions, corrections, and miscellaneous. Each facility on the revisions list is coded. This code refers to the code key preceding the lists, and indicates the specific reason(s) for revision. The second section is the list of new facilities (not facilities added as corrections) that are being added at this six month update.

All facilities added to the docket today, either as revisions or newly added facilities have a "date of listing" indicator, shown as "* *" in this column. All facilities with "* *" in the date of listing column must submit PAs and SIs, if warranted, to EPA within 18 months of the date of this publication. This includes any facility changing responsible agencies (codes 21 and 22). These reports should be submitted to the CERCLA Federal Facility Coordinator in the appropriate EPA Regional office. Facilities listed in the corrections subsection do not have a date of listing column since the correction(s) for these facilities as shown in this notice do not affect the statutory assessment deadline; these facilities should have already submitted the required assessment(s) to EPA by April 17, 1988.

Facilities in both the revisions section and the update section are organized by State and then grouped alphabetically within each State by the Federal agency responsible for the facility, except for the corrections. As mentioned before, these entries are organized alphabetically by state. This information is then followed by the facility name and address, the statutory provision(s) under which the facility was reported to EPA (indicated by an "x" in the appropriate column(s)), the EPA Region where the facility is located, the correction code, and date of listing if appropriate.

The complete list of Federal facilities that now comprises the docket is not being published today. However, the list is available to interested parties and can be obtained by calling the Federal Facilities Docket Hotline. As today, the total number of Federal facilities that appear on the docket is 1,170.

J. Winston Porter,
Assistant Administrator.

Date: October 21, 1988.

I. DOCKET REVISIONS

Categories of Revisions for Docket Update by Correction Code

Categories for Facility Removal

1 Small Quantity Generator
2 Not Federally Owned
3 Formerly Owned
4 No Hazardous Waste Generated
5 Temporary Storage/One Time Permitted Disposal
6 Redundant Listing/Site on Facility
7 Combining Sites into One Facility/ Entries Combined

8 Does not Fit Facility Definition (all are vessels)
9 No Hazardous Waste (Reponsible Agency Changed)
10 Small Quantity Generator (Responsible Agency Changed)
11 No Hazardous Waste (Temporary Storage Only)
12 Not Federally Owned (Small Quantity Generator)
13 Redundant Listing/Site on Facility (Agencies will Coordinate)
14 Small Quantity Generator (Never Actually Built)

Categories for Facility Addition

15 Small Quantity Generator w/either a 3016 or 103
16 One Entry Being Split into Two/ Agency Responsibility Being Split
17 New Information Obtained Showing that Facility Should be Included
18 Facility was a Site on a Facility that was Disbanded, Now a Separate Facility
19 Sites was Combined into one Facility

Corrections

20 Typo Correction/Name Change/ Address Change/Reporting Provisions Change

Miscellaneous

21 Changing Responsible Agencies (New Responsible Agency has 18 mos. to submit PA)
22 Changing Responsible Agencies and Title (New Responsible Agency has 18 mos. to submit PA)

REVISIONS TO 2/12/88 DOCKET.—REMOVALS

Agency	Facility Name	Facility address	City	State	ZIP Code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103	EPA Reg	Corr Code
Army	US Army National Guard Alaska CSMS.	5300 E Tudor Rd.	Anchorage	AK	99507		X			10	2
Army	US Army National Guard 4th SCT BN HQ.	The Armory	Juneau	AK	99801		X			10	2
Army	US Army National Guard 1st BN SCT HQ.	433 Front St.	Nome	AK	99762		X		X	10	2
Army	US Army National Guard 5th SCT BN HQ.	4902 Jewel Lake Rd.	Anchorage	AK	99502		X			10	2
Army	US Army National Guard 2nd BN SCT HQ.	The Armory 370 4th Ave.	Bethel	AK	99559		X			10	2
Army	US Army Whittier Oil Storage Tank.	¾ Mi N of Town.	Whittier	AK	99693				X	10	2
Corps of Engineers, Civil.	US Army-COE Long Island.	Long Island (Ft. Tidball).	Long Island	AK	99506		X			10	3
Transportation	US Coast Guard Cutter Sedge (WLB-402).	Homer Spit	Homer	AK	99603		X			10	8
Transportation	US Coast Guard Cutter Sweetbriar WLB-405.	Coast Guard Dock.	Cordova	AK	99574		X		X	10	8
Transportation	US Coast Guard Cutter Woodrush WLB-407.	Government Pier.	Sitka	AK	99835		X			10	8
Army	US Army Phosphate Development Works.	Natl Fertilizer Dev Center.	Muscle Shoals	AL	35660				X	4	13
NASA	Marshall Space Flight Center.	AB 44	Marshall Space Flight Ctr.	AL	35812	X	X	X	X	4	13
Army	Millwood Resevoir.	Route 1	Ashdown	AR	71822			X	X	6	4
Army	161st AREFG Air National Guard.	2001 S 32nd Street.	Phoenix	AZ	85034		X			9	10
Army	NI IND INC Riverbank Plt.	5300 Claus Rd.	Riverbank	CA	95367	X	X			9	6
Housing and Urban Development.	Oakland City of Housing Authority.	1180 25th Ave.	Oakland	CA	94601		X			9	2
Interior	US Bureau of Reclamation.	5520 Knoxville Rd.	NAPA	CA	94558		X			9	1
Interior	BLM-Washington Mine No. 5.	T33NR7WSEC17 St. NW.	French Gulch	CA	96033					9	2
Justice	US Border Patrol Station.	225 Kenney	El Cajon	CA	92020		X			9	9

REVISIONS TO 2/12/88 DOCKET.—REMOVALS—Continued

Agency	Facility Name	Facility address	City	State	ZIP Code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103	EPA Reg	Corr Code
NASA	NASA JPL Goldstone Tacking Facil.	36 Mi N of Barstow & Ft. Irwin.	Barstow	CA	92311		X			9	13
NASA	H.L. Dryden Flight Research Facility.	PO Box 273	Edwards	CA	93523-5000	X	X	X	X	9	13
Navy	Naval Training Center Camp Nimitz.		San Diego	CA	92133				X	9	6
Navy	Public Works Center San Franciso.	Naval Supply Cetner Oakland.	Oakland	CA	94623		X			9	4
Air Force	Dept. of Military Affairs.	1400 S. 3rd Ave.	Sterling	Co	80751		X			8	1
Commerce	Delta Air Lines—Denver.	Stapleton Intl Airport.	Denver	CO	80238		X			8	2
Interior	Rocky Mountain Nat'l Park.	Rocky Mtn. Nat'l Park.	Estes Park	Co	80517		X			8	1
Interior	BLM-Standard Metals Corp. (Mayflower Mill).	T41NR7WSEC21 Hwy 110.	Silverton	CO	81433				X	8	2
Postal Service	US Postal Service.	915 Housatonic Ave.	Bridgeport	CT	06604		X			1	2
General Services Admin.	National Archives & Records Admin.	7th & Pennsylvania Ave NW.	Washington	DC	20408		X			3	10
Health and Human Services.	Food and Drug Administration.	Second & C Streets SW.	Washington	DC	20204		X			3	1
Health and Human Services.	Saint Elizabeth's Hospital.	2700 Martin L King Ave SE.	Washington	DC	20032		X			3	2
Agriculture	Osceola Forest Site #3.	Cortez Rd., South of Hwy 90.	Unincorporated Lake City.	FL	32055				X	4	7
Agriculture	Osceola Forest Site #4.	West of Dirt Rd., off Rte. 772.	Unincorporated Lake City.	FL	32055				X	4	7
Agriculture	Osceola Forest Site #6.	S. of Hwy 90 on Possum Trot Rd.	Unincorporated Lake City.	FL	32055				X	4	7
Agriculture	Osceola Forest Site #2.	North of Hwy 100.	Unincorporated Lake City.	FL	32055				X	4	7
Agriculture	Osceola Forest Site #1.	Hwy 100	Unincorporated Lake City.	FL	32055				X	4	7
Agriculture	Osceola Forest Site #5.	Hwy 90 to Osceola Forest Off ?.	Unincorporated Lake City.	FL	32055				X	4	7
Army	USA Palatka AMSA 55-M.	4300 St. Johns Ave.	Palatka	FL	32077	X	X			4	3
Interior	Everglades National Park.	PO Box 279	Homestead	FL	33030		X			4	1
Navy	Naval Air Station Trumbo PT.	Palm Ave Causeway.	Key West	Fl	33040		X			4	6
Navy	Naval Air Station Richmond.	Coral Reef Dr	Perrine	FL	33157			X	X	4	2
Navy	Naval Supply Center Fuel Depot Jacksonville.	Somers Road	Jacksonville	FL	32208		X		X	4	6
Army	USA AMSA 54G-Augusta.	DFAE AFZP-FEC.	Fort Stewart	GA	31314	X	X		X	4	6
EPA	US EPA Environmental Research Lab.	College Station Road.	Athens	GA	30613		X			4	1
Health and Human Services.	Center for Disease Control.	Bldg 4 RM 232 1600 Clifton Rd.	Atlanta	GA	30333		X			4	1
Health and Human Services.	Centers for Disease Control.	447 Buford Highway.	Chamblee	GA	30341		X			4	1

REVISIONS TO 2/12/88 DOCKET.—REMOVALS—Continued

Agency	Facility Name	Facility address	City	State	ZIP Code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103	EPA Reg	Corr Code
Army	Army Aviation Support Facility #2.	General Lymanb Field Bldg 619.	Hilo	HI	96720		X			9	2
Labor	Chevron USA Inc. Hawaiian Refinery.	91-480 Malakole Rd.	Ewa Beach	HI	96706	X				9	2
Energy	Burley Maint HQ.	1247 W Main	Burley	ID	83318		X			10	1
Energy	Idaho Falls Dist Maint HQ.	2275 N Yellowstone Ave.	Idaho Falls	ID	83401		X			10	1
Interior	Owyhee CO, Marshing/ Homedale LF.	Johnson Rd-T4N R5W S 32 SW¼.	Marsing-Homedale	ID	83639				X	10	6
Interior	BLM-Bunker Hill.	834 McKinley Avenue.	Shoshone	ID				X	X	10	2
Transportation	USDOT-FAA Mica Peak.	Cougar Gulch Rd.	Coeur D'Alene	ID	83814				X	10	1
Army	US Army Joliet Lap Honeywell.	Highway 53 & Arsenal Ave.	Jolet	IL	60436	X	X			5	6
Corps of Engineers, Civil.	US Army-COE IL ANG Maint Cir.	8660 W. Cermak Road.	North Riverside	IL	60546		X			5	2
Energy	ICGG Pipeline Gas Demonstration Plant.	Trico Rd 1 Mile South of Pyatt Road.	Perry County	IL	62272	X	X			5	14
Energy	US DOE Radiation Lab Univ of Notre Dame.	University of Notre Dame.	Notre Dame	IN	46556		X			5	1
Army	National Guard Armory & Parking Lot.	18th & Ridge	Kansas City	KS	67201				X	7	2
Veterans Administration.	VA Medical Center.	4104 S. 4th St Trafficway.	Leavenworth	KS	66048		X		X	7	2
Energy	US DOE Kentucky Ordinance Works.	Kentucky Wildlife Area.	Paducah	KY	42001				X	4	2
Agriculture	US Department of Agriculture.	4115 Gourrier	Baton Rouge	LA	70808		X			6	1
Health and Human Services.	Food and Drug Administration.	4298 Elysian Fields.	New Orleans	LA	70122		X			6	1
Health and Human Services.	Gillis Long Hansen's Disease Center.	River Rd 2 M SE H-75.	Carville	LA	70721			X		6	1
Army	General Electric Co.—Everett.	62 Tremont Street.	Everett	MA	02149					1	3
Army	General Electric—Lynn.	40 Federal Street.	Lynn	MA	01901					1	3
Navy	Boston Naval Shipyard.		Charlestown	MA	02129				X	1	9
Postal Service	US Postal Service.	Post Office Square.	Lowell	MA	01853		X			1	2
Army	Fort Ritchie	Fort Ritchie	Fort Ritchie	MD	21719		X			3	1
Army	National Security Agency.	9800 Savage Road.	Fort Meade	MD	20755		X			3	13
Defense	Granite-Control	2845 Herwood Road.	Woodstock	MD	21163				X	3	2
Health and Human Services.	FDA Center of Veterinary Medicine.	Muirkirk & Odell Rd.	Beltsville	MD	20705		X			3	13
Health and Human Services.	FDA Beltsville Research Com.	8301 Muirkirk Rd Rte 2.	Beltsville	MD	20705		X			3	4
Health and Human Services.	NIH Animal Center.	Elmer School Road.	Poolesville	MD	20837		X			3	1
Health and Human Services.	FDA Center for Devices and Radiation Health.	12709 Twinbrook Pkwy.	Rockville	MD	20857		X			3	12

REVISIONS TO 2/12/88 DOCKET.—REMOVALS—Continued

Agency	Facility Name	Facility address	City	State	ZIP Code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103	EPA Reg	Corr Code
Health and Human Services.	NIH-NIA Gerontology Research.	4940 Eastern Ave.	Baltimore	MD	21224		X			3	1
Navy	Naval Air Faciality.	Andrews Air Force Base.	Camp Springs	MD	20390		X			3	13
Interior	Isle Royale National Park.	87 N. Ripley St	Houghton	MI	49931		X			5	1
Postal Service	US Postal Service Garage.	10325 Lyndon	Detroit	MI	48238		X			5	1
Postal Service	USPS Allen Park Garage.	17500 Oakwood Blvd.	Allen Park	MI	48101		X			5	1
Agriculture	US Dept of Agri. Chipewa Nat. Forest.	Rt. 1	Cass Lake	MN	56633		X	X		5	5
Health and Human Services.	Red Lake PHS Indian Hospital.	PHS Hospital	Red Lake	MN	56671		X			5	1
Interior	US DOI Tamarac National Wildlife Refuge.	Rural Route	Rochert	MN	56578		X			5	1
Interior	US Fish & Wildlife Regional Sign Center.	Front and Kansas.	Winona	MN	55987		X			5	1
Army	MO Aviation Classification & Repair Activity Depot.	2501 Lester Jones Ave. RFD 6 Box 383.	Springfield	MO	65803		X		X	7	2
Army	US Corp of Engineers.	Clear Water Lake.	Piedmont	MO	63956		X			7	1
Army	Ft. Leonardwood.	Artillery Firing Range.	Ft. Leonardwood	MO	65473	X	X		X	7	6
Army	Jefferson Barracks LDF.	Gregg and South Road.	St. Louis	MO	63123				X	7	2
Interior	Jefferson National Expansion.	2nd & Poplar Street.	St. Louis	MO	63102		X			7	1
Agriculture	USDA Sea IFA Research Laboratory.	3505 25th Ave PO Box 3209.	Gulfport	MS	39503	X	X			4	1
Army	Mt. ANG OMS #5.	Gallitin County Airport.	Belgrande	MT	59714		X			8	2
Agriculture	US Forest Service.	Swain County Landfill SR 1311.	Bryson City	NC	28713			X		4	7
Agriculture	USDA-FS Graham County Landfill.		Graham County	NC				X	X	4	7
Army	MD ANG Army Aviation Support Facility.	Bismark City Airport-Bldg. 100.	Bismarck	ND	58502		X			8	2
Army	ND ANG Combined Support Maint. Shop.	Camp Gilbert Grafton-Bldg. 5800.	Devils Lake	ND	58201		X			8	2
Army	ND ANG Organ. Maint Shop No. 3.	2013 No. Washington Street.	Grand Forks	ND	58206		X			8	2
Army	ND ANG Organ. Maint Shop No. 4.	Fraine Baracks, Bldg. 250.	Bismarck	ND	58502		X			8	2
Army	ND ANG Organ. Maint Ship.	US Hwy 281 North and 15th.	Jamestown	ND	58402		X			8	2
Army	ND ANG Organ. Maint Shop No. 7.	Old at Hwy. 21 & Indiana Ave.	Mott	ND	58646		X			8	2
Army	MD ANG Organ. Maint Shop No. 6.	Valley City Municipal Airport.	Valley City	ND	58072		X			8	2

REVISIONS TO 2/12/88 DOCKET.—REMOVALS—Continued

Agency	Facility Name	Facility address	City	State	ZIP Code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103	EPA Reg	Corr Code
Army	ND ANG Unit Training Equipment Shop.	Camp Gilbert Grafton Bldg. 6900.	Devils Lake	ND	58301		X			8	2
Army	Unit Training and Equipment Site.	P.O. Box 278, County Hwy 539.	Plumstead TWP	NJ	08533		X			2	2
Army	Fort Dix Landfill	Juliustown-Browns Mills Road.	Wrightstown	NJ	08562				X	2	6
Commerce	Macom Laser Diode.	130 Somerset Street.	New Brunswick	NJ	08901		X			2	2
Interior	Morristown National Historical Park.	Jockey Hollow Road.	Morristown	NJ	07960		X			2	1
Transportation	USCG Station—Barnegat.	6th and Bayview.	Barnegat Light	NJ	08006		X			2	1
Army	US Prop Fiscal Ofc for NV.	2601 S. Carson St.	Carson City	NV	89701		X			9	2
Army	USA-Comb Spt Main Shop "C".	1500 East Henrietta Rd.	Rochester	NY	14623		X			2	1
Army	Organizational Maint Shop 45.	70 Brentwood Rd.	Bayshore	NY	11706		X			2	2
Army	McDonald USARC.	168 Goethals Ave.	Jamaica	NY	11432		X			2	1
Army	Air Force Plant #68.	Lutts Road	Model City	NY	14107				X	2	3
Army	U.S. Army Engineer District.	1776 Niagra St	Buffalo	NY	14127		X			2	1
Corps of Engineers, Civil.	USCOE-East Sidney Lake.	NY State Route 357.	Franklin	NY	13775		X			2	1
Corps of Engineers, Civil.	USCOE-Troy Lock & Dam.	Bond St	Troy	NY	12180		X			2	1
Energy	Lake Ontario Ordnance Works.	1397 Pletcher Rd.	Model City	NY	14107				X	21	3
General Services Admin.	Federal Building	111 West Huron St.	Buffalo	NY	14202		X			2	1
General Services Admin.	Jacob K. Javitz Fed Bldg.	26 Federal Plaza.	New York	NY	10278		X			2	1
Health & Human Services.	U.S. Food & Drug Adm.	850 Third Ave	Brooklyn	NY	11232		X			2	1
Postal Service	U.S. Postal Service.	550 Manor Rd	Staten Island	NY	10314		X			2	1
Postal Service	U.S. Postal Service Western Nassau.	830 Stewart Ave.	Garden City	NY	11599		X			2	1
Postal Service	Hicksville Post Office.	260 Engineers Drive.	Hicksville	NY	11802		X			2	2
Transportation	USCG Base Buffalo.	1 Frihrmann Blvd.	Buffalo	NY	14203		X			2	1
Veterans Administration.	VA Medical Center.	800 Irving Ave	Syracuse	NY	13201		X			2	1
Veterans Administration.	VA Medical Center.	800 Poly Place	Brooklyn	NY	11209		X			2	1
Veterans Administration.	VA Extended Health Care Center.	179th Street and Linden Blvd.	St. Albans	NY	11425		X			2	1
Veterans Administration.	VA Medical Center.	113 Holland Ave.	Albany	NY	12208		X			2	1
Agriculture	Ohio Agri Research and Devel Center.	1680 Madison Ave Wayne County.	Wooster	OH	44691			X	X	5	2
Health and Human Services.	US FDA Cincinnati CFSAN Food Res. Lab.	1090 Tusculun Ave.	Cincinnati	OH	45226		X			5	1
Health and Human Services.	US NIOSH Ridge Avenue.	5555 Ridge Avenue.	Cincinnati	OH	45213		X			5	1

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Agency	Facility Name	Facility address	City	State	ZIP Code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103	EPA Reg	Corr Code
Health and Human Services.	US NIOSH Taft Laboratories.	4676 Columbia Parkway.	Cincinnati	OH	45226		X			5	1
Postal Service	USPS-Cleveland.	3695 Green Road.	Cleveland	OH	44122		X			5	1
Interior	USODI-NPS Crater Lake National Park.	Hwy 62	Crater Lake	OR	97604		X			10	1
Navy	LSC Marine INC/USNS Wilkes T-AGS.	Dillingham Yard, Swan Island.	Portland	OR	97208		X			10	6
Army	AJCC-Fort Ritchie.	Harbaugh Valley Rd.	Blue Ridge Sum	PA	17214		X			3	1
Army	PA Army Natl Guard Maint Shop 28.	1300 Penn St.	Williamsport	PA	17702		X			3	2
Army	PA Army Natl Guard Maint Shop.	14th & Calder St.	Harrisburg	PA	17105		X			3	2
Army	PA Army Natl Guard Maint Shop 10.	2736 Southhampton.	Philadelphia	PA	19154		X			3	2
Army	Willow Grove ASF.	Off of US Rte 611.	Hatboro	PA	19090				X	3	6
Corp of Engineers, Civil.	USA-COE Shenango Lake.	2442 Kelly Road.	Sharpsville	PA	16150			X		3	11
Transportation	USCG Base—San Juan.	Santo Toribio	San Juan	PR	00903		X			2	1
Army	US Army N. Smithfield Nike Site.	Poundhill Rd	N. Smithfield	RI	02876				X	1	6
Army	RI ANG	Old Oxford Road.	North Smithfield	RI	02876					1	2
Navy	Naval Air Station Quonset Point.		North Kingston	RI	02854	X	X		X	1	2
Army	SD ANG.OMS 4 Webster.	120 W. 11th Ave.	Webster	SD	57274		X			8	2
Army	SD ANG-OMS 2 Rapid City.	City Limits	Rapid City	SD	57702		X			8	2
Army	SD ANG-OMS 3 Lemmon.	Armory	Lemmon	SD	57638		X			8	2
Army	SD ANG-OMS 10 Sioux Falls.	Fairgrounds	Sioux Falls	SD	57107		X			8	2
Army	SD ANG-OMS 7 Pierre.	3440 E-W Hwy. 34.	Pierre	SD	57501		X			8	2
Army	SD ANG-OMS 8 Brookings.	300 Fifth Ave. S.	Brookings	SD	57006		X			8	2
Energy	USDOE Y-12 Plant.	Bear Creek Rd.	Oak Ridge	TN	37830	X	X		X	4	6
Interior	Great Smoky Mtns Natl Park.	USNPS Rt2	Gatlinburg	TN	37738	X	X			4	1
NASA	NASA Ellington Field.	Highway 3	Houston	TX	77088		X	X		6	1
Army	US Army Reserve HQ 25G Petroleum BTN.	1355 No 200 West.	Provo	UT	85601		X			8	4
Army	Arlington National Cemetery.	Unobtainable	Arlington	VA	22211		X			3	1
Interior	US Geological Survey.	12201 Sunrise Valley Drive.	Reston	VA	22092		X			3	1
Army	Washington Army Natl Guard.	298 Clemons Rd.	Montesano	WA	98430		X			10	2
Army	Washington Army National Guard.	1702 Pacific Way.	Yakima	WA	98901		X			10	2
Army	Washington Army National Guard.	1st & East Street Corner.	Ephrata	WA	98823		X			10	2

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Agency	Facility Name	Facility address	City	State	ZIP Code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103	EPA Reg	Corr Code
Army	Washington Army National Guard.	309 Byrd Street	Centralia	WA	98531		X			10	2
Interior	USDOI-FWS Nisqually Natl Wildlife Refuge.	Brown Farm Rd, End of.	Olympia	WA	98506		X			10	1
Justice	USDOJ-DEA/ Seattle.	Pier 37	Seattle	WA	98134		X			10	5
Transportation	USDOT-CG Cutter Confidence (WMEC 619).	City Pier	Port Angeles	WA	98362		X			10	8
Army	WI Army National Guard OMS 14.	1710 Second Street.	Wisconsin Rapids	WI	54494		X			5	2
Army	WI Army National Guard 13.	833 S. 17th Avenue.	Wausau	WI	54401		X			5	2
Army	WI Army National Guard AASF 1.	2079 Highway 33 E.	West Bend	WI	53905		X			5	2
Army	WI Army National Guard OMS 12.	735 Iowa Avenue.	Hayward	WI	54843		X			5	2
Army	WI Army National Guard OMS 5.	1225 E. Henry Clay Street.	Whitefish Bay	WI	53217		X			5	2
Army	WI Army National Guard AASF 2.	1950 Peatson Street.	Madison	WI	53704		X			5	2
Army	WI Army National Guard OMS 8.	1120 S. Academy Street.	Janesville	WI	53545		X			5	2
Army	WI Army National Guard OMS 11.	800 N. Military Avenue.	Green Bay	WI	54304		X			5	2
Army	WI Army National Guard OMS 6.	4200 43rd Street.	Kenosha	WI	53141		X			5	2
Interior	Horicon National Wildlife Refuge.	Rural Rt. 2	Mayville	WI	53050		X			5	1
Health and Human Services.	National Inst for Occupational Safety.	944 Chestnut Ridge Road.	Morgantown	WV	26505		X			3	1

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Agency	Facility name	Facility address	City	State	ZIP code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103	EPA reg	Corr code	Date of listing
Air Force	USAF—Aniak AFB LDFL.	Head Shank Kuskokwim, Riv/Slogh.	Aniak	AK	99557				X	10	15	**
Air Force	USAF—Bethel AFS LDFL.	Airport—W End of Main Road.	Bethel	AK	99559		X		X	10	15	**
Air Force	USAF—Big Mountain AFS LDFL.	S Shoure Iliamma/S Side Big Mtn.	Big Mountain AFS	AK	99501		X		X	10	15	**
Air Force	USAF—Clear AFS LDFL.	Hwy 3 & Nenana Rd.	Anderson	AK	99704		X		X	10	15	**
Air Force	USAF—Dewline Site LIZ-2.	Kasegalik Lagoon—Chukchi Sea.	Point Lay	AK	99766		X		X	10	15	**
Air Force	USAF—Dewline Site POW-3.	E of Flaxman Island.	Bullen Point	AK	99723				X	10	15	**

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Agency	Facility name	Facility address	City	State	ZIP code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103	EPA reg	Corr code	Date of listing
Air Force	USAF—Driftwood Bay AFS LDFL.	N Coast Unalaska Island.	Driftwood Bay	AK	99553				X	10	15	**
Air Force	USAF—Duncan Canal LDFL.	12 mi SW of cy	Petersburg	AK	99883				X	10	15	**
Air Force	USAF—Fort Yukon AFS LDFL.	N of Yllota Slough.	Fort Yukon	AK	99740				X	10	15	**
Air Force	USAF—Kalakaket Creek.	S Shore of Kala Creek.	Galena	AK	99741		X		X	10	15	**
Air Force	USAF—North River AFS LDFL.	Mouth of North River.	Unalakleet	AK	99684				X	10	15	**
Air Force	USAF—Port Heiden AFS LDFL.	NW Shore of Heiden Bay.	Port Heiden	AK	99549				X	10	15	**
Air Force	USAF-White Alice Site Kotzebue.	NW Corner of Baldwin Peninsula.	Kotzebue	AK	99752				X	10	15	**
Air Force	USAF-White Alice Site Nome.	Anvil Mt 6.5 mi N of Nome.	Nome	AK	99762				X	10	15	**
Air Force	USAF—Dewline Site POW-1.	Lonely	Lonely	AK	99999		X		X	10	15	**
Air Force	USAF—Dewline Site Pow—Main.	Point Barrow	Point Barrow Station.	AK	99723		X		X	10	15	**
Air Force	USAF—Dewline Site-L12-3.	Wainwright	Wainwright	AK	99782		X		X	10	15	**
Air Force	USAF-King Salmon Airport.	5071 CSS/CC	King Salmon Airport.	AK	99613		X	X	X	10	17	**
Army	US—Army National Guard 3rd SCT BN HQ.	Kotzebue Air Force Site.	Kotzebue	AK	99752		X		X	10	15	**
Transportation	USCG—Point Spencer USCG Dump Site.	Port Clarence—60 mi NW of cy.	Nome	AK	99762				X	10	15	**
Transportation	USDOT—CG Kodiak san LDFL.	USCG Support Center.	Kodiak	AK	99619				X	10	15	**
Air Force	USAF Maxwell Air Force Base.	3800 Air Base Group DEE.	Maxwell AFB	AL	36112	X	X		X	4	17	**
Army	USA Redstone Arsenal.	CMDR USAMICOM DRSMI—K.	Huntsville	AL	35898	X	X	X	X	4	17	**
Commerce	Central Foundry		Tuscaloosa	AL				X		4	17	**
Air Force	USAF Blytheville Air Force Base.	97 CSG/DEE	Blytheville	AR	72315	X	X		X	6	17	**
Air Force	Arizona Air Natl Guard 162 TAC Ftr Gp.	1500 E. Valencia Road.	Tucson	AZ	85706	X	X		X	9	17	**
Air Force	Lawndale Annex LAAFB.	6592 ABG/CC	Hawthorn	CA	90260				X	9	15	**
Air Force	Los Angeles Air Force Station.	2400 El Segundo Blvd.	Los Angeles	CA	90009		X		X	9	15	**
Air Force	Camp Kohler	Roseville Road	Sacramento	CA	95652				X	9	17	**
Air Force	Davis Transmitter Site.		Davis	CA	95620				X	9	17	**
Army	Presidio of San Francisco.	Presidio of San Francisco.	San Francisco	CA	94129		X		X	9	15	**
Army	Camp Roberts Nat. Guard Unit.	Hwy. 101 12 mi N of Paso Robles.	Paso Robles	CA	93446		X		X	9	15	**
Defense	Defense Fuel Supply Center-Estero Bay.	3300 Panoroma Drive.	Morro Bay	CA	93442		X	X	X	9	15	**
Energy	Oxnard Facility	1235 E Wooley Street.	Oxnard	CA	93031		X		X	9	17	**
General Services Admin.	Chet Holifield Federal Energy Building.	24000 Avila Road	Laguna Niguel	CA	92677		X		X	9	17	**
Interior	Sequoia & Kings Canyon Natl Park.		Three Rivers	CA	93271	X	X	X	X	9	17	**

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Agency	Facility name	Facility address	City	State	ZIP code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103	EPA reg	Corr code	Date of listing
Interior	BLM—Clainete Resource Area, Parcel No. 147-090-06.	520 Butte Street	Bakersfield	CA	93305				X	9	17	**
Justice	Federal Correctional Institute LOMPOC.	US Penitentiary	Lompoc	CA	93436			X	X	9	15	**
Navy	Naval Industrial Reserve Ordinance Plant.	PO Box 3504	Sunnyvale	CA	94088-3504				X	9	17	**
Navy	Sere Camp		Warner Springs	CA					X	9	17	**
Transportation	Fort MacArthur	Pacific Avenue	San Padro	CA	90731				X	9	15	**
Transportation	USCG Loran C Sta Middletown.	Loran C Sta	Middletown	CA	95461				X	9	15	**
Air Force	Peterson Air Force Base.	All Bldgs. On base.	Colorado Springs	CO	80914		X		X	8	15	**
Air Force	US Air Force Academy.	10 mi. N. Colorado Springs on I-25.	Colorado Spring	CO	80912		X		X	8	15	**
Army	Fitzsmons Army Medical Ctr.	Corner of Colfax and Peoria.	Aurora	CO	80045		X		X	8	15	**
Energy	Western Area Power Adm. Power Operations.	1800 S. Rio Grande Ave.	Montrose	CO	81401				X	8	15	**
Interior	Water & Power Resources Serv.	910 Van Buren	Loveland	CO	80537		X		X	8	15	**
Transportation	FHWA Central Direct Fed. Div. Materals.	6th St., Bldg. 52, DFC.	Denver	CO	80225		X		X	8	15	**
Transportation	Us Coast Guard—Avery Point.		Groton	CT	06340				X	1	15	**
Air Force	Bolling Air Force Base.	HG110th Air Base Wing.	Washington	DC	20331				X	3	15	**
Agriculture	Osceola National Forest.		Unincorporated Lake City.	FL	32055				X	4	19	**
Air Force	USAF Hurlburt Field.	Terry & Lokasik Ave.	Hurlburt Field	FL	32544		X	X	X	4	15	**
Air Force	Kaena Pt Sat Tracking Sta.	33 mi NW of Honolulu on Rte 930.	Waianae	HI	96792				X	9	15	**
Air Force	Kokee Air Force Station.	Kokee State Park	Waimea	HI	96796				X	9	15	**
Air Force	Punamano Air Force.	28 mi NNE Honolulu On Rte 83.	Kahuku	HI	96731				X	9	15	**
Energy	Kauai Test Facility.	PO Box 478	Waimea	HI	96796				X	9	17	**
Navy	Naval Communication Area Master Station, Eastern.		Honolulu	HI				X	X	9	17	**
Agriculture	USDA-FS Forestry Sciences Lab.	1221 S Main St	Moscow	ID	83843				X	10	15	**
General Services Admin.	Federal Bldg	205 N 4th Street	Coeur D'Alene	ID	83814		X		X	10	15	**
Air Force	US Air Force 183 Tactical Fighter Group.	Capitol Airport	Springfield	IL	62707	X	X	X		5	17	**
Commerce	Wisconsin Steel	E. 106th & Torrence Avenue.	Chicago	IL			X			5	17	**
Army	USA Lexington Blue Grass Depot Activity.	US Hwy 421	Richmond	KY	40475				X	4	16	**
Veterans Administration.	Bedford VA Hospital.	200 Springs Road.	Bedford	MA	02173		X		X	1	15	**
Defense	Davidsonville—Launch.	3737 Elmer Hagner Lane.	Davidsonville	MD	21035				X	3	15	**

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Agency	Facility name	Facility address	City	State	ZIP code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103	EPA reg	Corr code	Date of listing
Defense	David Taylor/ Annapolis—Control.	640A Broadneck Road.	Annapolis	MD	21401				X	3	15	**
Defense	David Taylor-Annapolis-Launch.	Bay Head Road	Annapolis	MD	21401				X	3	15	**
Defense	Gaithersburg-Control.	8510 Snouffers School Road.	Gaithersburg	MD	20879				X	3	15	**
Defense	Gaithersburg-Launch.	Off Snouffers School Road.	Gaithersburg	MD	20879				X	3	15	**
Defense	Granite-Launch	3085 Hernwood Road.	Woodstock	MD	21163				X	3	15	**
Defense	Greenspring Control.	Greenspring Road.	Greenspring	MD	21117				X	3	15	**
Defense	Laytonsville-Launch.	5321 Riggs Road	Laytonsville	MD	20879				X	3	15	**
Defense	Pomonkey-Launch.	Bumpy Oak Road	Pomonkey	MD	20646				X	3	15	**
Defense	Rockville-Control	10901 Darnstown Road.	Gaithersburg	MD	20878				X	3	15	**
Defense	Rockville-Launch	Muddy Branch	Gaithersburg	MD	20879				X	3	15	**
Defense	US Naval Research Lab—Control.	End of Laurel Branch Drive.	Waldorf	MD	20601				X	3	15	**
EPA	EPA Central Regional Laboratory.	839 Bestgate Road.	Annapolis	MD	21401		X			3	17	**
Navy	NSWC Solomons Island.	Dept of the Navy	Solomons	MD	20688				X	3	15	**
Transportation	USCG Air Sta (Ave "E" Groundwater Contamination).	Aeropark Dr. Sec 12 T27A R1 1W Grand Traverse County.	Traverse City	MI	45685		X		X	5	17	**
Air Force	Twin Cities Air Force Reserve Base.	Minneapolis/St. Paul Hennepin County.	Minneapolis	MN	54450		X		X	5	17	**
Commerce	Brainerd Foundry	10th & Pine Streets.	Brainerd	MN				X		5	17	**
Agriculture	Nantahala National Forest.	Post & Otis Streets, PO Box 2750.	Asheville	NC	28802			X		4	19	**
Army	USA Army Reserve XVIII ARBN Corps.	AFZA FE EE	Fort Bragg	NC	28307			X	X	4	15	**
Army	USA Army Reserve XVIII ARBN Corps.	2144 Lakeshore Dr.	Wilmington	NC	28401		X		X	4	15	**
Army	USA Army Reserve XVIII ARBN Corps.	804 Fairview Rd	Rocky Mount	NC	28701		X		X	4	15	**
Army	USA Army Reserve XVIII ARBN Corps.	E. French Broad St.	Brevard	NC	28712		X		X	4	15	**
Army	USA Army Reserve XVIII ARBN Corps.	1300 Westover Dr.	Charlotte	NC	28205		X		X	4	15	**
Army	USA Army Reserve XVIII ARBN Corps.	1228 Carrol St	Durham	NC	27701				X	4	15	**
Army	USA Army Reserve XVIII ARBN Corps.	224 Louisiana	Asheville	NC	28806		X		X	4	15	**
Army	USA Army Reserve XVIII ARBN Corps.	2017 Garner St	Garner	NC	27529		X		X	4	15	**
Army	USA Army Reserve XVIII ARBN Corps.	156 Parris Ave	High Point	NC	28307		X		X	4	15	**
Army	USA Army Reserve XVIII ARBN Corps.	1825 Woodleaf Rd, PO Box 1927.	Salisbury	NC	28114		X		X	4	15	**
Army	USA Army Reserve XVIII ARBN Corps.	1816 E Main St	Albermarie	NC	28001		X		X	4	15	**

REVISIONS to 2/12/88 DOCKET.—ADDITIONS—Continued

[** = Date of publication]

Agency	Facility name	Facility address	City	State	ZIP code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103	EPA reg	Corr code	Date of listing
Army	USA Army Reserve XVIII ARBN Corps.	405 Fisher St	Morehead City	NC	28557		X		X	4	15	**
Army	USA Army Reserve XVIII ARBN Corps.	3115 Western Blvd.	Raleigh	NC	27606				X	4	15	**
Army	USA Army Reserve XVIII ARBN Corps.	1500 12th Street NW.	Hickory	NC	28601		X		X	4	15	**
Army	USA Army Reserve XVIII ARBN Corps.	1412 Westover Dr.	Charlotte	NC	28205				X	4	15	**
Army	USA Army Reserve XVIII ARBN Corps.	1391 N Mem Dr	Greenville	NC	27834		X		X	4	15	**
Army	USA Army Reserve XVIII ARBN Corps.	1120 Church St	Greensboro	NC	27405		X		X	4	15	**
Army	USA Army Reserve XVIII ARBN Corps.	1400 Carthage Rd.	Lumberton	NC	28358		X		X	4	15	**
Army	USA Army Reserve XVIII ARBN Corps.	724 Foster St	Durham	NC	27701		X		X	4	15	**
Agriculture	NE National Forest.	State Rt 2 West	Halsey	NE	69142			X		7	17	**
Army	Fort Monmouth—Evans Area #1.	Marconi Road	Wall Twp	NJ	07719				X	2	16	**
EPA	GSA Raritan Depot.	4700 Woodbridge Avenue.	Edison	NJ	08817	X	X	X	X	2	16	**
General Services Admin.	GSA/VA Depot	Route 206	Somerville	NJ	08876				X	2	16	**
Transportation	U.S. Coast Guard—Sandy Hook Station.	Hartshorne Drive	Highlands	NJ	07732		X		X	2	15	**
Air Force	Hancock Field	Taft and Thompson Roads.	North Syracuse	NY	13212		X	X	X	2	15	**
Energy	Niagra Falls Storage Site.	E. of Rt 18, N. Of Fletcher RD.	Lewistown	NY	14092				X	2	18	**
Navy	Fort Wadsworth	Ft. Wadsworth	Staten Island	NY	10305		X		X	2	15	**
Defense	US DOD Defense Electronic Supply Center.	1507 Wilmington Pike Montgomery County.	Dayton	OH	45444	X	X	X	X	5	15	**
Air Force	USAF Altus Air Force Base Landfill.	443 ABG/DEEV	Altus	OK	73521		X		X	6	15	**
Energy	USDOE—BPA Alvey Substation.	86000 Franklin	Eugene	OR	97405		X		X	10	15	**
Energy	USDOE—BPA Troutdale Substation.	Sundial Rd	Troutdale	OR	97060		X		X	10	15	**
Army	Camp Santiago	Route 1	Salinas	PR	00751				X	2	15	**
Energy	Western Area Power Admin. Watertown Sub.	1 mi. E. of 1-29	Watertown	SD	57201		X		X	8	15	**
Tennessee Valley Authority.	TVA Silver King Mines Inc.	US Hwy. 18	Edgemont	SD	57735		X		X	8	15	**
Energy	US DOE K-25 Site.	Oak Ridge Turnpike at Blair Road.	Oak Ridge	TN	37830	X	X	X		4	17	**
Air Force	USAF Brooks Air Force Base.	N Gollad Road	San Antonio	TX	78235	X	X	X	X	6	17	**
Air Force	USAF Ellington Air Force Base Hazardous Waste.	Clothier Avenue	Houston	TX	77209				X	6	15	**
Air Force	USAF Goodfellow Air Force Base.	Fort McKavitt Road NS.	San Angelo	TX	76903		X	X	X	6	15	**
Army	US Army Fort Sam Houston.	Bldg 1183 Taylor Road.	San Antonio	TX	78234	X	X	X	X	6	17	**
Army	US Army McAllen Reserve Center.	600 South Second.	McAllen	TX	78501			X		6	15	**

REVISIONS to 2/12/88 DOCKET.—ADDITIONS—Continued

[** = Date of publication]

Agency	Facility name	Facility address	City	State	ZIP code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103	EPA reg	Corr code	Date of listing
Interior	Padre Island National Seashore Bone Yard.	Park Road 22	Corpus Cristi	TX	78418		X	X	X	6	15	**
Navy	Fleet Combat Training Ctr.	Dam Neck	Virginia Beach	VA	23461		X	X	X	3	15	**
Navy	NSC Cheatham Annex.	Naval Supply Center, NORF.	Williamsburg	VA	23185	X	X	X		3	17	**
Air Force	Vermont ANG	Burlington IAP	Burlington	VT	05401		X		X	1	15	**
Energy	USDOE—BPA Bell Substation 3.	2400 Hawthorne	Mead	WA	98218		X	X	X	10	15	**
Energy	USDOE—BPA Columbia Substation.	St Hwy 28 6 mi S of cy.	Rock Island	WA	98850			X	X	10	15	**
Energy	USDOE-BPA Covington Substation.	28401 Covington Way SE.	Kent	WA	98031		X	X	X	10	15	**
Energy	USDOE—BPA Custer Substation.	Portal Way 1 mile So of cy.	Custer	WA	98240		X		X	10	15	**
Energy	USDOE-BPA Midway Substation.	Priest Rapids off Hwy 24.	Vernia	WA	98944		X	X	X	10	15	**
Energy	USDOE—BPA Olympia Substation.	5240 Trosper St SW.	Opympia	WA	98502		X	X	X	10	15	**
Energy	USDOE—BPA Ross Complex.	5411 NE Hwy 99	Vancouver	WA	98666		X	X	X	10	15	**
Energy	USDOE—BPA Snohomish Substation.	10th & D St	Snohomish	WA	98290		X	X	X	10	15	**
Agriculture	US DOA—FS Chequamegon National Forest.	157 N. 5th Avenue.	Park Falls	WI			X	X		5	15	**
Air Force	Wake Island Air Field.		Wake Island Air Field.	WQ	96798				X	9	15	**
Veterans Administration.	VA Medical Ctr	None Per V.A.M.C..	Sheridan	WY	82801				X	8	15	**

REVISIONS TO 2/12/88 DOCKET—MISCELLANEOUS

[** = Date of Publication

Agency	Facility name	Facility address	City	State	Zip Code	RCRA 3005	RCRA 3010	RCRA 3016	CER-CLA 103	EPA Reg	CORR code	Date of listing
Air Force	Port Moller	55 59'22" N 160 34' 29.374" W.	Port Moller	AK	99999		X		X	10	22	**
Interior	Amchitka Island.	51-32 N 179-00 E.	Amchitka Island	AK	99502		X			10	22	**
Energy	Naval Petroleum Reserve #1.	ELK HILLS	Tupman	CA	93276			X	X	9	21	**
Navy	Moffett Field ANG.	129 ARRG/CC.	Sunnyvale	CA	94031		X			9	21	**
Energy	Anvil Points	7 mi W. of Rifle.	Rifle	CO	81650				X	8	21	**
Defense	US Soldiers and Airmens Home.	Unobtainable.	Washington	DC	20317		X	X		3	21	**
Air Force	US Air Force Plant 85.	4300 E. 5th Avenue.	Columbus	OH	43216	X	X	X	X	5	21	**
Corps of Engineers, Civil.	US Army Engineer District Pittsburgh.	Ohio Rt. 88 County Road 225.	Vernon Township	OH	44428		X	X		5	21	**

REVISIONS TO 2/12/88 DOCKET—MISCELLANEOUS—Continued

[** = Date of Publication

Agency	Facility name	Facility address	City	State	Zip Code	RCRA 3005	RCRA 3010	RCRA 3016	CER-CLA 103	EPA Reg	CORR code	Date of listing
Corps of Engineers, Civil.	USA-COE Willamette.	West Linn	West Linn	OR	97068				X	10	21	**
Interior	Charlestown NAS.	PO Box 307	Charlestown	RI	02813			X	X	1	21	**
Navy	Defense Printing Service Office.	RMBE 854 The Pentagon.	Arlington	VA	20301		X			3	21	**
Corps of Engineers, Civil.	USA-COE Lake Washington.	3015 NW 54th St.	Seattle	WA	98107		X		X	10	21	**
Treasury	Customs Service-Seattle.	909 First Ave.	Seattle	WA	98174		X			10	21	**

CORRECTIONS TO DOCKET LISTING

[Code 20]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103
Corrections to Docket Listing (O=Original Listing published in February; C=Corrected Listing)									
O—Air Force	Cape Newenham AFS.	11 TCG/CC Bay	Elmendorf AFB	AK	99506				X
C—Air Force	Cape Newenham AFS.	11 TCG/CC Bay	Elmendorf AFB	AK	99506		X		X
O—Air Force	Cape Romanzof AFS	11 TCG/CC	Elmendorf	AK	99506		X		X
C—Air Force	Cape Romanzof AFS	11 TCG/CC	Elmendorf	AK	99506		X		X
O—Air Force	Eielson AFB	5010 CSG/DE	Eielson AFB	AK	99702				X
C—Air Force	Eielson AFB	5010 CSG/DE	Eielson AFB	AK	99702	X			X
O—Air Force	Elmendorf AFB	215 CSG/DEEV	Anchorage	AK	99506		X		
C—Air Force	Elmendorf AFB	21 CSG/DE	Elmendorf AFB	AK	99506-5000	X	X		
O—Air Force	Galena Air Force Station.	5072 CSS/CC	Galena AFS	AK	99741		X		X
C—Air Force	Galena Air Force Station.	5072 CSF/CC	Galena AFS	AK	99741		X		X
O—Air Force	Shemya AFB	5073rd ABG/CC	Shemya AFB	AK	98736				X
C—Air Force	Shemya AFB	5073rd ABG/CC	Shemya AFB	AK	98736		X		X
O—Air Force	Tatalina AFS	11 TCG/CC	Elmendorf AFB	AK	99506				X
O—Air Force	Tatalina AFS	11 TCG/CC	Elmendorf AFB	AK	99506		X		X
O—Air Force	Tin City AFS	11 TCG/CC	Elmendorf AFB	AK	99506				X
C—Air Force	Tin City AFS	11 TCG/CC	Elmendorf AFB	AK	99506		X		X
O—Air Force	USAF Cape Lisbourne AFS.	40 Miles NE of Point Hope.	Cape Lisbourne AFB	AK	99766		X		
C—Air Force	USAF Cape Lisbourne AFS.	11 TCG/CC	Elmendorf AFB	AK	99506		X		X
O—Army	US Army Gerstle River Test Site.	T13S R14E Sec 9, 15, 16.	Fort Greely	AK	98733				X
C—Army	US Army Gerstle River Test Site.	T13S R14E Sec 9, 15, 16.	Fort Greely	AK	98733	X	X		X
O—Army	US Army National Guard Alaska USPFO.	Army Guard Rd & Davis Hwy.	Fort Richardson	AK	99505				
C—Army	Fort Richardson	Army Guard Rd & Davis Hwy.	Fort Richardson	AK	99505	X	X	X	
O—Corps of Engineers, Civil.	US Army-COE Port Moller.	55 59'22 N 160 34'29.374 W.	Port Moller	AK	99999		X		
C—Air Force	Port Moller	55 59'22 N 160 34'29.374 W.	Port Moller	AK	99999		X		
O—Corps of Engineers, Civil.	US-COE Amchitka Island.	51-32 N 179-00 E	Amchitka Island	AK	99502		X		
C—Interior	Amchitka Island	51-32 N 179-00 E	Amchitka Island	AK	99502		X		
O—Interior	FWS—Kenai National Wildlife Refuge.	Ski Hill Road	Soldotna	AK	99669				X
C—Interior	FWS—Kenai National Wildlife Refuge.	Ski Hill Road	Soldotna	AK	99669			X	X
O—Navy	US Navy Adak Naval Station.	51-54N, 176-45W	Adak Island	AK	99599				X
C—Navy	US Navy Adak Naval Station.	51-54N, 176-45W	Adak Island	AK	99599	X	X	X	X

CORRECTIONS TO DOCKET LISTING—Continued

[Code 20]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103
O—Transportation	USDOT-CG Kodiak Support Ctr.	Womans Bay Kodiak Isl.	Kokiak	AK	99619				X
C—Transportation	USDOT-CG Kodiak Support Ctr.	Womans Bay Kodiak Isl.	Kodiak	AK	99619		X		X
O—Transportation	USDOT—FAA Fire Is Air Warning Station.	Cook Inlet Section 7 & 8 Rnge.	Anchorage	AK	99506				X
C—Transportation	USDOT—FAA Fire Is Air Warning Station.	Cook Inlet Section 7 & 8 Rnge.	Anchorage	AK	99506		X		X
O—Tennessee Valley Authority.	TVA Bellefonte Nuclear Plt.	Off US Hwy 72	Hollywood	AL	36401				X
C—Tennessee Valley Authority.	TVA Bellefonte Nuclear plt.	Off US Hwy 72	Hollywood	AL	36401		X		X
O—Tennessee Valley Authority.	TVA Guntersville Hydro Plant.	Off US Hwy 431, 11 Mi. NW of.	Guntersville	AL	35976		X		
C—Tennessee Valley Authority.	TVA Guntersville Hydro Plant.	Off US Hwy 431, 11 Mi. NW of Guntersville.	Guntersville	AL	35976		X		
O—Tennessee Valley Authority.	TVA Muscle Shoals Power Stores.	AL Hwy 133	Muscle Shoals	AL	35660		X		X
C—Tennessee Valley Authority.	TVA Muscle Shoals Power Stores.	AL Hwy 133	Muscle Shoals	AL	35660	X	X		X
O—Tennessee Valley Augnority.	TVA National Fertilizer Dev Ctr.	Wilson Dam Road	Muscle Shoals	AL	35660		X	X	X
C—Tennessee Valley Augnority.	TVA National Fertilizer Dev Ctr.	Wilson Dam Road	Muscle Shoals	AL	35660	X	X	X	X
O—Tennessee Valley Authority.	TVA Wilson Hydro Plant.	Al Hwy 133	Florence	AL	35660				X
C—Tennessee Valley Authority.	TVA Wilson Hydro Plant.	Al Hwy 133	Florence	AL	35660		X		
O—Army	US Army Fort Chaffee.		Fort Chaffee	AR	72905	X	X	X	X
C—Army	US Army Fort Chaffee.	Building 239	Fort Chaffee	AR	72905	X	X	X	X
O—Air Force	Air Force Plant 44	Emery Port Station	Tucson	AZ	85734			X	
C—Air Force	Air Force Plant 44 (Hughes Aircraft Co.).	Emery Port Station	Tucson	AZ	85734	X		X	
O—Air Force	Davis-Monthan AFB	836 CSG/CC	Tucson	AZ	85707	X	X	X	X
C—Air Force	Davis-Monthan AFB	836 CSG/CC	Davis-Monthan AFB	AZ	85707	X	X	X	X
O—Air Force	Luke Air Force Base	832 CSG/DE	Luke Air Force Base	AZ	85309	X	X	X	X
C—Air Force	Luke Air Force Base	832 CSG/DE	Luke Air Force Base	AZ	85309	X	X	X	X
O—Army	Ft Huachuca, US Army.		Fort Huachuca	AZ	85613		X		X
C—Army	Ft Huachuca, US Army.		Fort Huachuca	AZ	85613		X	X	X
O—Army	Yuma Proving Ground US Army.	US Army Yuma Providing Ground.	Yuma	AZ	85364	X	X		X
C—Army	Yuma Proving Ground US Army.	US Army Yuma Providing Ground.	Yuma	AZ	85364	X	X	X	X
O—Interior	BLM—Asarco Inc., Silver Bell Mine & Mill.	T12SR8ESEC2		AZ	85658				X
C—Interior	BLM—Asarco Inc., Silver Bell Mine & Mill.	T12SR8ESEC2 Avra Vly Rd.	Silver Bell	AZ	85658				X
O—Interior	BLM—Congress Con Gold Mine.	T10NR6WSEC22,23		AZ	85442				X
C—Interior	Blm—Congress Con Gold Mine.	T10NR6WSEC22,23	Congress	AZ	85332				X
O—Interior	BLM-Cyprus Bagdad Copper Co.	T14NR9WSEC8,9		AZ	86321				X
C—Interior	BLM—Cyprus Bagdad Copper Co.	T14NR9WSEC8,9		AZ	86321		X		X
O—Interior	BLM—DateLand Landfill.	T78SR13WSEC3		AZ	85333				X
C—Interior	BLM—DateLand Landfill.	T17SR13WSEC3	Dateland	AZ	85333				X
O—Interior	BLM—Dome Landfill	T8SR20WSEC13		AZ	85369				X
C—Interior	BLM—Dome Landfill	T8SR20WSEC 13	Dome	AZ	85364				X
O—Interior	BLM—Golden Valley Landfill.	T21NR17WSEC17		AZ	86401				X
C—Interior	BLM-Golden Valley Landfill.	T21NR17WSEC17	Kingman	AZ	86401				X
O—Interior	BLM-Inspiration Con. Copper—Oxhide Area.	T1NR15ES2, 5, 13, 15, 18.		AZ	85501				X

CORRECTIONS TO DOCKET LISTING—Continued

[Code 20]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103
C—Interior	BLM-Inspiration Con. Copper—Oxhide Area.	T1NR15SES2, 5, 13, 15, 18.	4 Mi W of Inspiration	AZ	85501				X
O—Interior	BLM-Inspiration Con. Copper—Inspir Area.	T1NR4ES2, 7, 9		AZ	85532				X
C—Interior	BLM-Inspiration Con. Copper—Inspir Area.	T1NR4ES2, 7, 9	Inspiration	AZ	85532				X
O—Interior	BLM-Kennecott Minerals Co. Mines Pit.	T2SR13ESEC36		AZ	85273				X
C—Interior	BLM-Kennecott Minerals Co. Mines Pit.	T2SR13ESEC36		AZ	85273				X
O—Interior	BLM-Lake Havasu San. District.	T14NR2OWSEC13, 14.		AZ	86403				X
C—Interior	BLM-Lake Havasu San. District.	T14NR2OWSEC13,14	Lake Havasu	AZ	86403				X
O—Interior	BLM-Ranchers Explo & Dev Corp. Bluebird.	T1NR14ESEC35, 36		AZ	85501				X
C—Interior	BLM-Ranchers Explo & Dev Corp. Bluebird Mine.	T1NR124ESEC35,36		AZ	85501				X
C—Interior	BLM-Roll Landfill	T7SR17WSEC34		AZ	85343			X	
C—Interior	BLM-Roll Landfill	T17SR17WSEC34		AZ	85343				X
O—Interior	BLM-Zonia Copper Mine.	T11NR4WSEC12, 13, 14.		AZ	86332				X
C—Interior	BLM-Zonia Copper Mine.	T11NR4WSEC12, 13, 14 Star Rt.	Kirkland	AZ	86332				X
O—Interior	Yuma Desalting Pit	7301 Calle Agua Salado.	Yuma	AZ	85364				
C—Interior	Yuma Desalting Pit	7301 Calle Agua Salado.	Yuma	AZ	85364	X	X		
O—Navy	Marine Corps Air Station, Yuma.	Ave 3-E	Yuma	AZ	85364	X	X	X	
C—Navy	Marine Corps Air Station, Yuma.	Ave 3-E	Yuma	AZ	85364	X	X	X	X
O—Air Force	Air Force Plant 42	20th Street & Aves. D & M.	Palmdale	CA	93550	X	X		X
C—Air Force	Air Force Plant 42 (Rockwell International).	20th Street & E Aves. D & M.	Palmdale	CA	93550	X	X		X
O—Air Force	George Air Force Base.	331 CSG/DE	Victorville	CA	92392	X	X	X	X
C—Air Force	George Air Force Base.	331 CSG/DE	George AFB	CA	92392	X	X	X	X
O—Air Force	Norton Air Force Base.	63ABG/DE	Norton AFB	CA	92409	X	X		X
C—Air Force	Norton Air Force Base.	63ABNG/DE	Norton AFB	CA	92409	X	X	X	X
O—Air Force	Sunnyvale Air Force Station.	6594 ABS/CC	Sunnyvale	CA	94088		X		X
C—Air Force	Camp Parks Communication Annex.	6594 ABS/CC	Pleasanton	CA	94088			X	X
O—Army	Oakland Army Base	Bldg-1 Alaska St	Oakland	CA	94626		X		X
C—Army	Oakland Army Base	Bldg-1 Alaska St	Oakland	CA	94626	X	X	X	X
O—Army	Riverbank Army Ammunition Depot.	5300 Claus Rd	Riverbrook	CA	95367-0678				X
C—Army	Riverbank Army Ammunition.	5300 Claus Rd	Riverbank	CA	95367-0678	X	X	X	X
O—Defense	Defense Fuel Supply Center Ozol.	Carquinez Scenic Drive.	Martinez	CA	94533		X	X	X
C—Defense	Defense Fuel Supply Center Ozol.	Carquinez Scenic Drive.	Martinez	CA	94553		X	X	X
O—Energy	Energy Technology Engineering Center.	Woolsey Canyon	Ventura County	CA	93063	X			
C—Energy	Energy Technology Engineering Center.	Santa Susana Mtn	Chatsworth County	CA	93063	X		X	
O—General Services Admin.	GSA Federal Building	450 Golden Gate Avenue.	San Francisco	CA	94102		X		
C—General Services Admin.	GSA Philip Burton Federal Building.	450 Golden Gate Avenue.	San Francisco	CA	94102		X		

CORRECTIONS TO DOCKET LISTING—Continued

[Code 20]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103
O—Interior	BLM—Shell Oil Co. of California Gore B.	T31SR22ESEC21	Taft	CA			X	X	X
C—Interior	BLM—Shell Oil Co. of California Gore B.	T31SR22ESEC21	Taft	CA					X
O—NASA	H.L. Dryden Flight Research Facility.	PO Box 273	Edwards	CA	93523-5000	X	X		
C—NASA	H.L. Dryden Flight Research Facility.	PO Box 273	Edwards	CA	93523-5000	X	X	X	
O—Navy	Marine Corps Air Station, El Toro.	EEPB Fac Mgmt Dept.	Santa Ana	CA	92709		X	X	X
C—Navy	Marine Corps Air Station, El Toro.	EEPB Fac Mgmt Dept.	Santa Ana	CA	92709	X	X	X	X
O—Navy	Marine Corps Air Station, Tustun.	USMC Air Station	Tustin	CA	92710-5001	X			X
C—Navy	Marine Corps Air Station, Tustin-Helicopter.	USMC Air Station	Tustin	CA	92710-5001	X	X		X
O—Navy	Marine Corps Mountain Warfare Training Center.	Pickle Meadows	Bridgeport	CA	92517		X		X
C—Navy	Marine Corps Mountain Warfare Training Center.	Pickle Meadows	Bridgeport	CA	93517		X		X
O—Navy	Naval Air Facility, El Centro.	Route 80	El Centro	CA	92234	X	X		
C—Navy	Naval Air Facility, El Centro.	Route 80	El Centro	CA	92234	X	X		X
O—Navy	Naval Air Logistics Force, Crows.	Nalf Crows Landing	Crows Landing	CA	95313		X		
C—Navy	Naval Air Logistics Force, Crows Landing.	Nalf Crows Landing	Crows Landing	CA	95313		X		
O—Navy	Naval Communication Station, Stockton.	Rough & Ready Island.	Stockton	CA	95203	X	X		X
C—Navy	Naval Communication Station, Stockton.	Rough & Ready Island.	Stockton	CA	95203	X	X	X	X
O—Navy	Naval Petroleum Reserve #1.	Elk Hills	Tupman	CA	93276	X	X	X	
C—Energy	Naval Petroleum Reserve #1.	Elk Hills	Tupman	CA	93276				X
O—Navy	Naval Shipyard, Mare Island.	W. End Of Tennessee St.	Vallejo	CA	94592	X	X		X
C—Navy	Naval Shipyard, Mare Island.	W. End Of Tennessee St.	Vallejo	CA	94592	X	X	X	X
O—Navy	Naval Station, San Diego.	Bldg 3275, P.O. Box 113.	San Diego	CA	92136	X	X		
C—Navy	Naval Station, San Diego.	Bldg 3275, P.O. Box 113.	San Diego	CA	92136	X	X	X	X
O—Navy	Naval Submarine Base, San Diego.	Naval Station	San Diego	CA			X		
C—Navy	Naval Submarine Base, San Diego.	Naval Station Building 545.	San Diego	CA			X	X	
O—Navy	Naval Supply Center, Oakland.	7th & Maritime Building 311 East.	Oakland	CA	94623	X	X		X
C—Navy	Naval Supply Center, Oakland.	7th & Maritime Building 311 East.	Oakland	CA	94623	X	X	X	X
O—Navy	Naval Supply Center, Point Loma Annex.	NAVSUBSUPPFAC San Diego.	San Diego	CA	92152	X	X		X
C—Navy	Naval Supply Center, Point Loma Annex.	NAVSUBSUPPFAC San Diego Bldg 546.	San Diego	CA	92152	X	X		X
O—Navy	Naval Weapons Station, China Lake.	Code 2632	China Lake	CA	93555	X	X		X
C—Navy	Naval Weapons Station, China Lake.	Code 2632	China Lake	CA	93555	X	X	X	X
O—Navy	Naval Weapons Station, Concord.	Port Chicago Hwy	Concord	CA	94520	X			X
C—Navy	Naval Weapons Station, Concord.	Port Chicago Hwy	Concord	CA	94520	X		X	X

CORRECTIONS TO DOCKET LISTING—Continued

[Code 20]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103
O—Navy	Nav Weapons Station, Seal Beach-Fallbrook.	600 Fallbarook W/ Ammunition Rd.	Fallbrook	CA	92028		X		
C—Navy	Nav Weapons Station, Seal Beach-Fallbrook.	600 Fallbrook W/ Ammunition Rd.	Fallbrook	CA	92028	X	X	X	X
O—Navy	Pacific Missile Test Center, Point Mugu.		Point Mugu	CA					
C—Navy	Pacific Missile Test Center, Point Mugu.		Point Mugu	CA	93042	X	X		X
O—Transportation	Twelfth Coast Guard, District FLP.	Coast Guard, Government Island.	Alameda	CA	94501		X		
C—Transportation	US Coast Guard Support Center, Alameda.	Coast Guard, Government Island.	Alameda	CA	94501		X		
O—Transportation	US Coast Guard Base.	Yerba Buena Island	San Francisco	CA	94130		X		
C—Transportation	US Coast Guard Base, San Francisco.	Yerba Buena Island	San Francisco	CA	94130		X		
O—Transportation	USCG Base Terminal Island.	1801 Seaside Ave	San Pedro	CA	90731		X		
C—Transportation	US Coast Guard Support Center, San Pedro.	1801 Seaside Ave	San Pedro	CA	90731		X		
O—Air Force	Air Force Plant Pjks	12250 S. Hwy 75	Waterton	CO	80120			X	X
C—Air Force	Air Force Plant Pjks Property.	12250 S. Hwy 75	Waterton	CO	80120			X	X
O—Army	Ft. Carson—U.S. Army.	DFAE Bldg. 304, AFZC-FE-EQ.	Ft. Carson	DO	80913	X	X		X
C—Army	Ft. Carson—U.S. Army.	DFAE Bldg. 304, AFZC-FE-EQ.	Ft. Carson	CO	80913	X	X	X	X
O—Energy	Solar Energy Research Inst.	1617 Cole Blvd	Golden	CO	80401		X		X
C—Energy	Solar Energy Research.	1617 Cole Blvd	Golden	CO	80401	X	X		X
O—EAP	US EPA-Nat'l Enforcement Invest Ctr..	DFC	Denver	CO	80225	X			
C—EPA	National Enforcement Investigation Center.	DFC	Denver	CO	80225	X			
O—Interior	BLM-Orchard Mesa Landfill.	T2SR1ESEC4, 5	Grand Junction	CO	81506				X
C—Interior	BLM-Orchard Mesa Landfill.	T2SR1ESEC4, 5 Hwy 5.-SW of 29¾ RD.	Grand Junction	CO	81506				X
O—Interior	BLM-Placerville Tram Site.	T44NR11WSEC35	Placerville	CO					X
C—Interior	BLM-Placerville Tram Site.	T44NR11WSEC35 HWY 62.	Placerville	CO	81430				X
O—Interior	BLM-Sawpit Tram Site.	T43NR10WSEC18		CO					X
C—Interior	BLM-Sawpit Tram Site (Ore Storage).	T43NR10WSEC18	Saw Pit	CO					X
O—Interior	US Bureau of Rec.-Engineering Lab/ Wtr&Pwr Resrces.	Denver Federal Center, Bldg. 56.	Denver	CO	80225	X	X		
C—Interior	US Bureau of Rec-Engineering & Research Center.	Denver Federal Center, Bldg. 56.	Denver	CO	80225	X	X		
O—Energy	Knolls Atomic Power Laboratory Windsor Site.	Prospect Hill Road	Windsor	CT	06095	X	X		
C—Energy	US DOE Knolls Atomic Power Laboratory Windsor Site.	Prospect Hill Road	Windsor	CT	06095	X	X		
O—Navy	Naval Underwater Systems Center.	New London Laboratory.	New London	CT	06302		X		
C—Navy	Naval Underwater Systems Center.	New London Laboratory.	New London	CT	06320		X		
O—Treasury	US Bureau of Engraving & Printing.	14th & C Sts SW	Washington	CD	20228	X	X		
C—Treasury	US Bureau of Engraving & Printing.	14th & C Sts SW	Washington	CD	20228		X		

CORRECTIONS TO DOCKET LISTING—Continued

[Code 20]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103
O—Corps of Engineers, Civil.	USA—COE Canal Site.	Main St. North St Georges.	Newcastle	E	19733			X	
C—Corps of Engineers, Civil.	USA—COE Canal Site.	Main St. North St Georges.	Newcastle	DE	19733			X	X
O—Air Force	Avon Park AFB	56 Combat Support Group/DE.	MacDill AFB	FL	33608		X		
C—Air Force	Avon Park AFB	56 Combat Support Group/DE.	MacDill AFB	FL	33608		X		
O—Air Force	Cape Canaveral	6550 ABW DER	Patrick AFB	FL	32925		X	X	X
C—Air Force	Cape Canaveral	6550 ABW/DER	Patrick AFB	FL	32925	X	X	X	X
O—Air Force	Eglin AFB	ADTC/CCN	Eglin AFB	FL	32542	X	X	X	X
C—Air Force	Eglin AFB	ADTC/CCN	Eglin AFB	FL	32542	X	X	X	X
O—Air Force	Homestead Air Force Base.	31 CSG/DE	Homestead AFB	FL	33039	X	X	X	
C—Air Force	Homestead Air Force Base.	31 CSG/DE	Homestead AFB	FL	33039	X	X	X	
O—Air Force	MacDill Air Force Base.	56 Combat Support Group/DE.	MacDill AFB	FL	33608	X	X	X	X
C—Air Force	MacDill Air Force Base.	56 Combat Support Group/DE.	MacDill AFB	FL	33608	X	X	X	X
O—Air Force	Patrick Air Force Base.	Base Civil Engineer	Patrick AFB	FL	32925		X	X	
C—Air Force	Patrick Air Force Base.	Base Civil Engineer	Patrick AFB	FL	32925	X	X	X	
O—Air Force	Tyndall Air Force Base.	4756 ABG/DE	Tyndall AFB	FL	32403		X	X	X
C—Air Force	Tyndall Air Force Base.	325 CSB/DE	Tyndall AFB	FL	32403	X	X	X	X
O—Army	USA AMSA 53G/ Tampa.	4823 N Hubert Ave	Tampa	FL	33614		X		
C—Army	USA AMSA 53G/ Tampa.	4823 N Hubert Ave	Tampa	FL	33614	X	X		
O—Energy	US Department of Energy—Pinellas Plant.	7887 Bryan Dairy Rd	Largo	FL	34294		X	X	
C—Energy	US Department of Energy—Penellas Plant.	7887 Bryan Dairy Rd	Largo	FL	34294	X	X	X	
O—EPA	US EPA/Research Laboratory.	Sabin Island	Gulf Breeze	FL	32561		X		
C—EPA	Environmental Research Facility.	Sabin Island	Gulf Breeze	FL	32561	X			
O—NASA	Kennedy Space Center.	NASA Mail Code DF-EMS.	Kennedy Space Center.	FL	32889		X		
C—NASA	Kennedy Space Center.	NASA Mail Code DF-EMS.	Kennedy Space Center.	FL	32889	X	X		
O—Navy	Naval Air Sta, Jacksonville.	Code 184 Public Wks Dept Box 5.	Jacksonville	FL	32212		X		
C—Navy	Naval Air Sta, Jacksonville.	Code 184 Public Wks Dept Box 5.	Jacksonville	FL	32212	X	X		
O—Navy	Naval Air Station, Cecil Field.	103rd St. & Normandy Blvd..	Jacksonville	FL	32215		X	X	
C—Navy	Naval Air Station, Cecil Field.	103rd St. & Normandy Blvd..	Jacksonville	FL	32215	X	X	X	
O—Navy	Naval Air Station, Key West.	Naval Air Station	Key West	FL	33042		X		
C—Navy	Naval Air Station, Key West.	Naval Air Station	Key West	FL	33042	X	X		
O—Navy	Naval Coastal Systems Ctr, Panama City.	Code 631OMC	Panama City	FL	32407		X	X	
C—Navy	Naval Coastal Systems Ctr, Panama City.	Code 631OMC	Panama City	FL	32407	X	X	X	X
O—Navy	Naval Station Mayport.	PO Box 265 Naval Station.	Mayport	FL	32228		X	X	X
C—Navy	Naval Station Mayport.	PO Box 265 Naval Station.	Mayport	FL	32228	X	X	X	X
O—Transportation	USCG Base, Miami Beach.	100 MacArthur Cswy	Miami Beach	FL	33139		X		
C—Transportation	USCG Base, Miami Beach.	100 MacArthur Cswy	Miami Beach	FL	33139		X	X	
O—Air Force	Moody Air Force Base/GA TAC.	347 CSG/DE	Moody AFB	GA	31669		X	X	X
C—Air Force	Moody Air Force Base/GA TAC.	347 CSG/DE	Moody AFB	GA	31669	X	X	X	X

CORRECTIONS TO DOCKET LISTING—Continued

[Code 20]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103
O—Air Force	Robins Air Force Base.	2853 CES/DE	Robins Air Force Base.	GA	31098		X	X	X
C—Air Force	Robins Air Force Base.	2853 CES/DE	Robins Air Force Base.	GA	31098	X	X	X	X
O—Air Force	USAF Plant No. 6 Lockheed.	86 S Cobb Drive	Marietta	GA	30063		X	X	X
C—Air Force	USAF Plant No. 6 Lockheed.	86 S Cobb Drive	Marietta	GA	30063	X	X	X	X
O—Army	USA Fort Benning	GA. Hwy 1 & US 27	Fort Benning	GA	31905		X		X
C—Army	USA Fort Benning	GA. Hwy 1 & US 27	Fort Benning	GA	31905	X	X		X
O—Army	USA Fort Gillem	Attn AFZK-EH-C	Forest Park	GA	30330		X	X	X
C—Army	USA Fort Gillem	Attn AFZK-EH-C	Forest Park	GA	30330		X	X	X
O—Army	USA Fort Gordon & HQ USA Signal Ctr.	ATZHFE EC	Fort Gordon	GA	30905		X		
C—Army	USA Fort Gordon & HQ USA Signal Ctr.	ATZHFE EC	Fort Gordon	GA	30905		X		X
O—Army	USA Fort Stewart	24th Infantry Div AFZP-DEN-E.	Fort Stewart	GA	31314		X	X	X
C—Army	USA Fort Stewart	24th Infantry Div AFZP-DEN-E.	Fort Stewart	GA	31314	X	X	X	X
O—Navy	Marine Corps Logistics Base, Albany.	Fleming Rd	Albany	GA	31704		X	X	X
C—Navy	Marine Corps Logistics Base, Albany.	Fleming Rd	Albany	GA	31704	X	X	X	X
O—Navy	Naval Submarine Base, Kings Bay.	GA State Hwy Spur	Kings Bay	GA	31547		X	X	X
C—Navy	Naval Submarine Base, Kings Bay.	GA State Hwy Spur	Kings Bay	GA	31547	X	X	X	X
O—Navy	Apra Harbor Naval Complex.	Apra Harbor Naval	Piti	GU	96630				X
C—Navy	Apra Harbor Naval Complex.	Apra Harbor Naval Complex.	Piti	GU	96630				X
O—Navy	Naval Air Station Agana.		Agana	GU	96637		X		X
C—Navy	Naval Air Station Agana.		Agana	GU	96637	X	X		X
O—Navy	Naval Station, Guam	Navy Public Wks Ctr.	Agana	GU	96630	X	X		X
C—Navy	Naval Station, Guam	Navy Public Wks Ctr.	Agana	GU	96630	X	X	X	X
O—Air Force	Johnston Atoll Nat'l Wildlife Refuge.	P.O. Box 50167	Honolulu	HI	96850			X	
C—Air Force	Johnston Atoll Nat'l Wildlife Refuge.	P.O. Box 50167	Honolulu	HI	96850		X	X	
O—Interior	Howland Island National Wildlife Refuge.	P.O. Box 50167	Honolulu	HI					X
C—Interior	Howland Island National Wildlife Refuge.	P.O. Box 50167	Honolulu	HI				X	
O—Navy	Kaneohe Bay Marine Corps Air Station.	MCAS Kaneohe Base Moakapu Penin.	Kaneohe Bay	HI	96863	X	X		
C—Navy	Kaneohe Bay Marine Corps Air Station.	MCAS Kaneohe Base Moakapu Penin.	Kaneohe Bay	HI	96863	X	X		X
O—Navy	Naval Magazine Lualualei.		Westloch	HI	96860	X	X		
C—Navy	Naval Magazine Lualualei.	Naval Magazine Demilitarization Furnace.	Westloch	HI	96860	X	X		X
O—Navy	Naval Shipyard, Pearl Harbor.		Pearl Harbor	HI	96860	X	X		X
C—Navy	Naval Shipyard, Pearl Harbor.		Pearl Harbor	HI	96860	X	X	X	X
O—Navy	Pacific Missile Range Facility.	Pacific Missile Range Facility.	Kekaha	HI	96752	X	X		
C—Navy	Pacific Missile Range Facility.	Pacific Missile Range Facility.	Kekaha	HI	96752	X	X	X	
O—Navy	Pearl Harbor Navy Public Works Ctr.	Naval Station Area	Pearl Harbor	HI	96860	X	X		X
C—Navy	Pearl Harbor Navy Public Works Ctr.	Naval Station Area	Pearl Harbor	HI	96860	X	X	X	X
O—Army	Iowa Army Ammunition Plant.	Hwy 79 Off Middletown Road.	Middletown	IA	52636	X	X		X
C—Army	Iowa Army Ammunition Plant.	Hwy 79 Off Middletown Road.	Middletown	IA	52636	X	X	X	X

CORRECTIONS TO DOCKET LISTING—Continued

[Code 20]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103
O—Agriculture	USDA FS Clayton Creek Dump.	T 39 N, R 11E, SEC 21.	Headquarters	ID	83534				X
C—Agriculture	Clearwater National Forest.	T 39 N, R 11E, SEC 21.	Headquarters	ID	83534				X
O—Air Force	Mountain Home AFB	366 CSG/DE	Mountain Home	ID	83648				X
C—Air Force	Mountain Home AFB	366 CSG/DE	Mountain Home AFB	ID	83648	X	X	X	X
O—Energy	USDOE Idaho Nat'l Engineering Lab.	AEC Testing Reservation.	Scoville	ID	83401				X
C—Energy	USDOE Idaho Nat'l Engineering Lab.	US Hwy 20/26, 40 mi west of Idaho Falls.		ID	83401	X	X		X
O—Interior	BLM-Champagne Creek Mine.	T3N R24W SEC15	Grouse	ID	83242			X	X
C—Interior	BLM-Champaigne Creek Mine.	T3N R24E SEC15	Grouse	ID	83242			X	X
O—Interior	BLM Shoshone (Glen Cave).	T4S R17E S14	Shoshone	ID	83352				X
O—Interior	BLM Shoshone (Gwinn Cave).	T4S R17E S14	Shoshone	ID	83352				X
O—Interior	BLM-Delmar Silver Mine.	T.15sS.R.35E		ID					X
C—Interior	BLM-Delamar Silver Mine.	T.15S.R.35E		ID					X
O—Interior	BLM-Owyhee Co. Marsing/Homedale Lf.	T2NR5WSEC8		ID					X
C—Interior	BLM-Owyhee Co. Marsing/Homedale Lf.	Johnson Rd. T4N R5W S32 SW ¼.	Marsing-Homedale	ID	83639				X
O—Air Force	Chanute Air Force Base.	3345 ABG/DE	Rantoul	IL	61858	X	X	X	X
C—Air Force	Chanute Air Force Base.	3345 ABG/DE	Rantoul	IL	61868	X	X	X	X
O—Army	Joliet Army Ammo Plant Uniroyal Mfg Area.	6 Miles S. of Elwood Off Rte. 53, Will County.	Joliet	IL	60634		X		X
C—Army	Joliet Army Ammunition Plant.	6 Miles S. of Elwood Off Rte. 53, Will County.	Joliet	IL	60634	X	X		X
O—EPA	US EPA Central Regional Lab.	536 S. Clark Street, 10th Floor.	Chicago	IL	60605		X		
C—EPA	Region 5, Environmental Services Division Laboratory.	536 S. Clark Street, 10th Floor.	Chicago	IL	60605		X		
O—Air Force	McConnell AFB	384 CSG/DE	Wichita	KS	67221	X	X		
C—Air Force	McConnell AFB	384 CSG/DE 2801	Wichita	KS	67221	X	X	X	X
O—Army	Combined Arms Cnt. & Ft. Leavenworth.	Ft. Leavenworth Reservation.	Leavenworth	KS	66027	X	X		
C—Army	Combined Arms Cnt. & Ft. Leavenworth.	Ft. Leavenworth Reservation.	Leavenworth	KS	66027	X	X	X	
D—Army	Ft. Riley 1st Infantry Div (M).	Dickmon Ave.	Junction City	KS	66442	X	X		
C—Army	Ft. Riley 1st infantry Div (M).	Dickman Ave.	Junction City	KS	66442	X	X	X	X
O—Army	Kansas AAP	3 Miles East of Town	Parsons	KS	67357	X	X		X
C—Army	Kansas AAP	3 Miles East of Town	Parsons	KS	67357	X	X	X	X
O—Army	Sunflower Army Ammunition Plant.	103 Rd St. South of Desoto.	Desoto	KS	66018	X	X		
C—Army	Sunflower Army Ammunition Plant.	103 Rd St. South of Desoto.	Desoto	KS	66018	X	X	X	X
O—Army	Lexington-Bluegrass Army Depot.	Haley Rd	Lexington	KY	40511		X	X	X
C—Army	Lexington-Bluegrass Army Depot.	Haley Rd	Lexington	KY	40511	X	X	X	X
O—Army	USA ARMC & Fort Knox.	Hwy 31 W	Fort Knox	KY	40121		X	X	
C—Army	USA ARMC & Fort Knox.	Hwy 31 W	Fort Knox	KY	40121	X	X	X	
O—Army	Fort Cambell	AFZB-FE-ECE	Fort Campbell	KY	42223			X	X
C—Army	Fort Cambell	AFZB-FE-ECE	Fort Campbell	KY	42223	X	X	X	X
O—Energy	US DOE Paducah Gas Diffusion Plt.	PO Box 1410	Paducah	KY	42001		X	X	
C—Energy	US DOE Paducah Gas Diffusion Plt.	PO Box 1410	Paducah	KY	42001	X	X	X	
O—Navy	Naval Ordinance Station, Louisville.	Southside Dr. MDS 42.	Louisville	KY	40214		X	X	

CORRECTIONS TO DOCKET LISTING—Continued

[Code 20]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103
C—Navy	Naval Ordinance Station, Louisville.	Southside Dr. MDS 42.	Louisville	KY	40214	X	X	X	
O—Air Force	Columbus Air Force Base.	14 ABG/DE	Columbus AFB	MS	39701	X	X	X	X
C—Air Force	Columbus Air Force Base.	14 ABG/DE	Columbus AFB	MS	39701		X	X	X
O—Air Force	Barksdale Air Force Base.	2CSG/CC	Barksdale AFB	LA	71110	X	X	X	X
C—Air Force	Barksdale Air Force Base.	2CSG/CC	Bossier City	LA	71110	X	X	X	X
O—Air Force	England Air Force Base.	23 CSG/DE	Alexandria	LA	71311	X	X	X	X
C—Air Force	England Air Force Base.	23 CSG/DE	England AFB	LA	71311	X	X	X	X
O—Army	IUS Army Fort Polk and Peason Ridge.	HQ. 5th Infantry Div. & Fort Polk.	Fort Polk	LA	71459		X	X	
C—Army	IUS Army Fort Polk and Peason Ridge.	HQ. 5th Infantry Div. & Fort Polk.	Fort Polk	LA	71459	X	X	X	X
O—NASA	NASA—Martin Marietta Aerospace.	13800 Old Gentilly Road.	New Orleans	LA	70129		X	X	
C—NASA	NASA—Martin Marietta Aerospace.	13800 Old Gentilly Road.	New Orleans	LA	70129	X	X	X	
O—Navy	Naval Air Station, New Orleans.	32 Belle Chase Hwy	Belle Chase	LA	70037		X		
C—Navy	Naval Air Station, New Orleans.	32 Belle Chase Hwy	Belle Chase	LA	70037		X		X
O—Air Force	Hascom Air Force Base.	3245 ABG/CC	Hanscom AFB	MA	01731		X		X
C—Air Force	Hascom Air Force Base.	3245 ABG/CC	Bedford	MA	01731		X		X
O—Army	US Army Fort Devens.	Buena Vista St	Ayer	MA	01433	X	X	X	X
C—Army	US Army Fort Devens.	Buena Vista St	Ayer	MA	01433	X	X	X	X
O—Army	US Army Research Devel and Engineering Ctr.	Kansas St	Natick	MA	01760		X	X	
C—Army	US Army Research Devel and Engineering Ctr..	Kansas St	Natick	MA	01760		X	X	
O—Army	USW Army Fort Devens Sudbury, Anex.	Hudson Rd	Sudbury	MA	01776				X
C—Army	USW Army Natick R&D Labs, Sudbury, Anx.	Hudson Rd	Sudbury	MA	01776				X
O—Army	US Army Matls Tech Lab.	Arsenal St	Watertown	MA	02172	X	X	X	X
C—Army	US Army Matls and Mech Res Ctr.	Arsenal St	Watertown	MA	02172	X	X	X	X
O—Interior	Cape Cod Seashore	East off Route 8	Well Fleet	MA	02667				X
C—Interior	Cape Cod Seashore—Camp Wellfleet.	East off Route 8	Well Fleet	MA	02667				X
O—Navy	USN NAS S Weymouth.		Weymouth	MA	02190		X		
C—Navy	Naval Air Station South Weymouth.	NAS S Weymouth PWD Code 72.3.	South Weymouth	MA	02190		X		
O—Transportation	Coast Guard, S. Weymouth Bouy Det.	Trotter Road	Weymouth	MA	02190	X	X		
C—Transportation	Coast Guard, S. Weymouth Bouy Depot.	Trotter Road	South Weymouth	MA	02190	X	X		
O—Transportation	USCG Base, Woods Hole.	Little Harbor Road	Falmouth	MA	02543		X		
C—Transportation	USCG Base, Woods Hole.	Little Harbor Road	Falmouth	MA	02543		X		
O—Agriculture	FDA—Beltsville Agricultural Res. Ctr.	Buildings 1321 & 204 BARL Muirkirk Rd.	Beltsville	MD	20705		X	X	X
C— Agriculture	Beltsville Agricultural Res. Ctr.	Buildings 1321 & 204 BARC Muirkirk Rd.	Beltsville	MD	20705		X	X	X
O—Defense	NSA (FANX I, II, III,)	Elkridge Landing Rd	Linthicum	MD	21090	X			
O—Defense	NSA (FANX I, II, III)	Elkridge Landing Rd	Linthicum	MD	21090		X		
O—Navy	David W Taylor Naval R&D Yard.	Old Severn River Bridge.	Annapolis	MD	21402		X		X

CORRECTIONS TO DOCKET LISTING—Continued

[Code 20]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103
C—Navy	US Naval Station, Annapolis.	Old Severn River Bridge.	Annapolis	MD	21402		X		X
O—Navy	Naval Communication Unit, Washington.	Dangerfield & Common Rd.	Clinton	MD	20735		X		
C—Navy	Naval Communication Unit, Washington.	Dangerfield & Common Rd.		MD	20735		X		
O—Navy	Naval Research Lab Launch.	Berry Road	Waldorf	MD					
C—Navy	US Naval Research Lab Launch.	Berry Road	Waldorf	MD	20601				X
O—Navy	NAVSUPPFAC Thurmont.	Box 1000	Thurmont	MD	21788				X
C—Navy	Naval Support Facility Thurmont.	Box 1000	Thurmont	MD	21788				X
O—Navy	NSWC White Oak	10901 New Hampshire Ave.	White Oak	MD	20903	X	X	X	X
C—Navy	Naval Systems Weapons Center White Oak.	10901 New Hampshire Ave.	Silver Spring	MD	209003	X	X	X	X
O—Defense	Fuel Support Pt Casco Bay.	Rt 123 South Harpswell Neck.	Cumberland	ME	04079		X	X	X
C—Defense	Defense Fuel Support Pt Casco Bay.	Rt 123 South Harpswell Neck.	Cumberland	ME	04079		X	X	X
O—Defense	Fuel Support Pt Searsport.	Trundy Road	Searsport	ME	04974		X	X	X
C—Defense	Defense Fuel Support Pt Searsport.	Trundy Road Box 112.	Searsport	Me	04974		X	X	X
O—Navy	USN Naval Communications Unit.		Cutler	ME	04626		X		
C—Navy	USN Naval Communications Unit Cutler.		Cutler	ME	04626		X		
O—Air Force	Richards Gebaur AFB.	424 CSG/DE	Belton	MO	64030			X	
C—Air Force	Richards Gebaur AFB.	424 CSG/DE	Belton	MO	64030			X	X
O—Air Force	Whiteman AFB	357 CSG/CC	Knobnoster	MO	65305	X	X		
C—Air Force	Whiteman AFB	357 CSG/CC	Knobnoster	MO	65336	X	X		X
O—Army	St. Louis Ordnance Plant.	4300 Goodfellow Blvd.	St. Louis	MO	63120		X		X
C—Army	St. Louis Army Ammo Plant.	4300 Goodfellow Blvd.	St. Louis	MO	63120			X	X
O—Defense	Defense Mapping—FEE.	3200 S. Second Street.	St. Louis	MO	63118		X		
C—Defense	Defense Mapping—FEE.	3200 S. Second Street.	St. Louis	MO	63118		X		X
O—Defense	Defense Mapping Agency—FEE.	8900 S. Broadway	St. Louis	MO	63118		X		
C—Defense	Defense Mapping Agency—FEE.	8900 S. Broadway	St. Louis	MO	63118		X		X
O—Energy	Weldon Spring Chemical Plant.	St Hyw 94 2 Mi S of US 40.		MO	63301		X		
C—Energy	Weldon Spring Chemical Plant.	St Hwy 94 2 Mi S of US 40.	St. Charles	MO	63301		X		X
O—EPA	US EPA Laboratory	25 Funston Road	Kansas City	MO	66115	X	X	X	
C—EPA	Region 7, Environmental Services Division Laboratory.	25 Funston Road	Kansas City	KS	66115	X	X	X	X
O—EPA	US EPA Mobile Incineration System.	SE ¼ NW ¼ NW ¼ SEC 20.	McDowell	MO	65769		X		
C—EPA	EPA Mobile Incinerator.	SE ¼ NW ¼ NW ¼ SEC 20.	McDowell	KS	65769		X		X
O—General Services Admin.	Federal Center	2306 East Bannister Road.	Kansas City	MO	64131			X	
C—General Services Admin.	Federal Center	2306 East Bannister Road.	Kansas City	MO	64131		X	X	X
O—General Services Admin.	General Services Administration.	1500 Bannister Road	Kansas City	MO	64131		X		
C—General Services Admin.	General Services Administration.	1500 Bannister Road	Kansas City	MO	64131		X	X	X

CORRECTIONS TO DOCKET LISTING—Continued

[Code 20]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103
O—Air Force	Keesler AFB	3380 CES/DE	Keesler AFB	MS	39534		X	X	X
C—Air Force	Keesler AFB	3380 CES/DE	Keesler AFB	MS	39534	X	X	X	X
O—Army	Mississippi Army Ammo Plant.	Bldg 9101 NASA NSTL.		MS	39529		X		X
C—Army	Mississippi Army Ammo Plant.	Bldg 9101 NASA NSTL.	Bay St. Louis	MS	39529		X		X
O—Army	USA Engr Environ Lab Waterways Exp Sta..	PO Box 631	Vicksburg	MS	39180		X	X	X
C—Army	USA Engr Environ Lab Waterways Exp Sta..	PO Box 631	Vicksburg	MS	39180	X	X	X	X
O—Interior	BLM—Ermont Mill Tailings.	T6SR11WSEC35		MT					X
C—Interior	BLM—Ermont Mill Tailings.	T6SR11WSEC35	Argenta	MT	59725				X
O—Interior	BLM—Thorium City Waste Dump.	T10SR15WSEC21		MT					X
C—Interior	BLM—Thorium City Waste Dump.	T10SR15WSEC21, 22, 27, 28.	Grant	MT	59734				X
O—Interior	BLM—Tungsten Mill Tailings.	T4WR9WSEC4, 5, 9		MT					X
C—Interior	BLM—Tungsten Mill Tailings.	T4WR9WSEC4, 5, 9	Glen	MT	59732				X
O—Air Force	Seymour Johnson Air Force Base.	4 CSG/DE	Seymour Johnson Air Force Base.	NC	27531		X	X	X
C—Air Force	Seymour Johnson Air Force Base.	4 CSG/DE	Seymour Johnson Air Force Base.	NC	27531	X	X	X	X
O—Health and Human Services.	Nat Inst. of Environ. Health Sci.	S on Alexander Dr	Research Tri Park	NC	27709		X		X
C—Health and Human Services.	Nat Inst. of Environ. Health Sci.	S on Alexander Dr	Research Triangle Park.	NC	27709	X	X		X
O—Navy	Marine Corps Air Station, Cherry Point.	NC Hwy 101	Cherry Point	NC	28533	X	X	X	X
C—Navy	Marine Corps Air Station, Cherry Point.	NC Hwy 101	Cherry Point	NC	28533	X	X	X	X
O—Navy	Marine Corps Air Station, New River.	Fire Fighting Training Pitt.	Jacksonville	NC			X		
C—Navy	Marine Corps Air Station, New River.	Fire Fighting Training Pitt.	Jacksonville	NC			X		X
O—Navy	Marine Corps Base, Camp Lejeune.	NC Hwy 24 & US Hwy 16.	Camp Lejeune	NC	28542		X	X	X
C—Navy	Marine Corps Base, Camp Lejeune.	NC Hwy 24 & US Hwy 16.	Camp Lejeune	NC	28542	X	X	X	X
O—Transportation	USCG Support Center.	Hwy 34 S/4 Mi. S of	Elizabeth City	NC	27909		X	X	
C—Transportation	USCG Support Center.	Hwy 34 S/4 Mi. S of Elizabeth City.	Elizabeth City	NC	27909	X	X	X	
O—Agriculture	Roman L. Hruska Meat Animal Resource Cntr	State Spur 18D		NE	66933		X		X
C—Agriculture	Roman L. Hruska Meat Animal Resource Cntr	State Spur 18D	Clay Center	NE	66933		X		X
O—Air Force	Offut Air Force Base	55 CSG/CC	Offutt AFB	NE	68113	X	X		X
O—Air Force	Offut Air Force Base	55 CSG/CC	Offutt AFB	NE	68113	X	X	X	
O—Interior	McMurtry Marsh	South Highway 6, 10 Miles East of Hastings.	Hastings	NE					X
C—Interior	McMurtry Marsh	South Highway 6, 10 Miles East of Hastings.	Hastings	NE	68933				X
O—Navy	Naval Support Activity.	Fort Omaha	Omaha	NE					X
C—Navy	Naval & Marine Corp Reserve Center.	Fort Omaha	Omaha	NE	68102				X
O—Defense	Defense Fuel Support Point Melville.	Route 114	Portsmouth	NH	02871		X	X	X
C—Defense	Defense Fuel Support Point Melville.	Route 114	Portsmouth	RI	02871		X	X	X
O—Defense	US Defense Fuel Support Pt. Newington.	Patterson Lane	Newington	NH	03801		X	X	X

CORRECTIONS TO DOCKET LISTING—Continued

[Code 20]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103
C—Defense	Defense Fuel Support Pt. Newington.	Patterson Lane	Newington	NH	03801		X	X	X
O—Army	U.S. Army Training Center at Ft Dix.	Juliustown—Browns Mill Road.	Wrightstown	NJ	08562	X	X	X	
C—Army	U.S. Army Training Center & Ft Dix.	Juliustown—Browns Mill Road.	Wrightstown	NJ	08562	X	X	X	X
O—Energy	WR Grace and Co	868 Black Oak Ridge	Pompton Plains	NJ	07444				X
C—Energy	Wayne Interim Storage Site (WR Grace and Co).	868 Black Oak Ridge	Wayne	NJ	07444				X
O—General Services Admin.	GSA Supply Depot	Belle Mead #1 Route 206.	Belle Mead	NJ	08502		X		X
C—General Services Admin.	GSA Supply Depot	Belle Mead #1 Route 206.	Belle Mead	NJ	08502		X		X
O—Interior	Edwin B. Forsythe Nat'l Wildlife Refuge.	700 West Bay Avenue.	Barnegat	NJ	08005			X	
C—Interior	Edwin B. Forsythe Nat'l Wildlife Refuge.	700 West Bay Avenue.	Barnegat	NJ	08005			X	X
O—Air Force	Cannon Air Force Base.	275 CSG/DE	Cannon AFB	NM	88103	X	X	X	X
C—Air Force	Cannon Air Force Base.	27 CSG/DE	Cannon AFB	NM	88103	X	X	X	X
O—Air Force	Holloman Air Force Base.	833 CSG/DE	Holloman AFB	NM	88330	X	X	X	X
C—Air Force	Holloman Air Force Base.	833 CSG/DE US Hwy 70.	Holloman AFB	NM	88330	X	X	X	X
O—Army	US Army—Fort Wingate Depot Activity.	10 Miles East of Gallup on 1-10.	Gallup	NM	87310	X	X		X
C—Army	US Army—Fort Wingate Depot Activity.	10 Miles East of Gallup on 1-10.	Gallup	NM	87310	X	X	X	X
O—Army	US Army—White Sands Missile Range.		White Sands	NM	88002	X	X		X
C—Army	US Army—White Sands Missile Range.	STEWS-FE	White Sands	NM	88002	X	X		X
O—Energy	US DOE Sandia National Laboratories.		Albuquerque	NM	87116	X	X	X	X
C—Energy	US DOE Sandia National Laboratories.	Kirkland AFB East	Albuquerque	NM	87116	X	X	X	X
O—Energy	US DOE Tonopah Test Range.	Albuquerque Operations Office PO Box 5400.	Albuquerque	NM	87115		X		
C—Energy	US DOE Tonopah Test Range (Sandia Nat'l Lab).	PO Box 10359	Tonopah	NV	89049	X	X		X
O—Interior	BLM—International Materials & Chemical.	Roswell	Roswell	NM					X
C—Interior	BLM—International Materials & Chemical.	Roswell	Roswell	NM					X
O—Interior	BLM—Marathon Oil Co., Indian Basin Plant.	Not Found in Region		NM					
C—Interior	BLM—Marathon Oil Co., Indian Basin Plant.	Not Found in Region		NM					X
O—Interior	Monterey Construction Company.	Highway 285	Carlsbad	NM	88220		X		
C—Interior	Monterey Construction Company.	12 Mi. N of Carlsbad Off Highway 285.	Carlsbad	NM	88220		X		
O—Interior	U of NM Haz Waste Storage Facility.	T23SR2ESEC23	Las Cruces	NM	88001	X		X	X
C—Interior	U of NM Haz Waste Storage Facility.	T23SR2ESEC23	Las Cruces	NM	88001	X	X	X	X

CORRECTIONS TO DOCKET LISTING—Continued

[Code 20]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103
O—NASA	NASA—JSC Whitesands Test Facility.	Las Cruces	Las Cruces	NM	88004	X	X	X	X
C—NASA	NASA—JSC Whitesands Test Facility.	14 Mi E. & 6 Mi N. of Las Cruces.	Las Cruces	NM	88004	X	X	X	X
O—Veterans Administration.	Veterans Administration Hospital.	2100 Ridgecrest	Albuquerque	NM	87106		X	X	
C—Veterans Administration.	Veterans Administration Hospital.	2100 Ridgecrest	Albuquerque	NM	87106	X	X	X	X
O—Army	Hawthorne Army Ammunition Plant.		Hawthorne	NM	89416	X	X	X	X
C—Army	Hawthorne Army Ammunition Plant.		Hawthorne	NV	89416	X	X	X	X
O—Energy	US DOE Nevada Test Site.	PO Box 98518	Las Vegas	NV	89193-8518	X	X	X	X
C—Energy	US DOE Nevada Test Site (Reynold's Elect).	Nevada Operations Office PO Box 98518.	Las Vegas	NV	89193-8518	X	X	X	X
O—Energy	US DOE Tonopah Test Range.	Albuquerque Operations Office PO Box 5400.	Albuquerque	NM	87115		X		
C—Energy	US DOE Tonopah Test Range (Sandia Nat'l Lab).	PO Box 10359	Tonopah	NV	89049	X	X		X
O—Interior	BLM-Antelope Valley Pesticide.	T25NR42ESEC18	Lander	NV	89310				X
C—Interior	BLM-Antelope Valley Pesticide Site.	T25NR42ESEC18	Lander	NV	89310				X
O—Interior	BLM-Candelaria Partners OMC.	T34NR35ESEC2233435		NV					
C—Interior	BLM-Candelaria Partners OMC.	T34NR35ESEC2233435		NV			X		X
O—Interior	BLM-Cortez Joint Venture.	T27NR47ESEC13		NV					
C—Interior	BLM-Cortez Joint Venture.	T27NR47ESEC13		NV			X		X
O—Interior	BLM-IMCO Services Inc.	T28NR44SEC4 and T28NR46ESEC32.		NV	89620				X
C—Interior	BLM-IMCO Services Inc.	T28NR44ESEC4 and T28NR46ESEC32.		NV	89620				X
O—Interior	BLM-Mound Mineral, Argentum.	T3NR365SSEC85	Esmerelda	NV	89049				X
C—Interior	BLM-Minerals Manage, Argentum Mill.	T3NR365SSEC85	Esmerelda	NV	89049				X
O—Interior	BLM-West Coast Oil & Gas Corp.	T19NR22ESEC26,36	Storey	NV					X
C—Interior	BLM-West Coast Oil & Gas Corp.	T19NR22ESEC26,36	Storey	NV		X		X	
O—Interior	BLM-Western States Minerals.	T36NR50ESEC29,30	Eureka	NV					X
C—Interior	BLM-Gold Strike Mine.	T36NR50ESEC29,30	Eureka	NV					X
O—Interior	Date Street Complex	500 DAte St.	Boulder City	NV	89005		X		X
C—Interior	Date Street Complex (Boulder City Eng. Lab).	500 Date St.	Boulder City	NV	89005	X	X		X
O—Interior	Hope Mine	T22NR51ESEC12	White Pine	NV	89301				X
C—Interior	Mt Hope Mine	T22NR51ESEC12	White Pine	NV	89301				X
O—Navy	Naval Air Station, Fallon.	Naval Air Station	Fallo	NY	89406	X	X	X	X
C—Navy	Naval Air Station, Fallon.	Naval Air Station	Fallon	NV	89406	X	X	X	X
O—Agriculture	Plum Island Animal Desease Center.	Plum Island	Orient Point	NY	11957				X
C—Agriculture	Plum Island Animal Disease Center.	Plum Island	Orient Point	NY	11957			X	X
O—Air Force	Air Force Plant #59	600 Main Street	Johnson city	NY	113790			X	X
C—Air Force	Air force Plant #59	600 Main Street	Johnson City	NY	13790				X
O—Air Force	US Air Force Plant #38.	Porter & Balmer Rds	Porter Twp	NY	14131	X	X		X
C—Air Force	US Air Force Plant #38.	Porter & Balmer Rds	Porter Twp	NY	14131	X	X		X
O—Army	Fort Drum #8	Btwn Rts 3 & 11	Watertown	NY	13601	X	X	X	X

CORRECTIONS TO DOCKET LISTING—Continued

[Code 20]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103
C—Army	Fort Drum #8	Btwn Rts 3 & 11	Watertown	NY	13601	X	X	X	X
O—Energy	Colonie Interim Storage/NL Nuclear Metals Div.	1130 Central Ave.	Colonie	NY	11205		X	X	
C—Energy	Colonie Interim Storage Site.	1130 Central Ave.	Colonie	NY	12205		X	X	
O—Transportation	CG Ant Red Beech-Saugerties.		Saugerties	NY	12477		X		
C—Transportation	USCG Aids to Navigation Team.		Saugerties	NY	12477		X		
O—EPA	Environmental Research Center.	26 W. St. Clair Street	Cincinnati	OH	45268	X	X	X	
C—EPA	Andrew W. Breidenbach Environmental Research Center.	26 W. St. Clair Street	Cincinnati	OH	45268	X	X	X	
O—EPA	US EPA Center Hill Solid Waste Lab.	5595 Center Hill Road.	Cincinnati	OH	45268	X	X	X	
C—EPA	Center Hill Hazardous Waste Engineering Research Laboratory.	5595 Center Hill Road.	Cincinnati	OH	45268	X	X	X	
O—EPA	US EPA T & E Facility.	1600 Gest Street	Cincinnati	OH	45203	X	X	X	
C—EPA	Testing and Evaluation Facility.	1600 Gest Street	Cincinnati	OH	45203	X	X	X	
O—Corps of Engineers, Civil.	Robert S. Kerr Lick Dam & Reservoir.	Star Route 4	Sallisaw	OK	74063		X		
C—Corps of Engineers, Civil.	Robert S. Kerr Lock Dam & Reservoir.	Star Route 4	Sallisaw	OK	74063		X		
O—Air Force	Kingsley Field	114 TFTS/CC	Klamath Falls	OR	97601		X		X
C—Air Force	Kingsley Field	114 TFTS/CC	Klamath Falls	OR	97601		X		X
O—Army	US Army Umatilla Depot Activity.	I-84 & Exit 178	Hermiston	OR	97838				X
C—Army	US Army Umatilla Depot Activity.	I-84 & Exit 178	Hermiston	OR	97838	X	X	X	X
O—Agriculture	US Dept of Agriculture Wyndmo*.	600 E Mermaid Ln	Wyndmoor	PA	19118		X		
C—Agriculture	US Dept of Agriculture Wyndmoor.	600 E Mermaid Ln	Wyndmoor	PA	19118		X		
O—Army	New Cumberland Army Depot.	Harrisburg	Harrisburg	PA	17070	X	X	X	X
C—Army	New Cumberland Army Depot.	Harriburg	New Cumberland	PA	17070	X	X	X	X
O—Army	USA Support Oakdale.	US Army	Oakdale	PA	15071				X
C—Army	Chas Kelly Support Ctr..	US Army	Oakdale	PA	15071		X		X
O—Commerce	DOC Econ Dev Adm-Robins Footwe.	208 N Division St	Mt Union	PA	17066			X	
C—Commerce	DOC Econ Dev Adm-Robins Footwear.	208 N Division St	Mt Union	PA	17066			X	
O—Navy	Naval Station Philadelphia.	NAVFAC North Div Code 114.	Philadelphia	PA	19112	X	X		X
C—Navy	Naval Station Philadelphia.	Broad St.-North Div Code 114.	Philadelphia	PA	19112	X	X		X
O—Army	Hayes Army Ammunition Plant.	U.S. Army	Pittsburgh	PA	15207			X	
C—Army	Hayes Army Ammunition Plant.	300 Mufflin Road	Pittsburgh	PA	15207			X	
O—Army	Fort Buchanan-U.S. Army Garrison.	Route 28	San Juan	PR	00934	X			X
C—Army	Fort Buchanan-U.S. Army Garrison.	Route 28	San Juan	PR	00934	X	X		X
O—Navy	Naval Ammunition Facility, Vieques.	Route 70	Vieques	PR	00765			X	X
C—Navy	Naval Ammunition Facility, Vieques.	Route 70	Vieques	PR	00765	X	X	X	X
O—Defense	Defense Fuel Support Point Melville.	Route 114	Portsmouth	NH	02871		X	X	X
C—Defense	Defense Fuel Support Point Melville.	Route 114	Portsmouth	NH	02871		X	X	X

CORRECTIONS TO DOCKET LISTING—Continued

[Code 20]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103
O—EPA	Environmental Research Laboratory.	South Ferry Road	Narragansett	RI	02882		X		
C—EPA	Narragansett Envrionmental Research Laboratory.	South Ferry Road	Narraganset	RI	02882		X		
O—Interior	Ninigret National Wildlife Refuge.	Third Beach Road, Sachvest Point.	Middletown	RI	02840				X
C—Interior	Ninigret National Wildlife Refuge.	Third Beach Road, Sachvest Point.	Middletown	RI	02840				X
O—Navy	Naval Construction Battalion Ctr, Davisville.	Off Quionessett Road.	North Kingston	RI	02854				X
C—Navy	Naval Construction Battalion Ctr, Davisville.	Off Quionessett Road.	North Kingston	RI	02854				X
O—Navy	Navy Marine Corps Reserve Center.	One Narragansett Ave.	Cranston	RI	02905		X		
C—Navy	Navy Marine Corps Reserve Center.	One Narragansett Ave.	Cranston	RI	02905		X		
O—Navy	US Naval Education and Training Center.		Newport	RI	02840	X	X	X	X
C—Navy	US Naval Education and Training Center.	Public Works Dept. Code 42.	Newport	RI	02840	X	X	X	X
O—Air Force	Charleston Air Force Base.	437 ABG/DE	Charleston	SC	29404		X	X	X
C—Air Force	Charleston Air Force Base.	437 ABG/DE	Charleston	SC	29404	X	X	X	X
O—Air Force	Myrtle Beach Air Force Base.	354 CSG/DE	Myrtle Beach	SC	29577		X	X	X
C—Air Force	Myrtle Beach Air Force Base.	354 CSG/DE	Myrtle Beach	SC	29577	X	X	X	X
O—Air Force	Shaw Air Force Base	363 CSG/DE	Shaw AFB	SC	29152		X	X	X
C—Air Force	Shaw Air Force Base	363 CSG/DE	Shaw AFB	SC	29152	X	X	X	X
O—Defense	Defense Fuel Supply Point—Charleston.	N Rhett Ave	Hanahan	SC	29406		X	X	X
C—Defense	Defense Fuel Supply Point—Charleston.	N Rhett Ave	Hanahan	SC	29406		X	X	X
O—Energy	US DOE Savannah River Pit.	PO Box A	Aiken	SC	29802		X	X	X
C—Energy	US DOE Savannah River Pit.	PO Box A	Aiken	SC	29802	X	X	X	X
O—Navy	Marine Corps Air Station, Beaufort.	Lafrene Road	Beaufort	SC	29904		X	X	X
C—Navy	Marine Corps Air Station, Beaufort.	Lafrene Road	Beaufort	SC	29904	X	X	X	X
O—Navy	Marine Corps Recruit Depot, Parris Island.	Marine Corps Recruit Depot.	Parris Island	SC	29905		X	X	X
C—Navy	Marine Corps Recruit Depot, Parris Island.	Marine Corps Recruit Depot.	Parris Island	SC	29905	X	X	X	X
O—Navy	Naval Shipyard, Charleston.	Viaduct Road	Charleston	SC	29408		X	X	X
C—Navy	Naval Shipyard, Charleston.	Viaduct Road	Charleston	SC	29408	X	X	X	X
O—Navy	Naval Weapons Station, Charleston.	Redbank Road	Charleston	SC	29408			X	X
C—Navy	Naval Weapons Station, Charleston.	Redbank Road	Charleston	SC	29408	X	X	X	X
O—Air Force	Arnold Engr Devlp Ctr.	Commander AEDC	Arnold Air Force Base.	TN	37389		X		X
C—Air Force	Arnold Engr Devlp Ctr.	Commander AEDC	Arnold Air Force Base.	TN	37389	X	X		X
O—Army	Milan Army Ammunition Plant.	Hwy 104	Milan	TN	38358		X	X	X
C—Army	Milan Army Ammunition Plant.	Hwy 104	Milan	TN	38358	X	X	X	X
O—Army	US DOD Defense Depot, Memphis.	2163 Airways Blvd.	Memphis	TN	38114				X
C—Army	US DOD Defense Depot, Memphis.	2163 Airways Blvd.	Memphis	TN	38114	X	X		X
O—Army	USA Holston Army Ammunition Plant.	West Stone Drive	Kingsport	TN	37660		X	X	X

CORRECTIONS TO DOCKET LISTING—Continued

[Code 20]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103
C—Army	USA Holston Army Ammunition Plant.	West Stone Drive	Kingsport	TN	37660	X	X	X	X
O—Army	USA Volunteer Army Ammo Plant.	Bonny Oaks Drive	Chattanooga	TN	37416		X	X	X
C—Army	USA Volunteer Army Ammo Plant.	Bonny Oaks Drive	Chattanooga	TN	37416	X	X	X	X
O—Navy	Naval Air Station Memphis.	Millington-Arlington Road.	Millington	TN	38054		X	X	X
C—Navy	Naval Air Station Memphis.	Millington-Arlington Road.	Millington	TN	38054	X	X	X	X
O—Tennessee Valley Authority.	TVA Bull Run Steam Plant.	Edgemoor Rd, 6 Mi SE of Oak Ridge.	Oak Ridge	TN	37930		X		X
C—Tennessee Valley Authority.	TVA Bull Run Steam Plant.	Edgemoor Rd, 6 Mi SE of Oak Ridge.	Oak Ridge	TN	37930		X		
O—Tennessee Valley Authority.	TVA Kingston Steam Plant.	Natural Resources Building.	Norris	TN	37828				X
C—Tennessee Valley Authority.	TVA Kingston Steam Plant.	Natural Resources Building.	Norris	TN	37828		X		X
O—Air Force	Air Force Plant #4 (General Dynamics).	Grants Lane	FortWorth	TX	76106	X	X		X
C—Air Force	Air Force Plant #4 (General Dynamics).	Grants Lane	Fort Worth	TX	76106	X	X	X	X
O—Air Force	Bergstrom Air Force Base.	67 CSG/DE	Austin	TX	78743	X	X	X	X
C—Air Force	Bergstrom Air Force Base.	67 CSG/DE	Bergstrom AFB	TX	78743	X	X	X	X
O—Air Force	Dyess Air Force Base.	96 CSG/CC	Abilene	TX	79607	X	X	X	X
C—Air Force	Dyess Air Force Base.	96 CSG/CC	Abilene	TX	79607	X	X	X	X
O—Air Force	Lackland Air Force Base.	3700 ABG/DE	San Antonio	TX	78236		X	X	X
C—Air Force	Lackland Air Force Base.	3700 ABG/DE	San Antonio	TX	78236	X	X	X	X
O—Air Force	Randolph Air Force Base.	12 ABG/DE	San Antonio	TX	78150		X	X	X
C—Air Force	Randolph Air Force Base.	12 ABG/DE	San Antonio	TX	78150	X	X	X	X
O—Army	Fuels and Lub Rsh Facility.	6220 Cuevra	San Antoni	TX	78284				X
C—Army	Belvoir Fuels and Lubricant Research Facility.	6220 Cuevra	San Antonio	TX	78284				X
O—Army	US Army Air Defense Center & Fort Bliss.	Pershing Drive	Fort Bliss	TX	79916	X	X	X	
C—Army	US Army Air Defense Center & Fort Bliss.	Pershing Drive	Fort Bliss	TX	79916	X	X	X	X
O—Army	US Army, Camp Stanley Storage.	Ralph Fair Road	San Antonio	TX	78204		X		
C—Army	US Army, Camp Stanley Storage.	Ralph Fair Road	San Antonio	TX	78229	X	X		
O—Army	US Army, Corpus Christi AMSA/AEC.	2022 Saratoga	Corpus Christi	TX	78415		X		X
C—Army	US Army, Corpus Christi AMSA/AEC.	2022 Saratoga	Corpus Christi	TX	78415	X	X		X
O—Army	US Army, Houston Armed Forces Center.	1850 Old Spanish Trail.	Houston	TX	77054		X		
C—Army	US Army, Houston Armed Forces Center.	1850 Old Spanish Trail Drive.	Houston	TX	77054	X	X	X	
O—Army	US Army, Longhorn Army Ammunition Plant.	Highway 43	Karnack	TX	75670	X	X	X	X
C—Army	US Army, Longhorn Army Ammunition Plant.	Highway 419 East	Karnack	TX	75661	X	X	X	X
O—Army	US Army, Saginaw Air Craft Plant.	Blue Mound Road East, Highway 156.	Saginaw	TX	76100		X		
C—Army	US Army Plant #2, Bell Helicopter Textron.	Blue Mound Road, Highway 156.	Saginaw	TX	76131		X		
O—Energy	Pantex Plant	2000 South Houston	Amarillo	TX	75142	X	X	X	X
C—Energy	US DOE Pantex Plant.	2000 South Houston	Amarillo	TX	79120	X	X	X	X

CORRECTIONS TO DOCKET LISTING—Continued

[Code 20]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103
O—General Services Admin.	General Services Administration 7FS.	501 Felix Street	Fort Worth	TX	78753		X		
C—General Services Admin.	GSA Federal Center 7FS.	501 Felix Street	Fort Worth	TX	78753		X		
O—NASA	NASA Ellington Field	Highway 3	Houston	TX	77088		X		
C—NASA	NASA Ellington Field	Highway 3	Houston	TX	77088		X		
O—Navy	Naval Air Station Chase Field.	Highway 202	Beeville	TX	78102		X		X
C—Navy	Naval Air Station Chase Field.	SW Hwy 202 5 Mi E. of Beeville.	Beeville	TX	78103	X	X		X
O—Navy	Naval Weapons Ind Res Plant, Dallas.	9314 W. Jefferson	Grand Prairie	TX	75222	X	X	X	X
C—Navy	Naval Weapons Ind Res Plant, Dallas.	9314 W. Jefferson	Dallas	TX	75211	X	X	X	X
O—Air Force	Air Force Plant 78	35 Mi. NW of Brigham City, Mail Stop 250.	Brigham City	UT	84302			X	X
C—Air Force	Air Force Plant 78	35 Mi. NW of Brigham City, Mail Stop 250.	Brigham City	UT	84302		X	X	X
O—Army	Dougway Proving Ground, US Army.	45 Mi. W. of Tooele	Dougway	UT	84022		X	X	X
C—Army	Dougway Proving Ground, US Army.	45 Mi. W. of Tooele	Dugway	UT	84022		X	X	X
O—Interior	BLM—Deseret Mound Mine.	T35NR13WSEC35	Cedar City	UT	84720				X
C—Interior	BLM—Deseret Mound & Mine.	T35NR13WSEC35	Cedar City	UT	84720				X
O—Interior	BLM—Ore Buying Station—Moab.	T26SR22ESEC6 Moab PARLABC.	Moab	UT	84532				X
C—Interior	BLM—Ore Buying Station—Moab.	T26SR22ESEC6 Moab PARLABC.	Moab	UT	84532				X
O—Interior	BLM—Frye Canyon Tailing.	T36SR16ESEC34	Blanding	UT	84511				X
C—Interior	BLM—Frye Canyon Tailing.	T36SR16ESEC34	Hite	UT	84511				X
O—Interior	BLM—Silver Maple Claims.	T2SR4ESEC3, 4	Park City	UT	84060			X	X
C—Interior	BLM—Silver Maple Claims.	T2SR4ESEC3, 4 Utah Hwy 248.	Park City	UT	84060			X	X
O—Interior	Ireco Chemical	17SR1ESEC5, 6, 7		UT		X			X
C—Interior	Ireco Chemical	17SR1ESEC5, 6, 7 Pelican Pt. Site A&B.	Lehi	UT	84043	X			X
O—Air Force	Langley AFB	1 CSG/DE	Hampton	VA	23665	X	X		X
C—Air Force	Langley AFB	1 CSG/DE	Langley	VA	23665	X	X		X
O—Army	Defense Printing Service Office.	RMBE 854	The Pentagon	VA	20301		X		
C—Army	Defense Printing Service Office.	RMBE 854 The Pentagon.	Arlington	VA	20301		X		
O—Army	DGSC Richmond	Jefferson Davis Highway.	Richmond	VA	23297	X	X	X	X
O—Army-Defense Logistics Agency.	Defense General Supply Center Richmond.	Jefferson Davis Highway.	Richmond	VA	23297	X	X	X	
O—Army	Harry Diamond Labs, Woodbridge.	US Army	Warrenton	VA	22186			X	X
C—Army	Harry Diamond Labs, Woodbridge.	US Army	Woodbrige	VA	22186			X	X
O—Army	US Army Engineer District Boydton.	John H Kerr Reservoir.	Boydton	VA	23917		X		
C—Army	US Army Engineer District Boydton.	John H Kerr Reservoir.	Boydton	VA	23917		X		
O—EPA	EPA Environmental Photo Int.	Bldg 166-Vint Hill Farm.	Warrenton	VA	22186		X		
C—EPA	EPA Environmental Photo graphic interpretation Center.	Bldg 166-Vint Hill Farm.	Warrenton	VA	22186		X		
O—Interior	E. Shore VA Fisherman Island.	RD 1 Box 1228	Cape Charles	VA	23310			X	
C—Interior	E. Shore VA Fisherman Island.	RD 1 Box 1228	Cape Charles	VA	23310			X	X
O—Navy	Naval Supply Center, Norfolk.	Craney Island	Norfolk	VA	23512	X	X	X	X
C—Navy	Naval Supply Center, Norfolk.	Craney Island	Portsmouth	VA	23703	X	X	X	X

CORRECTIONS TO DOCKET LISTING—Continued

[Code 20]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103
O—Navy	NWS Yorktown	N/A	Yorktown	VA	23691	X	X	X	
C—Navy	Naval Weapons Station Yorktown.	N/A	Yorktown	VA	23691	X	X	X	X
O—Interior	BLM-ENLO Powerhouse AKA Similkameen.	T40NR27ESEC13	Oroville	OR	98844				X
C—Interior	BLM-ENLO Powerhouse AKA Similkameen.	T40NR27ESEC13	Oroville	WA	98844				X
O—Agriculture	Holden Mine Tailing/ Wenachee NF.	T31NR17E WM SEC7.	Holden	WA	98816				X
C—Agriculture	Wenachee National Forest.	T31R17E WM SEC7	Holden	WA	98816				X
O—Agriculture	Yakima Agricultural Res Lav-U.	3706 W Nob Hill Blvd.	Yakima	WA	98902		X		
C—Agriculture	Yakima Agricultural Res Lav-U.	3706 W Nob Hill Blvd.	Yakima	WA	98902		X	X	
O—Air Force	Fairchild AFB	92 CSG/CC	Spokane	WA	99011		X		
C—Air Force	Fairchild AFB	92 CSG/CC	Fairchild AFB	WA	99011	X	X		
O—Air Force	USAF McChord AFB	62 ABG/DE	Tacoma	WA	98438				X
C—Air Force	USAF McChord AFB	62 ABG/DE	Fairchild AFB	WA	98438	X	X	X	X
O—Army	USA-COE Lake Washington.	3015 NW 54th St.	Seattle	WA	98017				X
C—Army	USA-COE Lake Washington.	3015 NW 54th St.	Seattle	WA	98017		X		X
O—Army	US Army Fort Lewis	Attn AFZH-FEQ	Fort Lewis	WA	98433				
C—Army	US Army Fort Lewis	9th Inf Div Attn AFZH-FEQ.	Fort Lewis	WA	98433	X	X	X	X
O—Commerce	USDOC-NOAA Western Regional Center.	7600 Sandpoint Way	Seattle	WA	98115		X		
C—Commerce	USDOC-NOAA Western Regional Center.	7600 Sandpoint Way	Seattle	WA	98115		X	X	
O—Defense	USDOD-DLA Defense Fuel Support Pt.	Front St & Loveland Ave.	Mukilteo	WA	98275				X
C—Defense	USDOD-DLA Defense Fuel Support Pt.	Front St & Loveland Ave.	Mukilteo	WA	98275		X	X	X
O—Energy	USDOE Hanford Site	Hanford Site	Richland	WA	99352				X
C—Energy	USDOE Hanford Site	Hanford Site	Richland	WA	99352	X	X		X
O—EPA	USEPA Manchester Laboratory.	7411 Beach Dr E	Manchester	WA	98353		X		
C—EPA	Region 10, Environmental Services Division Laboratory.	7411 Beach Dr E	Manchester	WA	98353		X		
O—Navy	Naval Air Station Whidbey Island.	Hwy 20 & Ault Field Rd.	Oak Harbor	WA	98278				X
C—Navy	Naval Air Station Whidbey Island.	Hwy 20 & Ault Field Rd.	Oak Harbor	WA	98278	X	X		X
O—Navy	Naval Shipyard Puget Sound.	1st Street Code 106	Bremerton	WA	98314				X
C—Navy	Naval Shipyard Puget Sound.	1st Street Code 106	Bremerton	WA	98314	X	X		X
O—Navy	Naval Undersea Warfare Eng Sta, Keyport.	Code 073 Hwy 306, E End.	Keyport	WA	98345				X
C—Navy	Naval Undersea Warfare Eng Sta, Keyport.	Code 073 Hwy 306, E End.	Keyport	WA	98345	X	X		X
O—Navy	US Navy-Naval Supply Center, Puget Snd.	Orchard Pt/Little Clam Bay.	Bremerton	WA	98353		X		
C—Navy	US Navy-Naval Supply Center, Puget Snd.	Orchard Pt/Little Clam Bay.	Bremerton	WA	98353	X	X	X	X
O—Navy	US Navy Bangor Submarine Base.	Clear Creek Rd	Bangor	WA	98315				
C—Navy	US Navy Bangor Submarine Base.	Clear Creek Rd	Bangor	WA	98315	X	X		
O—Navy	Nav Comm Area	10 mi off Rte 33	Sugar Grove	WV	26815		X		X
C—Navy	Naval Radio Station LF#1.	10 mi off Rte 33	Sugar Grove	WV	26815		X		X
O—Navy	USN Allegheny Ballistics Lab.	West Virginia Secondary R.	Rocket Center	WV	26753	X	X	X	X

CORRECTIONS TO DOCKET LISTING—Continued

[Code 20]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103
C—Navy	USN Allegheny Ballistics Lab.	West Virginia Secondary Route 9.	Rocket Center	WV	26753	X	X	X	X

II. DOCKET UPDATE

UPDATE TO 2/12/88 DOCKET—NEW FACILITIES

[** = DATE OF PUBLICATION]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103	EPA reg	Date of listing
Air Force	USAF—Bear Creek AFS LDFL.	Yukon River on N Shore.	Tanana	AK	99777				X	10	**
Air Force	USAF—Nikolski AFS LDFL.	W Coast of Umnak Is.	Nikolski	AK	99638				X	10	**
Air Force	USAF—Dewline Site Bar-Main.	Barter Isl., ⅛ mi E of NE Shr.	Kaktovik	AK	99747				X	10	**
Air Force	USAF—Granite Mountain AFS LDFL.	14 mi NW of Cy.	Haycock	AK	99762				X	10	**
Air Force	USAF—Dewline Site POW-2.	Simpson Lagoon-Beaufort Bay.	Oliktok	AK	99599				X	10	**
Army	Fort Greely		Fort Greely	AK	98733			X		10	**
Army	Fort Wainwright.		Fort Wainwright	AK	99793-5500	X	X	X	X	10	**
Interior	Glacier Bay National Park and Preserve.	PO Box 140	Gustavus	AK	99826			X		10	**
Interior	Denali National Park and Preserve.	PO Box 9	Denali Park	AK					X	10	**
Interior	USDOI-BLM Cape Sabine Dewline Site.	Point Hope, 65 mi SE.	Point Hope	AK	99766				X	10	**
Army	DA/Wheeler National Wildlife Refuge.	PO Box 1643	Decatur	AL	35602			X		4	**
Tennessee Valley Authority	TVA Colbert Steam Plant.	Off US Hwy 72 W.	Tuscumbia	AL	35674				X	4	**
Agriculture	South Central Family Farm Research Center.	Rt. 2, Box 144A Hwy 23 South.	Booneville	AR				X		6	**
Air Force	Little Rock AFB.	314 CSG/CG	Little Rock AFB AR	AR	72979	X	X	X	X	6	**
Interior	US Dept of Interior Hope Wildlife Area.	4 Mi N off Hwy 32.	Hope	AR	71801				X	6	**
Interior	Glen Canyon Dam.	805 Hemlock	Page	AZ	86040			X		9	**
Agriculture	Aquatic Weed Research Facility.	University of CA.	Davis	CA	95616			X		9	**
Agriculture	Fresno Research Center.	2021 South Peach Ave.	Fresno	CA	93727			X		9	**

UPDATE TO 2/12/88 DOCKET—NEW FACILITIES—Continued

[** = DATE OF PUBLICATION]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103	EPA reg	Date of listing
Air Force	Los Angeles Air Force Station.	2400 El Segundo Blvd.	Los Angeles	Calif.	90009		X		X	9	**
Interior	Afton Canyon/ Union Pacific Railroad.			CA				X		9	**
Interior	Lassen College Site.	Hwy 139 PO-Box 3000.	Susanville	CA	96130			X		9	**
Interior	Cuyama Drug Lab.	T10N,R28W, sec15, NESE.		CA				X		9	**
Interior	Stateline Dump (landfill).	N/A		CA				X		9	**
NASA	Canoga Manufacturing Facility.	6633 Canoga Ave.	Canoga Park	CA	91303			X		9	**
Air Force	Buckley Air National Guard Base (ANGB).	Buckley Road and East 6th Ave.	Aurora	CO	80011-9599			X	X	8	**
Energy	Grand Junction Projects Office.	3597 B-3/4 Rd PO2567.	Grand Junction	CO	81502-5504			X		8	**
Transportation	Transportation Test Center.	212 Miles NE Pueblo Mem Airport.	DOT Test Track Rd	CO	81001	X	X	X		8	**
Transportation	US Coast Guard Bldg 37 Anx.	Avery Pt	Groton	CT	06340				X	1	**
Army	Walter Reed Army Medical Center.	16th Steet, NW.	Washington	DC	20307-5001			X		3	**
Interior	Bombay Hook National Wildlife Refuge.	Marshtown Rd.	Little Creek	DE	19977				X	3	**
Navy	Naval Dental Clinic Guam.	FPO	San Francisco	GU	96630-1670			X		9	**
Army	Ordinance Disposal Area, Makua Mil Res.		Waianae	HI	97692			X		9	**
Navy	Defense Reutilization & Mktg Reg-Pac.	Waimano Home Rd/ P.O. Box 580.	Pearl Harbor	HI	96782-0580	X	X		X	9	**
Agriculture	National Animal Disease Center.	2300 Dayton Road PO Box 70.	Ames	IA	50010			X		7	**
Corps of Engineers	US Army Corps of Engr. OD-Rm.	67 & Dam #14 Rd.	Pleasant Valley	IA	52767		X			7	**
Energy	Ames Laboratory.	107 Office & Lab ISU.	Ames	IA	50011			X	X	7	**
Energy	Hinton Hazardous Waste Storage Facility.	PO Box 1012	Hinton	IA	51024	X	X	X		7	**
Air Force	US Air Force Scott AFB.	375 ABG/ DEEY Bldgs 59 & 540.	Scott Air Force Base.	IL	62225	X			X	5	**

UPDATE TO 2/12/88 DOCKET—NEW FACILITIES—Continued

[** = DATE OF PUBLICATION]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103	EPA reg	Date of listing
Army	Defense Industrial Plant, Equipment Facil.	Old Rte 1	Atchison	KS	66002				X	7	**
Agriculture	Kisatchie Work Center.			LA				X		6	**
Energy	Weeks Island Spr.	2 Mi NW of Cypremont.	Cypremont	LA	70560				X	6	**
Interior	Iberville Land Company, Well #3.	2.2 mi E of H-975,5.5 mi W I10.	Henderson	LA	70517				X	6	**
Interior	Iberville Land Co. Well #1.	3.03 Mi E of LA975 & 5.5 Mi N of I-10.	Henderson	LA	70517				X	6	**
NASA	Michoud Assembly Facility.	13800 Old Gentily Rod.	New Orleans	LA	70129			X		6	**
Navy	Navpro Bedford.	Hartwell Road	Bedford	MA	01730			X		1	**
Army	Harry Diamond Lakes, Blossom Point Facility.	Blossom Point Rd.	La Plata	MD				X		3	**
Transportation	USCG Back Creek Rear, Range Structure.	25 Ft Square Position.	Chesapeake City	MD	21915				X	3	**
Agriculture	Regional Poultry Research Laboratgory.	3606 East Mount Hope.	Rd., East Lansing	MI	48823			X		5	**
Air Force	US AFB Duluth Intl Airport.	Stebner Rd	Duluth Intl Airport	MN	55814				X	5	**
Army	Goodfellow US Army Reserve Cnt Area #2.	E Natural Bridge, Goodfellow Rd.	St Louis	MO	63120				X	7	**
Army	Ft Crowder Military Installation.	D Hwy	Neosho	MO	64850				X	7	**
Interior	Rolla Research Center-US Bureau of Mines.	1300 Bishop Ave.	Rolla	MO	65401				X	7	**
Navy	Naval Air Facility Midway Island.	FPO	San Francisco	MQ	96614-1200			X		9	**
Agriculture	Fort Keogh Livestock and Range Research Lab.	Route 1, Box 2021.	Miles City	MT	59301			X		8	**
Energy	Component Development and Integration Facility.	Industrial Park	Butte	MT	59702			X		8	**
Army	Fort Bragg	AFZA-DE-D	Fort Bragg	NC	28307			X		4	**
Agriculture	Northern Great Plains Research Lab.	PO Box 459, Hwy 6 S.	Mandan	ND	58554			X		8	**
Corps of Engineers	Garrison Project.	201 First St., Box 517.	Riverdale	ND	58565			X		8	**

UPDATE TO 2/12/88 DOCKET—NEW FACILITIES—Continued

[** = DATE OF PUBLICATION]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103	EPA reg	Date of listing
Energy	Great Plains Coal Gasification PLant.	7 Mi NW of Beulah.	Beulah	ND	58523	X	X	X		8	**
Army	Cornhusker Army Ammunition Plant.	6 Mi W of	Grand Island	NE	68802			X	X	7	**
Air Force	BOMARC/ McGuire Msl.	Rt 539	New Egypt	NJ	08533				X	2	**
Agriculture	JORNADA Experimental Range.	1700 Jornada Road.	Las Cruces	NM	88001			X		6	**
Agriculture	Cobb Resources Corp.	Cibola National Forest.	Magdalena	NM	87825				X	6	**
Agriculture	Mineral Creek Tailing.	Forest Route 701 3.5 Mi E of Hwy 180.	Alma	NM	88039				X	6	**
Interior	Hyde Mine	Gallup	McKinley	NM	87301				X	6	**
Interior	High Rolls Mining Dist.-US Forest Service.	3.3 M S of Inter. of W US 82.	High Rolls	NM	88325				X	6	**
Small Business Admin	US Sml Business Admin Cal West.	West Frontage Road.	Lemitar	NM	87801	X	X			6	**
Army	United States Military Academy.	Stewart Army Subpost.	West Point	NY	10996			X		2	**
Interior	Fire Island National Seashore.	120 Laurel Street.	Patchogue	NY	11772			X		2	**
Navy	Naval Facil N Div/ Engineering Command.	Camp Hreo Military Reservation.	Montauk	NY	11954				X	2	**
Agriculture	Nursery Crops Research Laboratory.	359 Main Road.	Delaware	OH	43015			X		5	**
Air Force	US Air Force Youngstown map Ohio.	King Graves Rd.	Vienna Twp	OH	44473				X	5	**
Agriculture	Forage and Livestock Research Laboratory.	PO Box 1199	El Reno	OK	73036			X		6	**
Agriculture	Plant Sciences and Water Conservation Laboratory.	1301 N. Western Rd.	PO Box 1029 Stillwater.	OK	74076			X		6	**
Interior	Wichita Mountains National Wildlife Refuge.			OK				X		6	**
Interior	Caddo County Landfill #1.	SE/4 SEC7 T5N R11W SW/4 SEC8.	Apache	OK	73006				X	6	**
Air Force	USAF-Portland Air National Guard Base.	6801 NE Corn Foot Rd.	Portland	OR	97208				X	10	**

UPDATE TO 2/12/88 DOCKET—NEW FACILITIES—Continued

[** = DATE OF PUBLICATION]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103	EPA reg	Date of listing
Energy	Center for Energy and Environmental Research.	Road 108 Km 1.1.	Mayaquez	PR	00708			X		2	**
Defense	Memphis Defense Depot.	Perey & Elliston Rd.	Memphis	TN	38106				X	4	**
Agriculture	Conservation and Production Research Laboratory.	½Mile W., T-40 S.	Bushland	TX	79012			X		6	**
Agriculture	Livestock Insects Laboratory.	SH 16/IH 10	Kerrville	TX				X		6	**
Agriculture	US Dept Agri Livestock Insects.	Fredericksburg Road.	Kerrville	TX	78028	X	X			6	**
Agriculture	Unidentified Site.	US Forest Service Property.	Huntsville	TX	77340				X	6	**
Air Force	USAF Perrin Air Force Base.	Grayton Cnty	Sherman	TX	75090				X	6	**
Army	US Army Fuels & Lubricant Research Lab.	6220 Cuevra	San Antonio	TX	78284				X	6	**
Army	US Army Canyon Lake Recreation Area.	North Side of Canyon Lake (by Dam).	San Antonio	TX	78234				X	6	**
Army	Terrell Nike Missile Site.	½Mi E. of Hwy 205.	Terrell	TX	75160				X	6	**
Corps of Engineers	Southwestern Division Laboratory.	4815 Cass St	Dallas	TX	75235			X		6	**
Corps of Engineers	Lake Lavon-St Paul-Site 2.	S End Rolling Meadows St.	Wylie	TX	75098				X	6	**
Energy	US Doe Spr Big Hill Site.	23 Mi SW of Pt. Arthur.	Port Arthur	TX	77641				X	6	**
Interior	Amarillo Shipping Terminal.	US Hwy 66, 6 Mi W of Amarillo.	Amarillo	TX	76106				X	6	**
Treasury	U.S. Customs-Millington Addition.	East of FM 170.	Presidio	TX	79845				X	6	**
Agriculture	Only Chance Mining Claim.	Vernal Ranger Dist.	Uintah County	UT				X		8	**
Energy	Monticello Uranium Mill Tailings Site.	SE of Monticello.	Monticello	UT				X		8	**
Interior	East Summit Mining Claims.			UT				X		8	**
Interior	Plumtree Island National Wildlife Refuge.	East of Poquoson.	Poquoson	VA	23662				X	3	**
Agriculture	USDA Pac NW Forest Range Exp Sta.	3625 93rd Ave S.	Tumwater	WA	98501				X	10	**
Army	US Army Yakima Firing Center.	Yakima Firing Center.	Yakima	WA	98901	X	X			10	**

UPDATE TO 2/12/88 DOCKET—NEW FACILITIES—Continued

[** = DATE OF PUBLICATION]

Agency	Facility name	Facility address	City	State	Zip code	RCRA 3005	RCRA 3010	RCRA 3016	CERCLA 103	EPA reg	Date of listing
Interior	Smith Wasteway.			WA				X		10	**
Interior	USDOI-WPR Chandler Power & Pumping Plant.	Old Inland Empire Hwy.	Benton City	WA	99320				X	10	**
Agriculture	Clam Lake		Clam Lake	WI				X		5	**
Agriculture	Northwoods Sanitary Landfill.			WI				X		5	**
Air Force	Wake Is Air Fld.	Wake Is	Wake Is	WQ	96798				X	9	**
Energy	Morgantown Energy Tech Center.		Morgantown	WV					X	3	**
Air Force	F.E. Warren Air Force Base.	I-25 and Randall Avenue.	Cheyenne	WY	82005-5000			X	X	8	**

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Part IX

Department of Education

34 CFR Part 250 et al.

Indian Education General Provisions and Discretionary Grants; Notice of Proposed Rulemaking

DEPARTMENT OF EDUCATION

34 CFR Parts 250, 252, 253, 254, 255, 256, 257, and 258

Indian Education General Provisions and Discretionary Grants

AGENCY: Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes to amend regulations governing the Indian Education Act general provisions and the Indian Education discretionary grant programs to incorporate new provisions of the Indian Education Act of 1988. The proposed regulations include amended definitions and requirements for grants under a new gifted and talented program. Regulations governing Indian-Controlled Schools—Establishment Grants have been deleted because the program is unfunded.

DATE: Comments must be received on or before January 17, 1989.

ADDRESS: All comments concerning these proposed regulations should be addressed to Mr. Brian Stacey, Acting Director, Indian Education Programs, Office of Elementary and Secondary Education, U.S. Department of Education, 400 Maryland Avenue SW., Room 2177 (Mail Stop 6267), Washington, DC 20202.

A copy of any comments that concern information collection requirements should also be sent to the Office of Management and Budget at the address listed in the Paperwork Reduction Act section of this preamble.

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

SUPPLEMENTARY INFORMATION: The Indian Education Act (The Act) was amended and reauthorized by Part C of Title V of Pub. L. 100-297 (Augustus F. Hawkins-Robert T. Stafford Elementary and Secondary School Improvement Amendments of 1988). The Act subsequently was amended by Pub. L. 100-427. These proposed regulations incorporate technical amendments to the Act.

Changes to Implement Amendments to the Act

- These proposed regulations would revise Part 250, General Provisions, and would include consortia of higher education institutions, local educational agencies, and Indian tribes and organizations as eligible applicants for special programs to encourage Indian students to acquire a higher education and to reduce the dropout rate among elementary and secondary school students.
- Under section 5324(c) of the Act, the Secretary is authorized to provide five grants to schools fudned or operated by BIA for program research, development and dissemination in several areas, including programs for gifted and talented students. The proposed regulations establish requirements and funding criteria for this small discretionary program. The regulations also clarify the extent to which recipients must coordinate certain activities with other recipients of funds under section 5324 of the Act. In addition, as required by section 5324(c)(4)(B) of the Act, the Secretary proposes a definition of the term "gifted and talented students." For the purpose of this program, the Secretary proposes to define that term as that term is defined in section 4103 of the Elementary and Secondary Education Act of 1965, as amended by section 1001 of Pub. L. 100-297. That definition includes children and youth who give evidence of high performance capabilities in a variety of areas and who require services or activities not ordinarily provided by the school, in order to develop those capabilities fully. This definition is inclusive and should accommodate any special requirements or criteria needed to serve gifted and talented Indian children.

Other Changes

- The proposed regulations would delete the current Part 252, governing the Indian-Controlled Schools—Establishment Program which is unfunded.
- The proposed regulations would delete the regulations governing what information an applicant must include in an application. These deletions would be consistent with the Department's policy that this information is not regulatory and more appropriately belongs in each program's application package.

Executive Order 12291

These proposed regulations have been reviewed in accordance with Executive Order 12291. They are not classified as major because they do not meet the criteria for major regulations established in the order.

Regulatory Flexibility Act Certification

The Secretary certifies that these proposed regulations would not have a significant economic impact on a substantial number of small entities. The small entities that would be affected by these proposed regulations are small school districts, tribal schools, schools operated by BIA, Indian tribes, and Indian organizations receiving Federal financial assistance under these programs. However, the regulations would not have a significant economic impact on these small entitites because the regulations would impose minimal requirements to ensure the proper expenditure of program funds, and would not impose excessive regulatory burdens or require unnecessary Federal supervision.

Paperwork Reduction Act of 1980

Section 255.31 contains information collection requirements. As required by the Paperwork Reduction Act of 1980, the Department of Education will submit a copy of this section to the Office of Management and Budget (OMB) for its review.

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, Room 3002, New Executive Office Building, Washington, DC 20503; Attention: James D. Houser.

(44 U.S.C. 3504(h))

Intergovernmental Review

Other than the Indian-Controlled Schools—Enrichment Projects, The Gifted and Talented Program and The Educational Personnel Development Program, the programs covered by these proposed regulations are subject to the requirements of Executive Order 12372 and the regulations in 34 CFR Part 79. The objective of the Executive Order is to foster an intergovernmental partnership and a strengthened federalism by relying on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

In accordance with the order, this document is intended to provide early notification of the Department's specific plans and actions for this program.

Invitation to Comment

Interested persons are invited to submit comments and recommendations regarding these proposed regulations.

All comments submitted in response to these proposed regulations will be available for public inspection, during and after the comment period, in Room 2177, FOB #6 (Mail stop 6267), 400 Maryland Avenue, SW., Washington, DC 20202 between the hours of 8:30 a.m.

and 4:00 p.m., Monday through Friday of each week except Federal holidays.

To assist the Department in complying with specific requirements of Executive Order 12291 and the Paperwork Reduction Act of 1980 and their overall requirement of reducing regulatory burden, the Secretary invites comment on whether there may be further opportunities to reduce any regulatory burdens found in these proposed regulations.

Assessment of Educational Impact

The Secretary particularly requests comments on whether the proposed regulations in this document would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects in 34 CFR Parts 250 and 252 through 258

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

(Catalog of Federal Domestic Assistance Numbers 84.061 Indian Education—Special Programs and Projects; 84.062 Indian Education—Adult Indian Education; and 84.072 Indian Education—Grants to Indian-Controlled Schools)

Dated: October 25, 1988.

Lauro F. Cavazos,

Secretary of Education.

The Secretary proposes to remove Part 252, add a new Part 255 and amend Parts 250, 253, 254, 256, 257, and 258 of Title 34 of the Code of Federal Regulations as follows:

PART 250–INDIAN EDUCATION ACT—GENERAL PROVISIONS

1. The authority citation for Part 250 is revised to read as follows:

Authority: 25 U.S.C. 2601–2651, unless otherwise noted.

2. Section 250.1 is revised to read as follows:

§ 250.1 What programs are governed by these regulations,

The regulations in this part apply to all programs conducted under the Indian Education Act except the Indian Fellowship Program (34 CFR Part 263). Programs governed by these regulations and their applicable program regulations are as follows:

(a) Formula Grants—Local Educational Agencies (34 CFR Part 251);

(Authority: 25 U.S.C. 2601–2606)

(b) Indian-Controlled Schools—Enrichment Projects (34 CFR Part 252).

(Authority: 25 U.S.C. 2602(c))

(c) Educational Services for Indian Children (34 CFR Part 253).

(Authority: 25 U.S.C. 2621 (a), (c))

(d) Planning, Pilot, and Demonstration Projects for Indian Children (34 CFR Part 254).

(Authority: 25 U.S.C. 2621 (a), (b))

(e) Gifted and Talented Program (34 CFR Part 255).

(Authority: 25 U.S.C. 2624(c))

(f) Educational Personnel Development (34 CFR Part 256).

(Authority: 25 U.S.C. 2621(d), 2622)

(g) Educational Services for Indian Adults (34 CFR Part 257).

(Authority: 25 U.S.C. 2631(b))

(h) Planning, Pilot, and Demonstration Projects for Indian Adults (34 CFR Part 258).

(Authority: 25 U.S.C. 2631(a))

3. Section 250.3(e) is amended by removing "253" and adding, in its place, "255" and by revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2601–2551)

4. In § 250.4, paragraph (a) is amended by removing "Local educational agency (LEA) (except as used in 34 CFR Parts 257 and 258)"; by removing "(except as used in 34 CFR Parts 254, 255, and 256)" following "Secondary school"; and by removing "(except as used in 34 CFR Parts 251, 252, and 253)" following "State". Paragraph (b) is amended by adding "except as defined in 34 CFR 251.32", after the words " "Free public education" "; and by revising the definitions of "Adult", "Adult education", "Indian" paragraph (l), "Local educational agency," and "Parent" paragraph (l) (introductory text), and adding new definitions of "Bureau school", "Bureau-funded school", "Gifted and talented students", and "Tribal school" in alphabetical order to read as follows:

§ 250.4 What definitions apply to these programs?

* * * * *

(b) * * *

"Adult" means any individual who is sixteen years old or older, or who is beyond the age of compulsory school attendance under State law.

* * * * *

"Adult education" means instruction or services below college level for adults who are not enrolled in a secondary school and who do not have—

(1) The basic skills to enable them to function effectively in society; or

(2) A certificate of graduation from a school providing secondary education, and who have not achieved an equivalent level of education.

* * * * *

"Bureau school" means an elementary or secondary day or boarding school operated by the Bureau of Indian Affairs (BIA) of the Department of the Interior.

"Bureau-funded school" means a Bureau school or an elementary or secondary school that receives Pub. L. 93–638 (Indian Self-Determination and Education Assistance Act) contract funds or assistance under the Tribally Controlled Schools Act of 1988 from the Bureau of Indian Affairs.

* * * * *

"Gifted and talented students" means children and youth who give evidence of high performance capability in areas such as intellectual, creative, artistic, or leadership capacity or in specific academic fields, and who require services or activities not ordinarily provided by the school in order to develop such capabilities fully.

* * * * *

"Indian" * * *

(1) A member (as defined by an Indian tribe, band, or other organized group) of such Indian tribe, band, or other organized group of Indians, including those Indian tribes, bands, or groups terminated since 1940 and those recognized by the State in which they reside;

* * * * *

"Local education agency" (LEA) means—

(1) A public board of education or other public authority legally constituted within a State for either administrative control or direction of, or to perform a service function for, public elementary or secondary schools in a city, county, township, school district, or other political subdivision of a State, or such combination of school districts or counties recognized in a State as an administrative agency for its public elementary or secondary schools. The term includes any other public institution or agency having administrative control and direction of a public elementary or secondary school.

(2) As used in 34 CFR Part 251 the term also includes tribal schools and Bureau schools.

"Parent"—

(1) Includes a legal guardian or other individual standing *in loco parentis* (in the place of the parent) other than by virtue of being a school administrator or official. Examples of individuals who

may stand *in loco parentis* with respect to a child are—

* * * * *

"Tribal school" means any school operated by an Indian tribe, or an organization controlled or sanctioned by an Indian tribal government for the children of that tribe if the school either—

(1) Provides its students an educational program that meets the standards estabished by the Secretary of the Interior in accordance with the Indian Self-Determination and Education Assistance Act; or

(2) Is operated by that tribe or organization under a contract with the Department of the Interior in accordance with the Indian Self-Determination and Education Assistance Act.

5. The authority citation for § 250.4 is revised to read as follows:

(Authority: 25 U.S.C. 2601–2651)

§ 250.20 [Amended]

6. The authority citation for § 250.20 is revised to read as follows:

(Authority: 25 U.S.C. 2601–2651)

PART 252—[Removed]

7. Part 252 is removed.

PART 253—[REDESIGNATED AS PART 252 AND AMENDED]

8. Part 253 is amended by redesignating it as Part 252 and revising the authority citation to read as follows:

Authority: 25 U.S.C. 2602(c), unless otherwise noted.

§ 252.1 [Amended]

9. The authority citation for § 252.1 is revised to read as follows:

(Authority: 25 U.S.C. 2602(c)) **§ 252.2 [Amended]**

10. The authority citation for § 252.2 is revised to read as follows:

(Authority: 25 U.S.C. 2602(c))

§ 252.3 [Amended]

11. In § 252.3, paragraph (b)(1)(iii) is amended by removing "and Tribal Schools) or a grant under 34 CFR Part 252 (Indian-Controlled Schools—Establishment)," inserting a closing parenthesis after "Agencies," removing paragraph (b)(3), redesignating paragraphs (b)(4) as (b)(3), and by revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2602(c))

§ 252.4 [Amended]

12. The authority citation for § 252.4 is revised to read as follows:

(Authority: 25 U.S.C. 2601–2606, 2651)

§ 252.10 [Amended]

13. The authority citation for § 252.10 is revised to read as follows:

(Authority: 25 U.S.C. 2602(c))

Subpart C—[Removed and Reserved]

14. Subpart C (consisting of § 252.20) is removed and reserved.

§ 252.30 [Amended]

15. In § 252.30, paragraph (a) is amended by removing "253.31" and adding, in its place, "252.31", and the authority citation is revised to read as follows:

(Authority: 25 U.S.C. 2602(c), 2604)

§ 252.31 [Amended]

16. Section 252.31 is amended by revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2602(c), 2604)

PART 254—[REDESIGNATED AS PART 253 AND AMENDED]

17. Part 254 is redesignated as Part 253.

18. The authority citation for redesignated Part 253 is revised to read as follows:

Authority: 25 U.S.C. 2621 (a), (c), unless otherwise noted.

§ 253.1 [Amended]

19. The authority citation for § 253.1 is revised to read as follows:

(Authority: 25 U.S.C. 2621 (a), (c))

20. Section 253.2 is amended by adding a new paragraph (f) and revising the authority citation to read as follows:

§ 253.2 Who is eligible for assistance under this program?

* * * * *

(f) Consortia of Indian tribes or Indian organizations, local educational agencies, and institutions of higher education for projects described in § 253.10(c).

(Authority: 25 U.S.C. 2621(c))

21. Section 253.3 is amended by revising paragraph (b) and the authority citation to read as follows:

§ 253.3 What regulations apply to the program?

* * * * *

(b) The regulations in this Part 253.

(Authority: 25 U.S.C. 2621 (a), (c))

§ 253.4 [Amended]

22. The authority citation for § 253.4 is revised to read as follows.

(Authority: 25 U.S.C. 2621 (a), (c))

23. Section 253.10 is amended by adding a new paragraph (c) and revising the authority citation to read as follows:

§ 253.10 What types of projects may be funded?

* * * * *

(c) Consortia of eligible applicants described in § 253.2(f) may receive grants to develop, improve, and implement programs to—

(1) Encourage Indian students to acquire a higher education; and

(2) Reduce the incidence of dropouts among Indian elementary and secondary school students.

(Authority: 25 U.S.C. 2621 (a)(2), (c))

Subpart C—[Removed and Reserved]

24. Subpart C (consisting of § 253.20) is removed and reserved.

§ 253.30 [Amended]

25. In § 253.30, paragraph (a) is amended by removing "254.32" and adding, in its place, "253.32", and the authority citation is revised to read as follows:

(Authority: 25 U.S.C. 3621 (a), (c), (f)(1), (2))

§ 253.31 [Amended]

26. Section 253.31 is amended by removing "254.32" and adding, in its place, "253.32", removing the period and adding ", or from a consortium that includes an Indian tribe, Indian organization, or Indian institution of higher education." after the word "institution" and revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2621(f)(2)(B))

§ 253.32 [Amended]

27. Section 253.32 is amended by revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2621 (c), (f)(1), (2))

PART 255—[REDESIGNATED AS PART 254 AND AMENDED]

28. Part 255 is redesignated as Part 254.

29. The authority citation for redesignated Part 254 is revised to read as follows:

Authority: 25 U.S.C. 2621 (a)(1), (b), unless otherwise noted.

§ 254.1 [Amended]

30. The authority citation for § 254.1 is revised to read as follows:

(Authority: 25 U.S.C. 2621 (a)(1), (b))

§ 254.2 [Amended]

31. The authority citation for § 254.2 is revised to read as follows.

(Authority: 25 U.S.C. 2621(b))

32. Section 254.3 is amended by revising paragraph (b) and the authority citation to read as follows:

§ 254.3 What regulations apply to this program?

* * * * *

(b) The regulations in this Part 254.

(Authority: 25 U.S.C. 2621 (a), (b))

§ 254.4 [Amended]

33. The authority citation for § 254.4 is revised to read as follows:

(Authority: 25 U.S.C. 2621 (a), (b))

§ 254.10 [Amended]

34. In § 254.10, paragraph (a)(2) is amended by removing "for one or more of the types of grants listed in 255.20(a)(2)" and adding, in its place, "separately for one or more planning grant, pilot grant, or demonstration grant." and revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2621 (a)(1), (b))

Subpart C—[Removed and Reserved]

35. Subpart C (consisting of § 254.20) is removed and reserved.

§ 254.30 [Amended]

36. In § 254.30, paragraph (a) is amended by removing "§ 255.32, 255.33, or 255.34" and adding, in its place, § 254.32, 254.33 or 254.34" and revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2621(b))

§ 254.31 [Amended]

37. Section 254.31 is amended by removing "§ 255.32, 255.33, or 255.34" from the undesignated introductory text and adding, in its place, "§ 254.32, 254.33, or 254.34", removing "255.10(d)" in paragraph (b) and adding, in its place, "254.10(d)", and revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2621(f)(2)(B))

§ 254.32 [Amended]

38. Section 254.32 is amended by revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2621 (b), (f)(1), (2))

§ 254.33 [Amended]

39. Section 254.33 is amended by revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2621 (b), (f)(1), (2))

§ 254.34 [Amended]

40. Section 254.34 is amended by revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2621 (b), (f)(1), (2))

41. A new Part 255 is added to read as follows:

PART 255—GIFTED AND TALENTED PROGRAM

Subpart A—General

255.1 What is the Gifted and Talented Program?
255.2 Who is eligible for an award?
255.3 What regulations apply?
255.4 What definitions apply?
255.10 What activities may the Secretary fund?
255.11 Must the applicant or grantee coordinate activities with other entities?

Subpart B—[Reserved]

Subpart C—How Does the Secretary Make an Award?

255.30 How does the Secretary evaluate an application?
255.31 What selection criteria does the Secretary use?
255.32 What other factors does the Secretary consider in selecting grantees?

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

Subpart A—General

§ 255.1 What is the Gifted and Talented Program?

This program provides five grants to Bureau-funded schools for gifted and talented program research, development and dissemination.

(Authority: 25 U.S.C. 2624(c))

§ 255.2 Who is eligible for an award?

Bureau-funded schools are eligible for grants under this program.

(Authority: 25 U.S.C. 2624(c), 2651)

§ 255.3 What regulations apply?

The following regulations apply to this program:

(a) The regulations in 34 CFR Part 250.

(b) The regulations in this Part 255.

(Authority: 25 U.S.C. 2624(c))

§ 255.4 What definitions apply?

The definitions in 34 CFR 250.4 apply to this program.

(Authority: 25 U.S.C. 2624(c))

§ 255.10 What activities may the Secretary fund?

The Secretary may fund program research and development, the development and dissemination of curriculum materials, and the development and dissemination of teacher training materials regarding one or more of the following:

(a) Gifted and talented students.

(b) College preparatory studies (including programs for Indian students interested in teaching careers).

(c) Students with special culturally related academic needs, including social, lingual, and cultural needs.

(d) Mathematics and science education.

(Authority: 25 U.S.C. 2624(c))

§ 255.11 Must the applicant or grantee coordinate activities with other entities?

(a) The supervisor of a Bureau school shall undertake jointly its application for, or administration of, a grant under this part with the supervisor of the local school board.

(b) Each grantee will work cooperatively with other recipients of funds under section 5324 of the Indian Education Act as part of a national network.

(Authority: 25 U.S.C. 2624 (c), (d))

Subpart B—[Reserved]

Subpart C—How Does the Secretary Make an Award?

§ 255.30 How does the Secretary evaluate an application?

(a) The Secretary evaluates an application on the basis of the applicable criteria in § 255.31.

(b) The Secretary awards up to 100 possible total points for these criteria.

(c) The maximum possible score for each complete criterion is indicated in parentheses.

(Authority: 25 U.S.C. 2624(c))

§ 255.31 What selection criteria does the Secretary use?

The Secretary uses the following selection criteria in evaluating each application:

(a) *Need.* (20 points). The Secretary assesses the need for the proposed project, including—

(1) The soundness of the rationale for the project and the extent and severity among Indian children of the educational needs to be addressed;

(2) The extent to which the educational approach to be developed is likely to be successful in meeting the needs;

(3) The extent to which the applicant is knowledgeable about other projects that address similar needs or have tried similar approaches; and

(4) The likelihood that the project will serve as a model for communities with similar educational needs.

(b) *Plan of operation.* (20 points). The Secretary reviews the plan of operation to ensure that—

(1) The purpose of the project is consistent with the needs identified and the purpose of the funding program;

(2) The design of the project is of high quality;

(3) The objectives of the project—

(i) Relate to the purpose of the project;

(ii) Will provide clear and measurable indices of the project in progress in achieving its purpose; and

(iii) Are capable of being achieved within the project period;

(4) The activities are appropriate and should result in the accomplishment of the project objectives; and

(5) The plan of management is effective and ensures proper and efficient administration of the project.

(c) *Parental and community involvement.* (10 points). The Secretary determines whether parents of the children to be served and other members of the Indian community will be involved in the project, including the extent of their involvement in—

(1) Planning and developing the project; and

(2) Operating and evaluating the project.

(d) *Quality of key personnel.* (15 points). The Secretary reviews the key personnel the applicant plans to use on the project to ensure that—

(1) The project director has the experience and training needed for the position;

(2) Other key personnel have the experience and training needed for their positions in the project; and

(3) Sufficient time will be committed to the project by key personnel.

(e) *Budget and cost effectiveness.* (5 points). The Secretary reviews the budget to ensure that—

(1) The budget is adequate to support the project activities; and

(2) The costs are reasonable in relation to the objectives of the project.

(f) *Evaluation plan.* (15 points). The Secretary reviews the evaluation plan to ensure that—

(1) The evaluation will measure the project's effectiveness in meeting each objective;

(2) The evaluation will measure the impact of the project on the children involved, if applicable;

(3) The instruments for collecting data and the methods for analyzing the data are appropriate;

(4) There is an appropriate timetable for collecting, analyzing, and reporting data;

(5) Procedures have been established for modification of the project, if necessary, as a result of periodic progress assessments; and

(6) Adequate provision has been made to cooperate with recipients of funds under section 5324 of the Indian Education Act in evaluating the project.

(g) *Dissemination.* (10 points). The Secretary reviews the plan for disseminating information about the project, including the results of the project and any materials developed by the project to ensure that—

(1) The dessemination plan is effective and efficient;

(2) The materials disseminated are appropriate in terms of quality and utility;

(3) The methods and techniques used by the project will be demonstrated;

(4) Schools interested in adapting or adopting the project's materials or methods will be assisted; and

(5) The findings of the project will be published at the local, State, or national level, and provision has been made to coordinate dissemination activities with recipients of funds under section 5324 of the Indian Education Act.

(h) *Adequacy of resources.* (5 points). The Secretary reviews the resources to be devoted to the project to ensure that—

(1) The facilities that the applicant plans to use are adequate; and

(2) The equipment and supplies that the applicant plans to use are adequate.

(Authority: 25 U.S.C. 2624(c), (d))

§ 255.32 What other factors does the Secretary consider in selecting grantees?

In addition to using the selection criteria in § 255.31 the Secretary selects projects that achieve a mixture of projects described in § 255.10 to ensure that students at all grade levels and students in all geographic areas of the country are able to participate in some projects funded under this program.

(Authority: 25 U.S.C. 2624(c), (d))

PART 256—EDUCATIONAL PERSONNEL DEVELOPMENT

42. The authority citation for Part 256 is revised to read as follows:

Authority: 25 U.S.C. 2621(d), 2622, unless otherwise noted.

43. Section 256.1 is amended by revising paragraphs (b)(1) and (b)(2) and the authority citation to read as follows:

§ 256.1 Educational Personnel Development.

* * * * *

(b) * * *

(1) The program authorized by section 5321(d) of the Indian Education Act and referred to in this part as the section 5321(d) Program; and

(2) The program authorized by section 5322 of the Indian Education Act and referred to in this part as the section 5322 Program.

Authority: 25 U.S.C. 2621(d), 2622)

§ 256.2 [Amended]

44. The § 256.2, paragraph (a) is amended by removing "1005(d)" and adding, in its place, "5321(d)", paragraph (b) is amended by removing "422" and adding, in its place, "5322", and the authority citation is revised to read as follows:

Authority: 25 U.S.C. 2621(d), 2622)

§ 256.3 [Amended]

45. The authority citation for § 256.3 is revised to read as follows:

(Authority: 25 U.S.C. 2621(d), 2622)

§ 256.4 [Amended]

46. The authority citation for § 256.4 is revised to read as follows:

(Authority: 25 U.S.C. 2621(d), 2622)

§ 256.10 [Amended]

47. The authority citation for § 256.10 is revised to read as follows:

(Authority: 25 U.S.C. 2621(d), 2622)

48. Section 256.20 is revised to read as follows:

§ 256.20 What provisions for participation must an applicant make?

Prior to the submission of an application under this Part, each applicant shall—

(a) To the extent consistent with the number of eligible children in the area to be served who are enrolled in private nonprofit elementary and secondary schools and whose needs are of the type that the program is intended to meet, make provision for the participation on an equitable basis of persons serving or preparing to serve these children as educational personnel or ancillary educational personnel; and

(b) Have provided for adequate participation by relevant tribal communities, including parents of Indian children, in planning and developing this project and have made provision for their participation in operating and evaluating the project.

(Authority: 25 U.S.C. 2621(d), (f)(1), (2), 2622)

49. Section 256.30 is amended by revising paragraph (a) and the authority citation to read as follows:

§ 256.30 How does the Secretary evaluate an application?

(a) The Secretary reviews and approves applications under the Section 5321(d) Program separately from applications under the Section 5322 Program.

* * * * *

(Authority: 25 U.S.C. 2621(d), 2622)

§ 256.31 [Amended]

50. In § 256.31, paragraph (b) is amended by removing "1005(d)" and adding, in its place, "5321(d)", paragraph (c) is amended by removing "1005(d)" and adding, in its place, "5321(d)", paragraph (d) is amended by removing "422" and adding, in its place "5322", and the authority citation is revised to read as follows:

(Authority: 25 U.S.C. 2621(d) and (f)(2)(B), 2622)

§ 256.32 [Amended]

51. Section 256.32 is amended by revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2621(d), and (f)(1), (2), 2622)

52. A new § 256.33 is added to read as follows:

§ 256.33 What other factors does the Secretary consider in selecting grantees under the section 5321(d) program?

In addition to using the selection criteria in § 256.32, the Secretary considers the prior performance of a grantee under the section 5321(d) program in selecting grantees for new awards under the section 5321(d) program.

(Authority: 25 U.S.C. 2621(d)(4))

§ 256.40 [Amended]

53. The authority citation for § 256.40 is revised to read as follows:

(Authority: 25 U.S.C. 2621(d), 2622)

54. A new § 256.41 is added to read as follows:

§ 256.41 What other conditionis must a grantee meet?

Each grantee shall provide adequate information to participants about the intent of the training program.

(Authority: 25 U.S.C. 2621(d), 2622)

§ 256.50 [Amended]

55. The authority citation for § 256.50 is revised to read as follows:

(Authority: 25 U.S.C. 2621(d), 2622)

PART 257—EDUCATIONAL SERVICES FOR INDIAN ADULTS

56. The authority citation for Part 257 is revised to read as follows:

Authority: 25 U.S.C. 2631, unless otherwise noted.

§ 257.1 [Amended]

57. The authority citation for § 257.1 is revised to read as follow:

(Authority: 25 U.S.C. 2631(b))

§ 257.2 [Amended]

58. The authority citation for § 257.2 is revised to read as follows:

(Authority: 25 U.S.C. 2631(b))

§ 257.3 [Amended]

59. The authority citation for § 257.3 is revised to read as follows:

(Authority: 25 U.S.C. 2631)

§ 257.4 [Amended]

60. The authority citation for § 257.4 is revised to read as follows:

(Authority: 25 U.S.C. 2631)

§ 257.10 [Amended]

61. The authority citation for § 257.10 is revised to read as follows:

(Authority: 25 U.S.C. 2631)

Subpart C—[Removed and Reserved]

62. Subpart C (consisting of § 257.20) is removed and reserved.

§ 257.30 [Amended]

63. The authority citation for § 257.30 is revised to read as follows:

(Authority: 25 U.S.C. 2631(b))

§ 257.31 [Amended]

64. Section 257.31 is amended by revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2631 (b), (d))

PART 258—PLANNING, PILOT, AND DEMONSTRATION PROJECTS FOR INDIAN ADULTS

65. The authority citation for Part 258 is revised to read as follows:

Authority: 25 U.S.C. 2631(a), unless otherwise noted.

§ 258.1 [Amended]

66. The authority citation for § 258.1 is revised to read as follows:

(Authority: 25 U.S.C. 2631(a))

§ 258.2 [Amended]

67. The authority citation for § 258.2 is revised to read as follows:

(Authority: 25 U.S.C. 2631(a))

§ 258.3 [Amended]

68. The authority citation for § 258.3 is revised to read as follows:

(Authority: 25 U.S.C. 2631(a))

§ 258.4 [Amended]

69. The authority citation for § 258.4 is revised to read as follows:

(Authority: 25 U.S.C. 2631(a))

§ 258.10 [Amended]

70. In § 258.10, paragraph (a)(2) is amended by removing "for one or more of the types of grants listed in § 258.20(a)(1)" and adding, in its place, "separately for one or more planning grants, pilot grants, or demonstration grants." and revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2631(a))

Subpart C—[Removed and Reserved]

71. Subpart C (consisting of § 258.20) is removed and reserved.

§ 258.30 [Amended]

72. The authority citation for § 258.30 is revised to read as follows:

(Authority: 25 U.S.C. 2631(a))

§ 258.31 [Amended]

73. The authority citation for § 258.31 is revised to read as follows:

(Authority: 25 U.S.C. 2631(d), (3))

§ 258.32 [Amended]

74. Section 258.32 is amended by revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2631 (a), (d))

§ 258.33 [Amended]

75. Section 25.33 is amended by revising the authority citaion to read as follows:

(Authority: 25 U.S.C. 2631 (a), (d))

§ 258.34 [Amended]

76. Section 258.34 is amended by revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2631 (a), (d))

[FR Doc. 88-26370 Filed 11-15-88; 8:45 am]

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federal register

Wednesday
November 16, 1988

Part X

Department of Education

34 CFR Part 251

Formula Grant Program; Local Educational Agencies; Notice of Proposed Rulemaking

DEPARTMENT OF EDUCATION

34 CFR Part 251

Formula Grant Program; Local Educational Agencies

AGENCY: Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes to amend regulations governing the Indian Education formula grant program to incorporate new provisions of the Indian Education Act of 1988. The proposed regulations include as eligible applicants (under certain circumstances) schools operated by the Bureau of Indian Affairs (BIA) and clarify the requirements for including children in the applicant's count of Indian students to generate funds under the program.

DATE: Comments must be received on or before January 17, 1989.

ADDRESSES: All comments concerning these proposed regulations should be addressed to Mr. Brian Stacey, Acting Director, Indian Education Programs, Office of Elementary and Secondary Education, U.S. Department of Education, 400 Maryland Avenue, SW., Room 2177, Washington, DC 20202-6139.

A copy of any comments that concern information collection requirements should also be sent to the Office of Management and Budget at the address listed in the Paperwork Reduction Act section of this preamble.

FOR FURTHER INFORMATION CONTACT: Ms. Sylvia Wright, Indian Education Programs, Office of Elementary and Secondary Education, U.S. Department of Education, 400 Maryland Avenue, SW., Room 2177, Washington, DC 20202-6139. Telephone (202) 732-1938.

SUPPLEMENTARY INFORMATION: The Indian Education formula grant program was amended and reauthorized by Part C of Title V of Pub. L. 100-297 (Indian Education Act of 1988; the Act). The Act subsequently was amended again by Pub. L. 100-427. Under Section 5312(b) of the Act, formula grants may be awarded to local educational agencies, certain tribal schools and, under certain circumstances, schools operated by the BIA. Except where noted, the term "LEA" includes tribal schools and schools operated by BIA.

- **Student Eligibility**

The Act also directs the Secretary to require that each application for a grant be supported by a student certification form, maintained in the applicant's files, for each eligible Indian child included in the applicant's count of children to generate formula grant funds. In order for a child to be counted to generate formula grant funds, the form must contain the name of the child, the name of the tribe, band or other organized group of Indians in which membership is claimed, and the parent's dated signature. The proposed regulations would permit LEAs to obtain the parent's signature and date as late as 90 days after the beginning of the relevant grant period if the signature and date cannot be obtained by the date the LEA compiles its Indian student count.

Other clarifications of the requirements for including students in the Indian student count are provided to assist LEAs in complying with the requirements. The proposed regulations would require each applicant to establish a specific date or period, not to exceed 30 days, to conduct its Indian student count, and would require that only students who are enrolled in the LEA and receiving a free public education from the LEA on the count date or during the count period be counted. The proposed regulations also describe the effect that failure to meet the minimum certification requirements would have on the grantee.

Section 251.22 has been removed because the information collection requirements described in that section are adequately prescribed in the authorizing statute and application package.

- **Program Improvement**

A new § 251.43 is proposed to encourage program improvement through the use of a grantee's self-evaluation of its project, in order to provide the best possible educational services to Indian children.

Executive Order 12291

These proposed regulations have been reviewed in accordance with Executive Order 12291. They are not classified as major because they do not meet the criteria for major regulations established in the order.

Regulatory Flexibility Act Certification

The Secretary certifies that these proposed regulations would not have a significant economic impact on a substantial number of small entities. The small entities that would be affected by these proposed regulations are small school districts, tribal schools, and schools operated by the BIA receiving Federal financial assistance under this program. The regulations clarify current recordkeeping requirements and impose penalties for failure to maintain proper records. The recordkeeping requirements are not excessively burdensome or expensive, and the penalties will affect only the limited number of entities found not to be in compliance with the regulations.

Paperwork Reduction Act of 1980

Sections 251.23, 251.50, 251.51, and 251.52(a)(2) contain information collection requirements. As required by the Paperwork Reduction Act of 1980, the Department of Education will submit a copy of these sections to the Office of Management and Budget (OMB) for its review.

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, Room 3002, New Executive Office Building, Washington, DC 20503; Attention: James D. Houser.

(44 U.S.C. 3504(h))

Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR Part 79. The objective of the Executive Order is to foster an intergovernmental partnership and a strengthened federalism by relying on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

In accordance with the order, this document is intended to provide early notification of the Department's specific plans and actions for this program.

Invitation to Comment

Interested persons are invited to submit comments and recommendations regarding these proposed regulations.

All comments submitted in response to these proposed regulations will be available for public inspection, during and after the comment period, in Room 2177, FOB #6 (Mail stop 6267), 400 Maryland Avenue, SW., Washington, DC 20202 between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

To assist the Department in complying with specific requirements of Executive Order 12291 and the Paperwork Reduction Act of 1980 and their overall requirement of reducing regulatory burden, the Secretary invites comment on whether there may be further opportunities to reduce any regulatory burdens found in these proposed regulations.

List of Subjects in 34 CFR Part 251

Education, Elementary and secondary education, Grant programs—education, Grant programs—Indians, Indians—

education, Reporting and recordkeeping requirements.

(Catalog of Federal Domestic Assistance Number 84.060 Development Awards Program—Indian Education—Local Educational Agencies and Tribal Schools)

Dated: November 8, 1988.

Lauro F. Cavazos,

Secretary of Education.

The Secretary proposes to amend Part 251 of Title 34 of the Code of Federal Regulations as follows:

1. The title of Part 251 is revised to read as follows:

PART 251—FORMULA GRANTS—LOCAL EDUCATIONAL AGENCIES

2. The authority citation for Part 251 is revised to read as follows:

Authority: 25 U.S.C. 2601–2606, unless otherwise noted.

§ 251.1 [Amended]

3. Section 251.1 is amended by removing the words "and Tribal Schools" in the section heading and text and revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2601)

4. Section 251.2 is revised to read as follows:

§ 251.2 Who is eligible for assistance under this program?

(a) An LEA is eligible for assistance under this program.

(b)(1) An LEA other than a tribal school or a Bureau school is entitled to receive a grant only if the number of Indian children enrolled in the LEA's schools is either—

(i) At least 10; or

(ii) At least one-half of the total enrollment for that agency.

(2) However, an LEA may apply without regard to the enrollment requirements of paragraph (b)(1) of this section if it is located—

(i) In Alaska, California, or Oklahoma; or

(ii) On, or in proximity to, an Indian reservation.

(c) An LEA that is a Bureau school is eligible only if funds are available in accordance with section 5312(b)(3) of the Act.

(Authority: 25 U.S.C. 2602 (a), (b))

5. Section 251.3 is amended by revising paragraph (b)(2) introductory text, redesignating paragraph (b)(2)(iii) as (b)(2)(iv), adding a new paragraph (b)(2)(iii), and revising redesignated paragraph (b)(2)(iv) and the authority citation to read as follows:

§ 251.3 What regulations apply to this program?

* * * * *

(b) * * *

(2) However, the following provisions of this part do not apply to tribal schools or Bureau schools:

* * * * *

(iii) Sections 251.31 and 251.32 relating to free public education.

(iv) Sections 251.40–251.42 relating to the maintenance of effort required for LEAs.

(Authority: 25 U.S.C. 2601–2606, 2651)

§ 251.4 [Amended]

6. The authority citation for § 251.4 is revised to read as follows:

(Authority: 25 U.S.C. 2601–2606)

7. Section 251.10 is amended by revising paragraph (a) and the authority citation to read as follows:

§ 251.10 What types of projects may be funded?

(a) The Secretary may fund applications proposing the—

(1) Establishment, maintenance, or operation of projects specifically designed to meet the special educational or culturally related academic needs, or both, of Indian children; or

(2) Training of counselors at the applicant's school in counseling techniques relevant to the treatment of alcohol and substance abuse.

* * * * *

(Authority: 25 U.S.C. 2603)

§ 251.20 [Amended]

8. Section 251.20 is amended by adding the words "—other than a tribal school or a Bureau School—" after the word "LEA" in paragraph (a) and by revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2604(b)(2)(B), 2651)

§ 251.21 [Amended]

9. In § 251.21, paragraph (b) is amended by removing the words "other than school administrators or officials" and revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2604(b)(2)(B)(i), 2651)

10. Section 251.22 is revised to read as follows:

§ 251.22 How does the LEA determine the student count?

(a) Before including a student in the count of Indian children to generate funds under this part, an LEA shall—

(1) Establish a date or a period, not exceeding 30 days, during which the LEA conducts the count;

(2) Determine that the child was enrolled in the LEA's elementary or secondary schools on the count date or during the count period;

(3) Determine that the child received a free public education in the LEA's schools on the count date or during the count period; and

(4) Obtain for each child included in the count the student certification form prescribed by the Secretary.

(b) Before including a student in the count of Indian children to generate funds under this part, the LEA shall determine that the student certification form referred to in paragraph (a)(4) of this section includes, at a minimum,—

(1) The student's name;

(2) The name of the eligible Indian tribe, band, or group of which the student, the parent, or the grandparent is a member, as defined by the tribe, band, or group; and

(3) The parent's signature and date.

(c) The LEA may include in the count a student whose student certification form does not have the parent's signature and date, provided that the parent's signature and date are obtained within 90 days of the start of the grant period for which the student is counted to generate funds under this part.

(Authority: 25 U.S.C. 2602(b), 2604(d), 2651)

§ 251.30 [Amended]

11. In § 251.30, paragraph (a) is amended by removing "303(a), Part A", and adding, in its place, "5312(b)"; paragraph (b)(2) is amended by removing "303(a)(2)(C), Part A", and adding, in its place, "5312(b)(2)(C)"; and the authority citation is revised to read as follows:

(Authority: 25 U.S.C. 2602(b), 2606)

§ 251.31 [Amended]

12. In § 251.31, the introductory text is amended by removing "303(a), Part A", and adding, in its place, "5312(b)"; authority citation is revised to read as follows:

(Authority: 25 U.S.C. 2602(b), 2651)

§ 251.32 [Amended]

13. In § 251.32, paragraph (a) introductory text is amended by removing "§ 251.30 and", paragraph (d)(2) is amended by removing "§ 303(a), Part A", and adding, in its place, "5312(b)", and the authority citation is revised to read as follows:

(Authority: 25 U.S.C. 2602(b), 2651)

14. Section 251.40 is amended by removing the words "does not make" in paragraph (a) and adding, in their place, the words "makes full"; removing the word "unless" in paragraph (a) and adding, in its place, the word "if"; redesignating paragraphs (b) and (c) as

(d) and (e), respectively; adding new paragraphs (b) and (c); and revising the authority citation to read as follows:

§ 251.40 What is the maintenance of effort requirement?

* * * * *

(b) The requirement of paragraph (a) of this section does not apply to an LEA that is a tribal school or a Bureau school.

(c) Subject to the granting of a waiver under § 251.41, if the Secretary determines that the LEA has failed to maintain the combined fiscal effort as required under paragraph (a) the Secretary reduces the LEA's award in the exact proportion by which the LEA failed to meet the combined fiscal effort requirement.

* * * * *

(Authority: 25 U.S.C. 2605(c), 2651)

§ 251.41 [Amended]

15. The authority citation for § 251.41 is revised to read as follows:

(Authority: 25 U.S.C. 2605(c))

§ 251.42 [Amended]

16. The authority citation for § 251.42 is revised to read as follows:

(Authority: 25 U.S.C. 2605(c))

17. A new § 251.43 is added to read as follows:

§ 251.43 How must a grantee use the results of its evaluations?

(a) If an evaluation under section 5314(a)(4) of the Act shows that a project is not making substantial progress toward meeting the goals of the project and this part, the granted shall amend its application in accordance with section 5314(c) of the Act.

(b) The amendments to the application must include changes that will enable the grantee to meet those goals.

(Authority: 25 U.S.C. 2604(a)(4), (c))

§ 251.50 [Amended]

18. Section 251.50 is amended by adding the words "in accordance with § 251.22 and" after the words "Indian students" and revising the authority citation to read as follows:

(Authority: 25 U.S.C. 2604(d))

19. A new § 251.51 is added to read as follows:

§ 251.51 How does the Secretary determine a grantee's compliance with the student certification requirements?

Periodically, the Secretary reviews a grantee's records to determine, for the current fiscal year and for prior fiscal years for which the grantee is required to maintain records, if—

(a) The requirements in § 251.22 were met;

(b) A certification form that meets the requirements of § 251.22 is on file for each child included by the grantee in the count of children to generate funds under this part; and

(c) Each child counted by the grantee is othewise eligible to be counted under this part.

(Authority: 25 U.S.C. 2601–2606)

20. A new § 251.52 is added to read as follows:

§ 251.52 What action does the Secretary take if a grantee fails to meet the student certification requirements?

(a) If the Secretary determines under § 251.51 that a grantee is not in compliance with the student certification requirements, the grantee shall repay to the Department the amount of funds improperly generated. The Secretary may—

(1) Collect the funds awarded for each child inappropriately counted in the fiscal year or years at issue by—

(i) Demanding direct repayment from the grantee;

(ii) Reducing the grantee's current grant award where the Secretary's determination under paragraph (a) of the section concerns the current fiscal year; or

(iii) Offsetting the equivalent amount from the grantee's award for a fiscal year following the determination; and

(2) For one to three years following that determination, require the grantee to submit with its application for funds under this part a verification by an independent auditor that student certification forms have been completed and maintained by the grantee for each child included in the count in the application.

(b) In applying an administrative offset under § 251.52(a)(1)(iii), the Secretary uses the procedures contained in 34 CFR Part 30.

(Authority: 25 U.S.C. 2601–2606) I40[FR Doc. 88–26372 Filed 11–15–88; 8:45 am]

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federal register

Wednesday
November 16, 1988

Part XI

Department of Education

Office of Postsecondary Education

34 CFR Part 659

Direct Individual Foreign Language and Area Studies Fellowships Program; Notice of Proposed Rulemaking

DEPARTMENT OF EDUCATION

Office of Postsecondary Education

34 CFR Part 659

Direct Individual Foreign Language and Area Studies Fellowships Program

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes regulations to govern the Direct Individual Foreign Language and Area Studies Fellowships Program. This fellowship program was added to Title VI of the Higher Education Act of 1965 (HEA) by the Higher Education Amendments of 1986, Pub. L. 99-498. Under this program, the Secretary awards fellowships directly to graduate students who have completed at least two years of graduate study to further their foreign language training.

DATE: Comments must be received on or before January 3, 1989.

ADDRESS: All comments concerning these proposed regulations should be addressed to Joseph F. Belmonte, Deputy Director, Center for International Education, U.S. Department of Education, 400 Maryland Avenue, SW. (Room 3054, ROB 3), Washington, DC 20202.

A copy of any comments that concern information collection requirements should also be sent to the Office of Management and Budget at the address listed in the Paperwork Reduction Act section of this preamble.

FOR FURTHER INFORMATION CONTACT: Joseph F. Belmonte, Telephone: (202) 732-3283.

SUPPLEMENTARY INFORMATION: Under the Direct Individual Foreign Language and Area Studies Fellowships Program, the Secretary awards fellowships of up to four years, on the basis of a national competition, to graduate students entering their third year of graduate study at an institution of higher education to enable them to continue their foreign language and area studies at that institution. Those studies may include language training and the conduct of research outside the United States.

The Secretary is authorized to award fellowships under this part in a fiscal year only when the funds appropriated for the Foreign Language and Area Studies Fellowships Program authorized under 34 CFR Part 657 for that fiscal year are at least equal to the amount necessary to award 720 academic year fellowships and 400 summer fellowships.

Executive Order 12291

These regulations have been reviewed in accordance with Executive Order 12291. They are not classified as major because they do not meet the criteria for major regulations established in the order.

Regulatory Flexibility Act Certification

The Secretary certifies that these proposed regulations would not have a significant economic impact on a substantial number of small entities.

These regulations will not affect a substantial number of small entities. Only a small number of awards is anticipated if funding becomes available for this program, and the proposed regulations would impose minimal burdens on applicants and grantees.

Invitation to Comment

Interested persons are invited to submit comments and recommendations regarding these proposed regulations.

All comments submitted in response to these proposed regulations will be available for public inspection, during and after the comment period, in Room 3054, Regional Office Building No. 3, 7th and D Streets SW, Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week, except Federal holidays.

To assist the Department in complying with the specific requirements of Executive Order 12291 and the Paperwork Reduction Act of 1980 and their overall requirement of reducing regulatory burden, the Secretary invites comment on whether there may be further opportunities to reduce any regulatory burdens found in these proposed regulations.

Assessment of Educational Impact

The Secretary particularly requests comments on whether the regulations in this document would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects in 34 CFR Part 659

Colleges and universities, Education, Educational study program, Fellowships, Grant program—education, Reporting and recordkeeping requirements.

Dated: November 8, 1988.

(Catalog of Federal Domestic Assistance Number not yet assigned).

Lauro F. Cavazos,

Secretary of Education.

The Secretary proposes to amend Title 34 of the Code of Federal Regulations by adding a new Part 659 to read as follows:

PART 659—DIRECT INDIVIDUAL FOREIGN LANGUAGE AND AREA STUDIES FELLOWSHIPS PROGRAM

Subpart A—General

Sec.
659.1 What is the Direct Individual Foreign Language and Area Studies Fellowships Program?
659.2 Who is eligible to receive a fellowship?
659.3 What regulations apply?
659.4 What definitions apply?

Subpart B—How Does a Student Apply for a Fellowship?

659.10 How does a student submit an application?

Subpart C—How is a Graduate Student Selected to Receive a Fellowship?

659.20 How is a student selected for a fellowship?
659.21 What criteria are used to select students for fellowship awards?
659.22 What priorities may the Secretary establish?

Subpart D—What Conditions Apply to a Fellowship?

659.30 What is the duration of and what are the limitations on an individual fellowship?
659.31 What is the amount of a fellowship?
659.32 What is the payment method for a fellowship?
659.33 What are the conditions for the use of an individual fellowship outside the United States?
659.34 Under what circumstances must the Secretary terminate an individual fellowship?

Authority: 20 U.S.C. 1122, unless otherwise noted.

Subpart A—General

§ 659.1 What is the Direct Individual Foreign Language and Area Studies Fellowships Program?

Under the Direct Individual Foreign Language and Area Studies Fellowships Program, the Secretary awards fellowships of up to four years, on the basis of a national competition, to graduate students entering their third year of graduate study at an institution of higher education to enable them to continue their foreign language and area studies at that institution. Those studies may include the conduct of research and language training outside the United States.

(Authority: 20 U.S.C. 1122)

§ 659.2 Who is eligible to receive a fellowship?

(a) A student is eligible to receive a fellowship if the student—

(1) Is a citizen or national of the United States;

(2) Is a permanent resident of the United States; or

(3) Is a permanent resident of the Trust Territory of the Pacific Islands (Republic of Palau);

(b) Is enrolled in a graduate program at an institution of higher education which provides advanced training in a foreign language combined with—

(1) Area or international studies; or

(2) Research and training in the international aspects of professional and other fields of study;

(c) Shows high academic achievement, based on indices such as grade point average, class ranking, or standardized achievement tests;

(d) Has provided evidence of—

(1) Exceptional performance in the foreign language or languages being studied as part of the student's graduate program; and

(2) Substantial multidisciplinary area training in activities described in paragraph (b) of this section; and

(e) Is beginning his or her third year of graduate study.

(Authority: 20 U.S.C. 1122, 1132; 48 U.S.C. 1681)

(Approved by the Office of Management and Budget under control No. 1840-0610.)

§ 659.3 What regulations apply?

The following regulations apply to this program:

(a) The regulations in 34 CFR Part 655.

(b) The regulations in this Part 659.

(Authority: 20 U.S.C. 1122)

§ 659.4 What definitions apply?

The following definitions apply to this part:

(a) The definitions in 34 CFR 655.4.

(b) "Fellow" means a person who receives a fellowship under this part.

(c) "Fellowship" means the payment a fellow receives under this part.

(d) "Multidisciplinary area training" means training in three or more academic disciplines that contribute to a fuller understanding of the region or field of international studies; and

(e) "Secretary" means the United States Secretary of Education.

(Authority: 20 U.S.C. 1122)

Subpart B—How Does a Student Apply for a Fellowship?

§ 659.10 How does a student submit an application?

(a) A student applies to the Secretary for a fellowship by providing sufficient information to enable the Secretary to determine—

(1) Whether he or she is eligible to receive a fellowship; and

(2) Whether he or she should be selected for a fellowship on the basis of the selection criteria listed in § 659.21.

(b) The information to be submitted for each application must include—

(1) Transcripts of the student's undergraduate and graduate academic record;

(2) References from at least three people familiar with the student's accomplishments and potential;

(3) Information from the institution at which the student is enrolled about his or her performance on a nationally-referenced language test, if available, or other evidence of language competency, in the proposed language of award;

(4) A statement of the student's goals and plan of study during his or her fellowship tenure, including the number of years for which the fellowship is requested and plans for language study or research outside the United States; and

(5) Endorsement of the student's plan of study by his or her academic advisor.

(Authority: 20 U.S.C. 1122)

(Approved by the Office of Management and Budget under OMB control No. 1840-0610.)

Subpart C—How Is a Graduate Student Selected To Receive a Fellowship?

§ 659.20 How is a student selected for a fellowship?

(a) The Secretary awards fellowships to graduate students selected by a panel of nationally recognized scholars.

(b) The panel of scholars evaluates an application for a fellowship on the basis of the quality of the applicant's record, language proficiency, and plan of study in accordance with the criteria listed in § 659.21.

(c) In general, the panel awards up to 100 possible points for these criteria. However, if priority criteria are used the panel awards up to 120 possible points. The maximum possible number of points for each criterion is shown in parentheses following the heading for the criterion.

(Authority: 20 U.S.C. 1122)

§ 659.21 What criteria are used to select students for fellowship awards?

The panel of scholars uses the following criteria in evaluating applications for fellowships under this part:

(a) *Qualifications of the applicant.* [40] The panel of scholars reviews each application to determine—

(1) The strength of the applicant's undergraduate and graduate record; and

(2) The extent of the applicant's preparation for the proposed course of study through evidence of substantial multidisciplinary training.

(b) *Foreign language skills.* [30] The panel of scholars reviews each application to determine—

(1) The excellence of the applicant's performance on either a nationally-referenced test, if available, or on other commonly accepted tests, in the foreign language to be studied;

(2) The relevance of the language to be studied for the applicant's overall proposed course of study; and

(3) Evidence of the applicant's skills in other foreign languages.

(c) *Proposed plan of study.* [30] The panel of scholars reviews each application to determine—

(1) The feasibility of the applicant's proposed plan of study; and

(2) The quality of the proposed plan of study in relation to the applicant's preparation and goals.

(d) *Priorities.* [20] The panel of scholars reviews each application to determine the extent to which the priorities established under § 659.22 will be met by the applicant.

(Authority: 20 U.S.C. 1122)

(Approved by the Office of Management and Budget under OMB control no. 1840-0610.)

§ 659.22 What priorities may the Secretary establish?

(a) The Secretary may establish one or more of the following priorities for selecting fellows:

(1) Languages, such as Chinese.

(2) World areas, or countries, such as East Asia, or Indonesia.

(3) Academic disciplines, such as linguistics or economics.

(4) Topics, such as population growth and planning, modernization, economic development, security issues, the arts, or international trade.

(5) A combination of any of these categories.

(b) The Secretary announces any priorities in the annual application notice published in the **Federal Register**.

(Authority: 20 U.S.C. 1122)

Subpart D—What Conditions Apply to a Fellowship?

§ 659.30 What is the duration of and what are the limitations on an individual fellowship?

(a) The Secretary awards a fellowship for the period requested by the fellow, which may not exceed four years.

(b) The continuation of a fellowship is contingent upon the fellow's—

(1) Periodically demonstrating a high level of proficiency in the language or languages being studied as part of the fellow's graduate program;

(2) Remaining in good standing at the institution in which the fellow is enrolled;

(3) Demonstrating satisfactory progress in the fellow's approved plan of graduate study; and

(4) Obtaining the Secretary's prior approval before making significant changes in the fellow's program of graduate study.

(Authority: 20 U.S.C. 1122)

§ 659.31 What is the amount of a fellowship?

(a) The Secretary awards a fellowship in an amount that does not exceed the cost of tuition and fees and an allowance for subsistence.

(b) The Secretary may also include an allowance for travel and an allowance for dependents.

(c) The Secretary announces in the annual application notice published in the **Federal Register**—

(1) The expected amount of subsistence allowances;

(2) Whether dependents' and travel allowances will be permitted; and

(3) The expected amount of the allowances.

(Authority: 20 U.S.C. 1122)

§ 659.32 What is the payment method for a fellowship?

(a) The Secretary may enter into an agreement with the institution in which the fellow is enrolled under which the institution agrees to disburse fellowship funds to the fellow, and the Secretary agrees to advance funds to the institution to enable it to make those payments.

(b) The institution shall pay a fellow his or her subsistence and any other allowance in installments during the term of the fellowship.

(c) A fellow shall notify the institution of any overpayment or underpayment and the institution shall make appropriate adjustments.

(Authority: 20 U.S.C. 1122)

§ 659.33 What are the conditions for the use of an individual fellowship outside the United States?

(a) Before using a fellowship outside the United States a fellow must obtain the approval of the Secretary.

(b) The Secretary approves the use of a fellowship outside the United States if—

(1) The institution in which the fellow is enrolled approves the fellow's engaging in research or undergoing advanced foreign language training in a country outside the United States; and

(2) The fellow—

(i) Is engaged in research that cannot be done effectively in the United States; and

(ii) Is affiliated with an institution of higher education or another appropriate organization in the foreign country.

(Authority: 20 U.S.C. 1122)

§ 659.34 Under what circumstances must the Secretary terminate an individual fellowship?

The Secretary terminates a fellowship if the fellow fails to satisfy the requirements of § 659.30(b).

(Authority: 20 U.S.C. 1122)

[FR Doc. 88-26373 Filed 11-15-88; 8:45 am]

BILLING CODE 4000-01-M

federal register

Wednesday
November 16, 1988

Part XII

Department of Agriculture

Cooperative State Research Service

Rangeland Research Grants Program for Fiscal Year 1989; Solicitation of Applications; Notice

DEPARTMENT OF AGRICULTURE

Cooperative State Research Service

Rangeland Research Grants Program for Fiscal Year 1989; Solicitation of Applications

Notice is hereby given that under the authority contained in section 1480 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended (7 U.S.C. 3333), the Cooperative State Research Service (CSRS) of the United States Department of Agriculture (USDA) anticipates awarding standard grants for basic studies in certain areas of rangeland research. No more than $80,000 will be awarded for the support of any one project, regardless of the amount requested. The total amount available for this program during Fiscal Year 1989 is $454,991.

Under this program, the Secretary may award grants to land-grant colleges and universities, State agricultural experiment stations, and to colleges, universities, and Federal laboratories having a demonstrable capacity in rangeland research. Except in the case of Federal laboratories, each grant recipient must match the Federal funds expended on a research project based on a formula of 50 percent Federal and 50 percent non-Federal funding. Proposals received from scientists at non-United States organizations or institutions will not be considered for support.

Applicable Regulations

This program is subject to the provisions found at 7 CFR Part 3401 (51 FR 16152, April 30, 1986). These provisions set forth procedures to be followed when submitting grant proposals, rules governing the evaluation of proposals, processes regarding the awarding of grants, and regulations relating to the post-award administration of grant projects. Pursuant to section 1473 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended (7 U.S.C. 3319), funds made available under this program to recipients other than Federal laboratories shall not be subject to reduction for indirect costs or for tuition remission costs. Since these costs are not allowable costs for purposes of this program, such costs incurred by a grant recipient may not be used to meet the matching funds requirement. In addition, USDA Uniform Federal Assistance Regulations, 7 CFR Part 3015, as amended, apply to this program.

How to Obtain Application Materials

Copies of this solicitation, the Grant Application Kit, and the Administrative Provisions for this program (7 CFR Part 3401) may be obtained by writing to the address or calling the telephone number which follows:

Proposal Services Unit, Grants Administrative Management, Office of Grants and Program Systems, Cooperative State Research Service, U.S. Department of Agriculture, Room 303, Aerospace Building, 901 D Street, SW., Washington, DC 20251-2200, Telephone: (202) 475-5048.

What to Submit

An original and nine copies of each proposal submitted under this program are requested. This number of copies is necessary to permit thorough, objective peer evaluation of all proposals received before funding decisions are made. Each copy of each proposal must include a Form CSRS-661, "Grant Application." Proposers should note that one copy of this form, preferably the original, must contain pen-and-ink signatures of the principal investigator(s) and the authorized organizational representative. (Form CSRS-661 and the other required forms and certifications are contained in the Grant Application Kit.)

Members of review committees and CSRS staff expect each project description to be complete in itself. Grant proposals must be limited to 10 pages (single-spaced) exclusive of required forms, bibliography and vitae of the principal investigator(s), senior associate(s) and other professional personnel. Attachment of appendices is discouraged and should be included only if pertinent to an understanding of the proposal.

All copies of each proposal must be mailed in one package. Please see that each copy of each proposal is *stapled securely* in the upper left-hand corner. DO NOT BIND. Information should be typed on one side of the page only.

Every effort should be made to ensure that the proposal contains all pertinent information when submitted. Prior to mailing, compare your proposal with the regulations contained in the Administrative Provisions which govern the Rangeland Research Grants Program, 7 CFR Part 3401. If applicable, the research grant proposal must state that the 50 percent non-Federal funding requirement will be met.

Where and When to Submit Grant Applications

Each research grant application must be submitted to:

Proposal Services Unit, Grants Administrative Management, Office of Grants and Program Systems, Cooperative State Research Service, U.S. Department of Agriculture, Room 303, Aerospace Building, 901 D Street, SW., Washington, DC 20251-2200.

To be considered for funding during fiscal year 1989, *proposals must be received* in the Proposal Services Unit *by close of business on Monday, February 6, 1989.* One copy of each proposal not selected for funding will be retained for a period of one year. The remaining copies will be destroyed.

Specific Areas of Research to be Supported in Fiscal Year 1989

Standard grants will be awarded to support basic research in certain areas of rangeland research. Proposals will be considered in the following specific areas: (1) Management of rangelands and agricultural land as integrated systems for more efficient utilization of crops and waste products in the production of food and fiber; (2) methods of managing rangeland watersheds to maximize efficient use of water and improve water yield, water quality, and water conservation, to protect against onsite and offsite damage to rangeland resources from floods, erosion and other detrimental influences, and to remady unsatisfactory and unstable rangeland conditions; and (3) revegetation and rehabilitation of rangelands including the control of undersirable species of plants.

If necessary, further information may be obtained by calling Dr. Wayne K. Murphey, CSRS-USDA; telephone: (202) 447-2044.

Supplementary Information

The Rangeland Research Grants Program is listed in the Catalog of Federal Domestic Assistance under No. 10.200. For reasons set forth in the Final Rule-related Notice to 7 CFR Part 3015, Subpart V (48 FR 29115, June 24, 1983), this program is excluded from the scope of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

Under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)), the collection of information requirements contained in this Notice have been approved under OMB Document No. 0524-0022.

Done at Washington, DC, this 10th day of November 1988.

John Patrick Jordan,

Administrator, Cooperative State Research Service.

[FR Doc. 88-26491 Filed 11-15-88; 8:45 am]

BILLING CODE 3410-22-M

federal register

Wednesday
November 16, 1988

Part XIII

Department of the Interior

Minerals Management Service

Outer Continental Shelf Lease Sale 119; Central California; Call for Information and Nominations and Intent To Prepare an Environmental Impact Statement; Notice

4310-MR

UNITED STATES
DEPARTMENT OF THE INTERIOR
MINERALS MANAGEMENT SERVICE
Central California
Outer Continental Shelf Lease Sale 119
Call For Information and Nominations
and
Notice of Intent To Prepare an Environmental Impact Statement

CALL FOR INFORMATION AND NOMINATIONS

Purpose of Call for Information and Nominations

The purpose of the Call is to assist the Secretary of the Interior in carrying out his responsibilities under the Outer Continental Shelf Lands Act (OCSLA) (43 U.S.C. 1331-1356 (1982)), as amended by the OCSLA Amendments of 1985 (100 Stat. 147), and the regulations issued thereunder (30 CFR Part 256) with regard to proposed OCS Lease Sale 119 in the Central California Planning Area, tentatively scheduled for March 1991.

This initial information gathering step is important for ensuring that all interests and concerns are communicated to the Department of the Interior (DOI) for future decision points in the leasing process. This Call does not indicate a preliminary decision to lease in the area described below.

Information submitted in response to this Call will be used for several purposes. Responses will be used to identify the areas of potential for oil and gas development. Comments on possible environmental effects and potential use conflicts will be used in the analysis of environmental conditions in and near the Call area. Particular consideration will be given to tracts identified as environmentally sensitive as a result of the comments received. Together, this information will be analyzed for future determinations of the potential advantages and disadvantages of oil and gas exploration and development to the region and the Nation and the relative environmental sensitivity of tracts being reviewed for this sale. Thus, it may be possible to make key decisions in connection with subsequent steps in the planning process (beginning with the Area Identification step) to further resolve conflicts by deleting additional blocks or conducting special environmental analyses where there is sufficient information to justify such actions.

The Call also initiates the scoping process for the EIS and is used to identify and analyze alternatives to the proposed action. The Notice of Intent to Prepare an EIS which includes a description of the scoping process is located later in this

document. There will be a series of public meetings as part of EIS scoping. These will be announced at a future date in the Federal Register and by press release. Comments may be used in developing lease terms and conditions to ensure safe offshore operations. Comments may also be used to point out potential conflicts between offshore oil and gas activities and California coastal zone management policies as established by the California Coastal Act of 1976, as amended, and approved local coastal plans.

The DOI made a commitment in the 5-Year OCS Oil and Gas Leasing Program (1987-1992) to provide environmental protection offshore California similar to the levels provided in OCS Lease Sales 73, Santa Maria Basin, and 80, Southern California. The mitigating measures to be developed and analyzed during the prelease process for proposed OCS Lease Sale 119, Central California, will address such issues as: air quality, transportation of hydrocarbons, oil spills, fisheries, hazardous waste dumps, biological resources, timing of operations, navigational safety, archaeological resources, military conflicts, water use, drilling discharges, onshore oil processing, sea otters, and marine biota. The Minerals Management Service (MMS) will consider in the more detailed scoping review conducted for proposed OCS Lease Sale 119 the stipulations included in the separate proposals of California Governor Deukmejian, Congressman Regula, and Congressman Panetta on the 5-year program.

Additionally, special attention will be focused on the resolution of any military conflicts. This will be carried out under the procedures of the 1983 Memorandum of Agreement between the DOI and the Department of Defense and may involve further block deferrals and the adoption of special protective measures.

Description of Area

The general area of this Call is Central California from 3 to 45 miles offshore the counties of San Mateo, Marin, Sonoma, and a small portion of Santa Cruz. The area is shown on the map at the end of this Call. A more detailed map of the Call for Information and Nominations is available free from the Regional Supervisor, Office of Leasing and Environment, MMS, Pacific OCS Region, at the address listed at the end of this section.

The following areas in the Central California Planning Area were deferred from leasing in the 5-year leasing program, approved in July 1987:

1. Deepwater areas beyond the 900-meter isobath;

2. A coastal buffer offshore the Kelp Beds at Saunders Reef Area of Special Biological Significance (ASBS), the Del Mar Ecological Reserve, and Gerstle Cove ASBS;

3. The area offshore Point Reyes, the Point Reyes - Farallon Islands National Marine Sanctuary, offshore San Francisco Bay, and the immediate vicinity of Cordell Bank;

4. A coastal buffer offshore the James V. Fitzgerald Marine Reserve;

5. A coastal buffer extending south of the Point Ano Nuevo Point and Island ASBS and overlapping the northern portion of the Sea Otter Range;

6. The large area offshore Monterey Bay and Big Sur; and

7. A coastal buffer south of the Big Sur proposed deferral, overlapping the southern portion of the Sea Otter Range and adjacent to the Mouth of Salmon Creek ASBS.

One Federal OCS lease sale encompassing Northern and Central California was held in 1963. Twenty-nine blocks within the present Central California Planning Area were leased: 27 off Bodega Bay south to Point Reyes, and 2 off Point Ano Nuevo. Of the 29 blocks leased, 11 are included in this Call. The mapping system has been revised since the 1963 Sale; the old blocks overlap portions of many blocks on the new system. Therefore, those 11 old leases encompass portions of 24 blocks in the Sale 119 Call area. Seven wells were drilled on 5 of those 11 leases. The other 18 blocks are within the deferred areas mentioned above. All the leases were relinquished in 1967 and 1968, prior to the expiration of their 5-year lease terms. An OCS Report, MMS 87-018, entitled "Northern and Central California Lease Sale/May 14, 1963," details the leasing and drilling history of this early sale. Copies of the report are available from the source listed for diagrams in the paragraph below.

The following list identifies the OCS Official Protraction Diagrams and blocks which comprise the Call area. For blocks that overlap deferral areas, the Call includes only those non-deferred portions in Federal waters. The diagrams may be purchased for $2.00 each from the Regional Supervisor, Office of Leasing and Environment, Pacific Region, MMS, 1340 West 6th Street, Los Angeles, California 90017, telephone (213) 894-7107. The purpose of these diagrams is not to delineate the Call area (the Call map mentioned above serves the purpose of delineating the Call area) but to more clearly show small blocks.

Official Protraction Diagram NJ 10-5 - Santa Rosa (Approved November 2, 1976) Blocks:

223-228, 267-273, 311-318, 356-362, 401-407, 445-452, 489-497, 534-542, 578-587, 622-632, 667-675, 711-719, 756-762, 800-807, 845-851, 889-895, 933-938, 977-982

Official Protraction Diagram NJ 10-8 - San Francisco (Approved November 2, 1976) Blocks:

10-14, 54-57, 99-100, 143-144, 332-334, 376-378, 419-422, 457, 462-466, 501-511, 544-555, 588-600, 632-644, 677-688, 721-732, 765-777, 809-822, 853-866, 899-911, 945-956, 992-1000

Official Protraction Diagram NJ 10-11 - Santa Cruz (Approved March 26, 1976) Blocks:

24-32, 70-77, 120-121, 164

Instructions on Call

Respondents are requested to nominate any or all of the Federal blocks within the Call area for inclusion in proposed OCS Lease Sale 119. Although the identities of those submitting nominations become a matter of public record, the individual indications of interest are considered to be proprietary and confidential information.

Those indicating such interest are required to do so on the Call map by listing block numbers or outlining the area(s) of interest along block lines. As stated in paragraph 1 under "Description of Area," the Call map is available free from the Regional Supervisor, Office of Leasing and Environment, MMS, Pacific OCS Region, at the address stated under "Description of Area."

Respondents may submit a detailed list of whole and partial blocks nominated (by OCS Official Protraction Diagram designations) to ensure correct interpretation of their nominations. The telephone number and name of a person to contact in the respondent's organization for additional information should be included.

Respondents should rank areas in which they have expressed interest according to priority of their interest (e.g., priority 1 (high), 2 (medium), or 3 (low)). We encourage respondents to be specific in listing blocks by priority. This information is very helpful in assessing the area to be identified for further study

at future sale decision points. Blanket nominations on large areas are not as useful in providing information pertinent to analysis of industry interest. Areas where interest has been indicated but which have no specified priorities will be considered priority 3. Information concerning both location and priority of interest submitted by individual respondents will be held proprietary and confidential and will help determine the area upon which the EIS analysis will be focused. In addition to indications of interest by respondents, further consideration of areas for analysis in the EIS will be based on hydrocarbon potential and environmental, economic, and multiple-use (including military use) conditions.

In addition to nominations (indications of interest), comments are sought from all interested parties about particular geologic, environmental, biological, archaeological, or socioeconomic conditions or conflicts, or other information that might bear upon potential OCS leasing and development in the Call area. In particular, respondents are requested to identify and characterize tracts of particular environmental sensitivity and to provide suggestions on the criteria that should be used in evaluating the relative environmental sensitivity of such tracts.

Comments are also sought on potential conflicts that may result from the proposed sale between future OCS oil and gas activities and California coastal zone management policies as established by the California Coastal Act and approved local coastal management plans. If possible, these comments should identify specific California Coastal Management Plan policies of concern, the nature of the conflict foreseen, and steps that MMS can take to avoid or mitigate the potential conflict. Comments may be either in terms of broad areas or restricted to particular blocks of concern. Those submitting comments are requested to list block numbers or outline the subject area on the Call map.

Comments are requested within the entire Call Area. All nominations and comments will be considered at the Area Identification stage for identification of the proposal to be analyzed in the EIS.

Nominations and comments must be received no later than 45 days following publication of this document in the Federal Register in envelopes labeled "Nominations for Proposed Central California OCS Lease Sale 119," or "Comments on Proposed Central California OCS Lease Sale 119," as appropriate. The original Call map showing indications of interest and/or comments must be submitted to the Regional Supervisor, Office of Leasing and Environment, MMS, Pacific OCS Region, at the address stated under "Description of Area," and a copy of the Call map showing indications of

interest and a copy of any comments are to be sent to the Chief, Offshore Leasing Management Division, Department of the Interior, Minerals Management Service, Room 4230, 18th and C Streets, NW., Washington, D.C. 20240.

Tentative Schedule

Final delineation of the area for possible leasing will be made at a later date only after compliance with established departmental procedures and applicable laws including all requirements of the National Environmental Policy Act of 1969 (42 U.S.C. 4321) and the OCSLA, as amended.

If a decision to offer blocks is made, a final Notice of Sale will be published in the Federal Register detailing areas to be offered for competitive bidding, stating the terms and conditions for leasing, and announcing the location, date, and time bids will be received and opened.

The following is a list of tentative milestones which will precede this sale, proposed for March 1991:

Comments Due on the Call	--January 1989
Area Identification	--February 1989
Draft EIS Published	--January 1990
Public Hearings on Draft EIS	--February 1990
Final EIS Published	--August 1990
Proposed Notice of Sale Published	--October 1990
Governor's Comments Due on Proposed Notice	--December 1990
Final Notice of Sale Published	--February 1991
Sale	--March 1991

Existing Information

Information already available on the Call area includes that gathered during the EIS process for the 5-Year OCS Oil and Gas Leasing Program (1987 - 1992). Also, the DOI has received extensive information from Congress and industry during negotiations over OCS leasing offshore California during development of the 5-year program. In addition, comments previously received by the DOI from State and local governments, other Federal Agencies, environmental groups, and the oil and gas industry concerning past OCS actions will be considered. The following is a list of additional information which will be available for consideration regarding proposed OCS Lease Sale 119.

Pacific OCS Region Summary Reports and Indices

Summary Reports	Indices
May 1980	October 1980
May 1982	June 1981
December 1982	March 1983
September 1983	October 1984
July 1984	
April 1985	
May 1986	
July 1987	

Summary Reports and Indices are available for review at the MMS, Pacific OCS Region (see address under "Description of Area"). Also available for review are technical and geologic reports. For more information, please contact Ms. Freida Star of that office at (213) 894-2062. Copies of the Pacific OCS Region Summary Reports and Indices may also be obtained from the following:

OCS Information Program
Office of Offshore Information and Publications
Minerals Management Service
1951 Kidwell Drive, Suite 601
Vienna, Virginia 22180

Environmental Studies - Central California Planning Area

A list of completed, active, and proposed environmental studies conducted by the MMS Environmental Studies Program in the Central California Planning Area is available. Completed study reports may be reviewed at the MMS, Pacific OCS Region, at the address listed under "Description of Area" and at many depositories throughout the State. Also, many reports may be purchased from the National Technical Information Service (NTIS). For a list of studies, depositories, or to obtain an NTIS phone number, please contact Ms. Ora Woods, Environmental Studies Section, MMS, Pacific OCS Region at (213) 894-6626.

NOTICE OF INTENT TO PREPARE AN ENVIRONMENTAL IMPACT STATEMENT

Pursuant to the regulations implementing the procedural provisions of the National Environmental Policy Act of 1969 (42 U.S.C. 4321), the MMS is announcing its intent to prepare an EIS regarding the oil and gas leasing proposal known as Central California OCS Lease Sale 119. This Notice of Intent also serves to announce the scoping process which will follow for this EIS. Throughout the scoping process, Federal, State, and local governments, and other interested parties aid the MMS in determining the significant issues and alternatives to be analyzed in the EIS.

Following a decision on Area Identification, the public may present comments and recommendations at scoping meetings which will be held in appropriate locations for the purpose of obtaining additional comments and information regarding the scope of the EIS. In addition, comments and recommendations may be submitted in writing. The times and locations of these scoping meetings and the date scoping comments are due will be announced at a future date in the Federal Register and by press release.

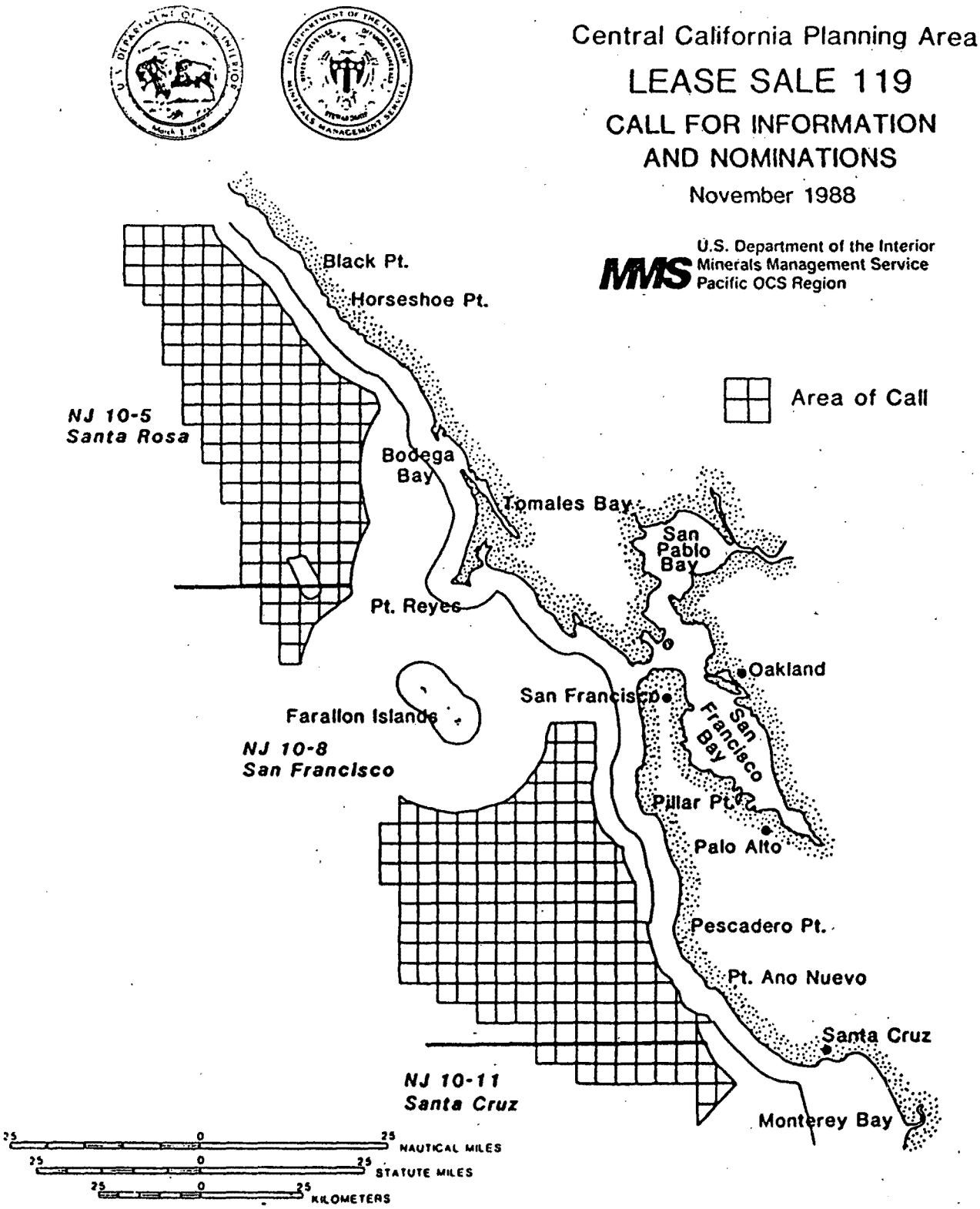
The EIS analysis will focus on the potential environmental effects of leasing, exploration, and development of the blocks included in the area defined in the Area Identification procedure as the proposed area of the Federal action. Alternatives to the proposal which may be considered include cancel the sale and modify the sale.

Robert E. Kallman
Director, Minerals Management Service

Approved:

Deputy James E. Cason
Assistant Secretary - Land and Minerals Management

11/10/88
Date



This map has been carefully prepared from the best existing data sources available at the time of its drafting, but the Minerals Management Service, U.S.D.I. does not guarantee the accuracy and is not responsible or liable for reliance thereon. It is not a legal document for federal leasing purposes nor is it to be used for navigation. Official OCS Leasing Maps and OCS Protraction Diagrams should be consulted for area measurements and locations of individual blocks.

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LIST OF PUBLIC LAWS

Last List November 15, 1988

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 523-6641. The text of laws is not published in the **Federal Register** but may be ordered in individual pamphlet form (referred to as "slip laws") from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone 202-275-3030).

H.R. 593/Pub. L. 100-639

To request the President to award a gold medal on behalf of Congress to Andrew Wyeth, and to provide for the production of bronze duplicates of such medal for sale to the public. (Nov. 9, 1988; 102 Stat. 3331; 2 pages) Price: $1.00

H.R. 1149/Pub. L. 100-640

To amend the Foreign Sovereign Immunities Act with respect to admiralty jurisdiction. (Nov. 9, 1988; 102 Stat. 3333; 2 pages) Price: $1.00

H.R. 3327/Pub. L. 100-641

To designate the Federal building located at 324 West Market Street in Greensboro, North Carolina, as the "L. Richardson Preyer, Jr. Federal Building and United States Courthouse and Post Office." (Nov. 9, 1988; 102 Stat. 3335; 2 pages) Price: $1.00

H.R. 4236/Pub. L. 100-642

To amend the Act of June 6, 1900, to increase the number of trustees of the Frederick Douglass Memorial and Historical Association. (Nov. 9, 1988; 102 Stat. 3337; 1 page) Price: $1.00

H.J. Res. 137/Pub. L. 100-643

Designating the month of May, 1989, as "National Asparagus Month." (Nov. 9, 1988; 102 Stat. 3338; 1 page) Price: $1.00

H.J. Res. 604/Pub. L. 100-644

Designating February 5 through 11, 1989, as "National Burn Awareness Week." (Nov. 9, 1988; 102 Stat. 3339; 1 page) Price: $1.00

H.J. Res. 626/Pub. L. 100-645

Designating September 13, 1989, as "Uncle Sam Day." (Nov. 9, 1988; 102 Stat. 3340; 1 page) Price: $1.00

H.J. Res. 677/Pub. L. 100-646

Changing the date for the counting of the Electoral vote by Congress to January 4, 1989. (Nov. 9, 1988; 102 Stat. 3341; 1 page) Price: $1.00

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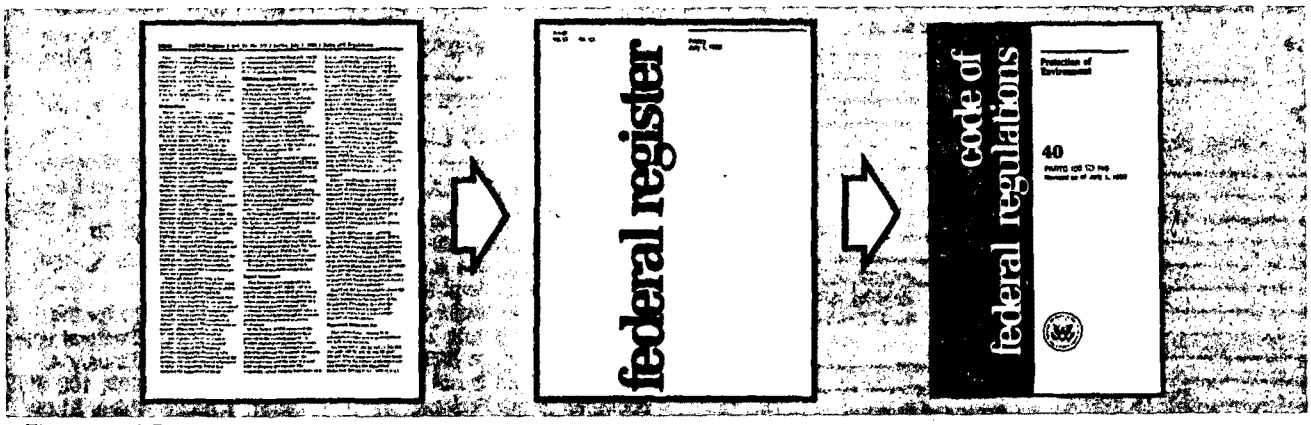

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