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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 74

[Docket No. 00–016–2]

Interstate Movement of Certain Land Tortoises

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are allowing the interstate movement of certain land tortoises if they are accompanied by a health certificate signed by a Federal or accredited veterinarian stating that the tortoises have been examined by that veterinarian and found free of ticks. This action is warranted to enable the export, interstate commerce, health care, and adoption of these types of tortoises while providing protection against the spread of exotic ticks known to be vectors of heartwater disease.

DATES: This interim rule was effective July 17, 2000. We invite you to comment on this docket. We will consider all comments that we receive by September 19, 2000.

ADDRESSES: Please send your comment and three copies to: Docket No. 00–016–2, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Please state that your comment refers to Docket No. 00–016–2.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

FOR FURTHER INFORMATION CONTACT: Dr. D. D. Wilson, Senior Staff Entomologist, Emergency Programs, VS, APHIS, 4700 River Road Unit 41, Riverdale, MD 20737–1231; (301) 734–8073.

SUPPLEMENTARY INFORMATION:

Background

On March 22, 2000, we published in the **Federal Register** (65 FR 15216–15218, Docket No. 00–016–1) an interim rule that prohibits, until further notice, the importation of the following tortoises into the United States: All species and subspecies of leopard tortoise (*Geochelone pardalis*), African spurred tortoise (*Geochelone sulcata*), and Bell's hingeback tortoise (*Kinixys belliana*). The interim rule also prohibits the interstate movement of all species and subspecies of these land tortoises. These prohibitions were established in order to prevent the spread of exotic ticks known to be vectors of heartwater disease, an acute infectious disease of ruminants.

We solicited comments on our interim rule for 60 days, ending May 22, 2000. We received 53 comments by that date. They were from tortoise breeders and owners, representatives of the reptile industry, animal advocacy groups, and other interested individuals. Many commenters supported the prohibition on importation of these tortoises, but most expressed concerns about the effect of prohibiting the interstate movement of these tortoises. Because of the prohibition, these tortoises may not be moved interstate for sale, health care, or adoption. In addition, many domestic tortoise breeders who must move their tortoises interstate prior to exporting them can no longer export these tortoises.

Therefore, based on these comments, we are taking immediate action to amend the regulations at 9 CFR part 74 to allow the interstate movement of leopard tortoise, African spurred tortoise, and Bell's hingeback tortoise if the tortoises are accompanied by a health certificate signed by a Federal or accredited veterinarian stating that the tortoises have been examined by that veterinarian and found free of ticks. The certification will help ensure that the interstate movement of these tortoises will pose no risk of spreading exotic ticks. This action is warranted to enable the export, interstate commerce, health care, and adoption of these types of tortoises while providing protection against the spread of exotic ticks known to be vectors of heartwater disease.

In the future, we will publish another document in the **Federal Register** that addresses all of the issues raised by the commenters.

Immediate Action

The Administrator of the Animal and Plant Health Inspection Service has determined that there is good cause for publishing this interim rule without prior opportunity for public comment. As a result of an interim rule published and effective on March 22, 2000, the importation and interstate movement of leopard tortoise, African spurred tortoise, and Bell's hingeback tortoise has been prohibited. While this action has been effective in preventing the spread of exotic ticks known to be vectors of heartwater disease, it has also resulted in increased health risks for some tortoises that may not be moved interstate for health care or adoption and resulted in financial burdens for owners who have not been able to move to their tortoises interstate sale or for export. The latter problem may also put some tortoises at risk if owners are unable to provide adequate care for those tortoises. This interim rule will allow the interstate movement of leopard tortoise, African spurred tortoise, and Bell's hingeback tortoise if the tortoises are accompanied by a health certificate signed by a Federal or accredited veterinarian stating that the tortoises have been examined by that veterinarian and found free of ticks. Immediate action is warranted to enable the export, interstate commerce, health care, and adoption of leopard tortoise, African spurred tortoise, and Bell's hingeback tortoise.

Because prior notice and other public procedures with respect to this action are impracticable and contrary to the public interest under these conditions, we find good cause under 5 U.S.C. 553

to make this action effective less than 30 days after publication. We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12866 and Regulatory Flexibility Act

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

We are allowing the interstate movement of certain land tortoises if they are accompanied by a health certificate signed by a Federal or accredited veterinarian stating that the tortoises have been examined by that veterinarian and found free of ticks. This action is warranted to enable the export, interstate commerce, health care, and adoption of these types of tortoises.

The United States accounts for about 80 percent of the world's live reptile trade. In 1998, a total of 1,921,272 reptiles were imported, valued at approximately $6.37 million. Of these, turtles, including tortoises, accounted for about 26.5 percent of imports. Three states, California (48 percent), Florida (33.2 percent), and Louisiana (11.7 percent), accounted for nearly 93 percent of turtle imports.

The United States exports about 9 million live reptiles annually. Red-eared slider turtles make up about 85 percent of these exports every year. South Korea, Japan, and European countries are the major importers of U.S. turtles. However, Canada appears to be the major importer of leopard tortoise, African spurred tortoise, and Bell's hingeback tortoise. In 1995, the United States exported to Canada 32 leopard tortoises, 527 African spurred tortoises, and 2,332 Bell's hingeback tortoises. During the same year, U.S. imports of these species were 2,683, 1,223 and 952, respectively.

In 1996, between 1.5 million and 2.5 million households in the United States owned various reptiles as pets. Of these, about 534,000 households, or about 35 percent, owned a total of 950,000 turtles, including tortoises. Overall, turtles represented about 27 percent of the total reptile pet population. The prices paid for turtles ranged between $25 and $750, depending on species, size, and age. Between 1993 and 1996, the average price in the United States for a leopard tortoise was $190, for an African spurred tortoise $578, and for a Bell's hingeback tortoise $35.

This rule will positively affect individuals involved in the interstate movement of leopard tortoises, African spurred tortoises, and Bell's hingeback tortoises. This rule will require persons wishing to move these tortoises interstate to acquire a health certificate from a Federal or accredited veterinarian. This will cost about $16 to $25 dollars per health certificate. These costs are small when compared to the potential losses in revenue and animals that may result from continuing to prohibit the interstate movement of these species of tortoises. Another benefit for U.S. exporters of these tortoises is that a health certificate will help ensure the acceptability of these animals in international markets and prevent the spread of exotic ticks known to be vectors of heartwater disease.

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

Executive Order 12372

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

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection and recordkeeping requirements included in this interim rule have been submitted for emergency approval to the Office of Management and Budget (OMB). OMB has assigned control number 0579–0156 to the information collection and recordkeeping requirements.

We plan to request continuation of that approval for 3 years. Please send written comments on the 3-year approval request to the following addresses: (1) Docket No. 00–016–2, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue, SW., Washington, DC 20250. Please state that your comments refer to Docket No. 00–016–2 and send your comments within 60 days of publication of this rule.

This interim rule requires that, prior to interstate movement of certain land tortoises, a Federal or accredited veterinarian must sign a health certificate stating that the tortoises have been examined by that veterinarian and found free of ticks. The health certificate must accompany the tortoises during interstate movement. This certification will help ensure that the interstate movement of these tortoises will pose no risk of spreading exotic ticks. We are soliciting comments from the public concerning our information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.083 hours per response.

Respondents: Tortoise breeders and owners, and members of tortoise adoption organizations, in the United States.

Estimated annual number of respondents: 150.

Estimated annual number of responses per respondent: 6.

Estimated annual number of responses: 900.

Estimated total annual burden on respondents: 75 hours.

Copies of this information collection can be obtained from Ms. Cheryl Groves, APHIS' Information Collection Coordinator, at (301) 734–5086.

List of Subjects in 9 CFR Part 74

Animal diseases, Livestock, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, we are revising 9 CFR part 74 to read as follows:

PART 74—PROHIBITION OF INTERSTATE MOVEMENT OF LAND TORTOISES

Sec.
74.1 General prohibition.

Authority: 21 U.S.C. 111–113, 114a, 115, 117, 120, 122–126, 134b, 134f; 7 CFR 2.22, 2.80, and 371.2(d).

§ 74.1 General prohibition.

The interstate movement of leopard tortoise (*Geochelone pardalis*), African spurred tortoise (*Geochelone sulcata*), and Bell's hingeback tortoise (*Kinixys belliana*) is prohibited except when tortoises are accompanied by a health certificate signed by a Federal or accredited veterinarian stating that the tortoises have been examined by that veterinarian and found free of ticks.

Done in Washington, DC, this 17th day of July 2000.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 00–18566 Filed 7–20–00; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–210–AD; Amendment 39–11824; AD 2000–14–14]

RIN 2120–AA64

Airworthiness Directives; BFGoodrich Main Brake Assemblies as Installed on Airbus Model A319 and A320 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to certain BFGoodrich main brake assemblies as installed on Airbus Model A319 and A320 series airplanes. This action requires repetitive inspections to determine the length of the wear indicator pins of the main brake assemblies of the main landing gear (MLG); follow-on inspections; and corrective actions, if necessary. This amendment is prompted by reports from several operators that severe oxidation was found on the rotor disk assemblies of the main brake assemblies. This action is necessary to detect and correct thermal oxidation of the main brake assemblies, which could result in deterioration of the MLG brakes, and consequent reduced braking performance.

DATES: Effective August 7, 2000.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the **Federal Register** as of August 7, 2000.

Comments for inclusion in the Rules Docket must be received on or before August 21, 2000.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–210–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: 9-anm-iarcomment@faa.gov. Comments sent via the Internet must contain ''Docket No. 2000–NM–210–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in this AD may be obtained from BFGoodrich Aerospace Wheel & Brake Systems Division, P.O. Box 340, Troy, Ohio, 45373. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: On November 24, 1999, the FAA issued AD 99–25–07, amendment 39–11450 (64 FR 68620, December 8, 1999), which is applicable to certain BFGoodrich main brake assemblies having part number (P/N) 2–1598 or P/N 2–1600 as installed on Airbus Model A319 and A320 series airplanes. That AD requires a one-time inspection of the wear indicator pins to determine the level of wear of the main brake assemblies of the main landing gear (MLG), and corrective actions, if necessary. That AD also requires modification of the main brake assemblies of the MLG to shorten the wear indicator pins, and change P/N 2–1598 to P/N 2–1598–1 or change P/N 2–1600 to P/N 2–1600–1. In addition, that AD requires incorporation of specified wear limits into the maintenance inspection program.

Since the issuance of AD 99–25–07, the FAA has received reports from several operators of severe oxidation on the carbon heat sinks used on BFGoodrich main brake assemblies, P/N 2–1598–1 and P/N 2–1600–1, installed on Airbus Model A319 and A320 series airplanes. Those reports indicate that the accomplishment of AD 99–25–07 did not adequately address the problem of oxidation on the main brake assemblies in time to correct the identified unsafe condition. Investigation has revealed that deterioration of the BFGoodrich main brake assemblies was caused by thermal oxidation of the carbon material on the heat sinks used in the main brake assemblies, P/N 2–1598–1 and P/N 2–1600–1, due to exposure to elevated temperatures for prolonged periods of time.

Further investigation revealed that the oxidation inhibitor process used by BFGoodrich does not completely prevent oxidation of the carbon brake material. BFGoodrich advises that the carbon brakes, which are susceptible to this oxidation condition, are used only on Airbus Model A319 and A320 series airplanes. Such oxidation first develops on the inner diameter of the rotor disk assemblies when the brake assembly is almost worn-to-limit. This condition, if not corrected, could result in deterioration of the MLG brakes, and consequent reduced braking performance.

Explanation of Relevant Service Information

BFGoodrich has issued Service Bulletins 2–1598–32–2 and 2–1600–32–3, both dated June 16, 2000, which describe procedures for an initial inspection to determine the length of the wear indicator pins of the MLG main brake assemblies and repetitive inspections thereafter at certain intervals. Procedures include follow-on inspections if the length of either wear indicator pin measures between 0.60 and 0.70 inches, or if the length of the pin measures between 0.20 and 0.30 inches; and corrective actions, if necessary. Follow-on inspections

include inspecting the rotor disks located in the center of the heat sinks of the main brake assemblies of the MLG to detect the level of oxidation on the brake assemblies. Corrective actions include replacement of the main brake assembly with a new assembly if any oxidation exceeding the limits specified in the applicable service bulletin is detected. Following such replacement, repetitive inspections of the wear indicator pins are continued.

FAA's Conclusions

These airplane models are manufactured in France and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement.

Explanation of Requirements of Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, this AD is being issued to detect and correct thermal oxidation of the main brake assemblies, which could result in deterioration of the MLG brakes, and consequent reduced braking performance. This AD requires repetitive inspections to determine the length of the wear indicator pins of each main brake assembly of the MLG; follow-on inspections; and corrective actions, if necessary. The actions are required to be accomplished in accordance with the applicable service bulletin described previously, except as discussed below.

Differences Between AD and Service Information

Operators should note that the previously referenced BFGoodrich service bulletins recommend accomplishment of an initial inspection on all MLG brake assemblies to determine the length of the wear indicator pins ''as soon as possible.'' However, the FAA finds that a definitive compliance time is necessary. Therefore, paragraph (a) of this AD requires the accomplishment of the repetitive inspections within 10 days after the effective date of this AD, or within 500 flight cycles after replacement of any brake assembly, whichever occurs later. The FAA considers that such a compliance time represents an appropriate interval of time allowable for affected airplanes to continue to operate without compromising safety.

Operators should note that the previously referenced service bulletins include procedures for a one-time inspection on all brakes when any wear indicator pin measures between 0.60 to 0.70 inches, and another such inspection when any pin measures between 0.20 to 0.30 inches. However, the FAA has determined that it is necessary to change those wear indicator pin measurements in this AD to ensure that all brakes are inspected at appropriate intervals. Paragraph (b) of this AD requires a one-time inspection of the brake if either wear indicator pin measures between 0.31 and 0.70 inches, and paragraph (c) of this AD requires an inspection of the brake if either wear indicator pin measures 0.30 inches or less. In the event that the special detailed inspection required by paragraph (c) of this AD is accomplished prior to paragraph (b) of this AD, the inspection required by paragraph (b) of this AD is deemed unnecessary.

Interim Action

This is considered to be interim action. The brake manufacturer has advised that it currently is developing a modification that will positively address the unsafe condition addressed by this AD. Once this modification is developed, approved, and available, the FAA may consider additional rulemaking.

Determination of Rule's Effective Date

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

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES.** All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the AD is being requested.
- Include justification (*e.g.,* reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2000–NM–210–AD.'' The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2000–14–14 BFGoodrich: Amendment 39–11824. Docket 2000–NM–210–AD.

Applicability: Model BFGoodrich main brake assemblies having part number (P/N) 2–1598–1 or P/N 2–1600–1, as installed on Airbus Model A319 and A320 series airplanes, certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To detect and correct thermal oxidation of the main brake assemblies, which could result in deterioration of the main landing gear (MLG) brakes, and consequent reduced braking performance, accomplish the following:

Initial and Repetitive Inspections

(a) Within 10 days after the effective date of this AD, or within 500 flight cycles after replacement of any brake assembly, whichever occurs later: Perform an inspection to determine the length of the wear indicator pins of each main brake assembly of the MLG, in accordance with the Accomplishment Instructions of BFGoodrich Service Bulletin 2–1598–32–2 or 2–1600–32–3, both dated June 16, 2000, as applicable. Repeat the inspection thereafter for each brake assembly as specified by paragraph (a)(1), (a)(2), (a)(3), or (a)(4), as applicable.

(1) If the length of both wear indicator pins is greater than 2.00 inches, repeat the inspection thereafter at intervals not to exceed 500 flight cycles.

(2) If the length of the shortest wear indicator pin is between 2.00 and 1.50 inches, repeat the inspection thereafter at intervals not to exceed 250 flight cycles.

(3) If the length of the shortest wear indicator pin is between 1.49 and 1.0 inches, repeat the inspection thereafter at intervals not to exceed 100 flight cycles.

(4) If the length of the shortest wear indicator pin is between 0.31 and 0.99 inches, repeat the inspection thereafter at intervals not to exceed 10 days.

(5) If the length of the shortest wear indicator pin is less than 0.31 inches, no further action is required by this paragraph until the brake is replaced.

Follow-on Inspections and Corrective Actions

(b) During any inspection required by paragraph (a) of this AD, if the length of the shortest wear indicator pin measures between 0.31 and 0.70 inches: Prior to further flight, perform a one-time special detailed inspection of the rotor disks located in the center of the heat sinks of the main brake assemblies of the MLG to detect the level of oxidation on the main brake assemblies in accordance with the Accomplishment Instructions of BFGoodrich Service Bulletin 2–1598–32–2 or 2–1600–32–3, both dated June 16, 2000, as applicable. The inspection required by this paragraph is required only the first time the length of the shortest wear indicator pin measures between 0.31 and 0.70 inches.

(1) If no oxidation is detected, or if oxidation within the limits specified in the applicable service bulletin is detected on any brake assembly, continue the inspections required by paragraph (a) of this AD.

(2) If any oxidation exceeding the limits specified in the applicable service bulletin is detected on any brake assembly, prior to further flight, replace the brake assembly with a new brake assembly in accordance with the applicable service bulletin. Within 500 flight cycles following such replacement, continue the inspections required by paragraph (a) of this AD.

Note 2: For the purposes of this AD, a special detailed inspection is defined as: ''An intensive examination of a specific item(s), installation, or assembly to detect damage, failure, or irregularity. The examination is likely to make extensive use of specialized inspection techniques and/or equipment. Intricate cleaning and substantial access or disassembly procedures may be required.''

(c) During any inspection required by paragraph (a) of this AD, if the length of the shortest wear indicator pin measures 0.30 inches or less: Prior to further flight, perform a one-time special detailed inspection of the rotor disks located in the center of the heat sinks of the main brake assemblies of the MLG to detect the level of oxidation on the main brake assemblies in accordance with the Accomplishment Instructions of BFGoodrich Service Bulletin 2–1598–32–2 or 2–1600–32–3, both dated June 16, 2000, as applicable. The inspection required by this paragraph is required only the first time the length of the shortest wear indicator pin measures 0.30 inches or less.

(1) If no oxidation is detected, or if oxidation within the limits specified in the applicable service bulletin is detected on any brake assembly, no further action is required by this AD until the brake is replaced in accordance with the FAA-approved maintenance program. Within 500 flight cycles following such replacement, continue the inspections required by paragraph (a) of this AD.

(2) If any oxidation exceeding the limits specified in the applicable service bulletin is detected on any brake assembly, prior to further flight, replace the brake assembly with a new brake assembly in accordance with the applicable service bulletin. Within 500 flight cycles following such replacement, continue the inspections required by paragraph (a) of this AD.

Spares

(d) As of the effective date of this AD, no person shall install on any airplane a BFGoodrich main brake assembly having P/N 2–1598–1 or P/N 2–1600–1 if the wear indicator pin measures 0.70 inches or less, unless an inspection to detect oxidation of the brake assembly has been accomplished in accordance with paragraph 3.A.(3) of the Accomplishment Instructions of BFGoodrich Service Bulletin 2–1598–32–2 or 2–1600–32–3, both dated June 16, 2000, as applicable.

Alternative Methods of Compliance

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

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

Incorporation by Reference

(g) Except as provided by paragraph (c)(1) of this AD, the inspections and replacement actions shall be done in accordance with BFGoodrich Service Bulletin 2–1598–32–2, dated June 16, 2000, or BFGoodrich Service Bulletin 2–1600–32–3, dated June 16, 2000; as applicable. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from BFGoodrich Aerospace Wheel & Brake Systems Division, P.O. Box 340, Troy, Ohio, 45373. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal

Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(h) This amendment becomes effective on August 7, 2000.

Issued in Renton, Washington, on July 13, 2000.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–18281 Filed 7–20–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 98F–0165]

Irradiation in the Production, Processing and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ionizing radiation for the reduction of *Salmonella* in fresh shell eggs. This action is in response to a petition filed by Edward S. Josephson.

DATES: This rule is effective July 21, 2000. Submit written objections and requests for a hearing by August 21, 2000.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: William J. Trotter, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3088.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of March 20, 1998 (63 FR 13675), FDA announced that a food additive petition (FAP 8M4584) had been filed by Edward S. Josephson, University of Rhode Island, Food Science and Nutrition Research Center, 530 Liberty Lane, West Kingston, RI 02892–1802. The petitioner proposed that the food additive regulations in part 179 Irradiation in the Production, Processing and Handling of Food (21 CFR part 179) be amended to provide for the safe use of ionizing radiation for the reduction of *Salmonella* in fresh shell eggs.

II. Safety Evaluation

Under section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s)), a source of radiation used to treat food is defined as a food additive. The additive is not, literally, added to food. Instead, a source of radiation is used to process or treat food such that, analogous to other food processes, its use can affect the characteristics of the food. In the subject petition, the intended technical effect is a change in the microbial load of the food, specifically, a reduction in the numbers of *Salmonella*, a human pathogen, in or on fresh shell eggs.

The petitioner submitted published articles and other study reports containing data and information related to eggs and other kinds of food in the areas of radiation chemistry, nutrition, toxicology, and microbiology. FDA has fully considered the data and studies submitted in the petition, as well as other information in its files relevant to the safety and nutritional adequacy of eggs treated with ionizing radiation.

The effects of ionizing radiation on the characteristics of treated foods are a direct result of the chemical reactions induced by the absorbed radiation. Scientists have compiled a large body of data regarding the effects of ionizing radiation on different foods under various conditions of irradiation. Research has established that the types and amounts of products generated by radiation-induced chemical reactions (hereinafter referred to as ''radiolysis products'') depend on the chemical constituents of the food and on the conditions of irradiation (e.g., temperature and presence or absence of air and moisture). Furthermore, the principles of radiation chemistry govern the extent of changes both in the nutrient levels and in the microbial load of irradiated foods. Key factors include the specific nutrient or microorganism of interest, the food, and the conditions of irradiation. (See the agency's final rule permitting the irradiation of meat (the meat final rule) in the **Federal Register** of December 3, 1997 (62 FR 64107) for FDA's discussion of radiation chemistry, nutrition, toxicology, and microbiology related to irradiation of foods composed primarily of water, protein, and lipids under various conditions of irradiation.)

FDA has reviewed the relevant data and information submitted in the petition regarding the radiation chemistry of fresh shell eggs, and data available in the agency's files. Fresh whole eggs are composed mainly of water (75.3 percent), protein (12.5 percent), and lipid (10.0 percent) (Ref. 1). As discussed in the meat final rule, the radiation chemistry associated with these types of compounds is well known. FDA has concluded that the concentrations and types of radiolysis products formed by the irradiation of eggs will be comparable to those products produced by the irradiation of other foods of similar composition, such as meat (Ref. 2). In addition, the petitioner's data support the conclusion that there is little change in the levels of individual fatty acids, or in the structure, digestibility, or biological value of protein, when shell eggs are treated with ionizing radiation up to 3 kiloGray (kGy) (Refs. 2 and 3). Most of the radiolysis products are either the same as, or structurally similar to, compounds found in foods that have not been irradiated, and are formed in very small amounts. In summary, an absorbed dose of 3 kGy for the irradiation of fresh shell eggs will result in only minimal changes in the macronutrients (protein, lipid, or carbohydrate), and the chemical composition of eggs will not differ in any significant manner from eggs that have not been irradiated.

The petitioner submitted studies and published reports relevant to the safety of irradiated foods, in general. In addition, a variety of irradiated foods including: Red meat, chicken, fish, and eggs, have been tested in earlier animal feeding studies and genotoxicity studies; and they were previously reviewed by FDA (see, *e.g.,* 62 FR 64107, December 3, 1997). Included in the information considered by FDA in the review of this petition are three studies conducted specifically on irradiated eggs (Ref. 4). In the first such study, rats were fed a biscuit diet containing whole eggs irradiated at 5 kGy at a dietary level of 25 percent on a dry weight basis for 3 years (two generations). No adverse effects were observed compared to the control group fed a diet containing nonirradiated eggs. In the second study, mice and rats were fed a diet containing dried eggs irradiated at 93 kGy and irradiated pork brain. No effects were observed that were attributed to the irradiated food. In the third study, rats were fed canned eggs irradiated at 5 kGy in their diet for two generations. No effects were observed that were attributed to the irradiated diet. Taken as a whole, based on the totality of evidence from all evaluated data and studies, FDA concludes that the petitioned use of

irradiation on fresh shell eggs raises no toxicity concerns (Refs. 4 and 5).

FDA also evaluated the effects of irradiation processing on micronutrients (*e.g.,* minerals, water-soluble vitamins, and fat-soluble vitamins). Minerals are unaffected by irradiation, but the levels of some vitamins may be reduced as a result of irradiation. For example, vitamin A levels did decrease with an increasing radiation dose. Not all vitamin loss is significant, however. The extent to which a reduction in a specific vitamin level is significant depends on the relative contribution from the food in question to the dietary intake of the vitamin and the overall sufficiency of the vitamin in the diet. Based upon data in the agency's files, FDA concludes that the intake of vitamins from other foods compensates for the vitamin loss from the irradiation of eggs (Refs. 4 and 5). For example, a fresh unirradiated egg contains approximately 95 retinol equivalents (RE) of Vitamin A (Ref. 4). In a study, shell eggs irradiated at 1.0 kGy and stored for 24 days contained approximately 72 RE's (Ref. 3). In comparison, 1 tablespoon of butter contains 108 RE's, one-half cup of bran cereal contains 258 RE's, and one-half cup of canned carrots contains 1,620 RE's of vitamin A (Ref. 4). FDA, therefore, concludes, based upon all the evidence before it, that irradiation of fresh shell eggs under the conditions set forth in the regulation below will not have an adverse impact on the nutritional adequacy of a person's diet.

Increased irradiation levels can also cause organoleptic changes in the egg. For example, data in the petition showed an increased color loss in the irradiated egg yolk and a change in the egg's viscosity as the radiation dose was increased. Thus, FDA expects that the acceptability of irradiated shell eggs, based on their color and viscosity, will limit, in a practical way, the maximum dose of irradiation applied to fresh shell eggs. Therefore, FDA has determined that there is no need to limit the irradiation level based on changes in micronutrient levels or organoleptic characteristics of the eggs.

Irradiation of fresh shell eggs at the doses requested in the petition will reduce, but not entirely eliminate, microorganisms in eggs. The stated purpose of this petition is for approval of radiation of fresh shell eggs to reduce the number of *Salmonella*. The data show that low dose irradiation in the range requested by the petitioner can reduce the levels of *S. enteritidis* in fresh shell eggs (Ref. 6). *Salmonella* strains, in addition to *S. enteritidis*, in fresh shell eggs should also be reduced by irradiation since *S. enteritidis* was found to have similar sensitivities to ionizing radiation as five other strains of *Salmonella* that were tested in various media (Ref. 7).

Based on the data and studies submitted in the petition and other information in the agency's files, FDA concludes that: (1) The proposed use of irradiation on fresh shell eggs at levels not to exceed 3.0 kGy is safe, (2) the irradiation can achieve its intended technical effect and, therefore, (3) the regulations in § 179.26 (21 CFR 179.26) should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the filing notice for FAP 8M4584 (63 FR 13675, March 20, 1998). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

IV. Objections

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by August 21, 2000. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. References

The following references have been placed on display at the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Nutrient Data Laboratory Food Composition Data, USDA Agricultural Research Service, available at Internet address: http://www.nal.usda.gov/fnic/foodcomp.

2. Memorandum from K. Morehouse, FDA, to W. Trotter, FDA, May 14, 1999.

3. Memorandum from K. Morehouse, FDA, to W. Trotter, FDA, April 11, 2000.

4. Memorandum from I. Chen, FDA, to W. J. Trotter, FDA, December 11, 1998.

5. Memorandum from I. Chen, FDA, to W. J. Trotter, FDA, March 31, 2000.

6. Memorandum from V. K. Bunning, FDA, to W. J. Trotter, FDA, April 4, 2000.

7. Thayer, D.W., et al., ''Radiation Resistance of *Salmonella*,'' *Journal of Industrial Microbiology*, 5:383–390, 1990.

List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 179 is amended as follows:

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

1. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

2. Section 179.26 is amended in the table in paragraph (b) by adding entry ''9.'' under the headings ''Use'' and ''Limitations'' to read as follows:

§ 179.26 Ionizing radiation for the treatment of food.

* * * * *

(b) * * *

Use	Limitations
* * * * * * *	
9. For control of *Salmonella* in fresh shell eggs.	Not to exceed 3.0 kGy.

* * * * *

Dated: July 14, 2000.

L. Robert Lake,

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–18496 Filed 7–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Selamectin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for topical veterinary prescription use of selamectin solution for the additional indication for control of intestinal hookworm and roundworm infections in cats.

DATES: This rule is effective July 21, 2000.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, filed supplemental NADA 141–152 that provides for topical veterinary prescription use of Revolution™ (selamectin) in dogs and cats for the additional indication for control of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in cats. The supplemental NADA is approved as of June 13, 2000, and the regulations are amended in 21 CFR 524.2098 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning June 13, 2000, because the application contains substantial evidence of effectiveness of the drug involved or any studies of animal safety required for approval of the application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(d)(1) 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

Authority: 21 U.S.C. 360b.

2. Section 524.2098 is amended by revising the third sentence in paragraph (d)(2) to read as follows:

§ 524.2098 Selamectin.

* * * * *

(d) * * *

(2) * * * Treatment and control of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in cats. * * *

* * * * *

Dated: July 3, 2000.

David R. Newkirk,

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

[FR Doc. 00–18458 Filed 7–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF STATE

Bureau of Political-Military Affairs

22 CFR Parts 124, 125 126

[Public Notice 3365]

Amendments to the International Traffic in Arms Regulation: NATO Countries, Australia and Japan

AGENCY: Bureau of Political-Military Affairs, Department of State.

ACTION: Final rule.

SUMMARY: This rule amends the International Traffic In Arms Regulations to implement reforms announced by the Secretary of State at the NATO Ministerial in Florence, Italy on May 24, 2000. The reforms of the U.S. export controls system are available to NATO Allies, Japan and Australia and are intended to streamline the U.S. defense export control licensing process and forge closer industrial linkage between the U.S. and allied defense suppliers. It is contemplated that it will increase our mutual security by enhancing NATO member defense capabilities, promoting interoperability with our allies and friends and promoting trans-Atlantic defense industrial cooperation. Part 124 of the International Traffic In Arms Regulations is being amended to permit U.S. companies to perform, using an exemption, certain maintenance and maintenance training for NATO government, Australia and Japan on US-origin inventoried defense articles. Part 125 is amended to provide authorization, without a license, to transfer technical data to support procurement of defense articles from defense firms in NATO countries,

Australia and Japan for use in the United States. This amendment also establishes four comprehensive export authorizations for use in circumstances where the full parameters of a commercial export endeavor, including the needed defense exports, can be well anticipated and described in advance.

EFFECTIVE DATE: September 1, 2000.

FOR FURTHER INFORMATION CONTACT: Rose Biancaniello, Office of Defense Trade Controls, Bureau of Political-Military Affairs, Department of State ATTN: Regulatory Change NATO, Australia and Japan at (202) 663–2862 or FAX (202) 261–8264.

SUPPLEMENTARY INFORMATION: In implementing the Secretary of State's announcement at the NATO Ministerial, May 24, 2000, in Florence, Italy, the International Traffic In Arms Regulations is being amended. Section 124.2 is amended to add a new paragraph (c) to permit U.S. companies to provide, without a license, defense services necessary to perform maintenance on and maintenance training for inventoried US-origin equipment of NATO countries, Australia and Japan, provided the maintenance and maintenance training does not result in any modification, enhancement, upgrade or other form of alteration or improvement that enhances the performance or capability of the defense article. Also, the export must not include the transfer of certain technologies; such as, design methodology, engineering analysis and manufacturing know-how. Section 125.4 is amended to add a new paragraph (c) to permit the transfer of technical data to NATO countries, Australia and Japan of technical data necessary to support offshore procurement of defense articles for use in the United States. In addition, Part 126 is amended to add, in § 126.9, a new paragraph (b) and a new § 126.14. These additions are being made to create four new comprehensive authorizations developed to limit the number of export approvals necessary to authorize the export of U.S. technology to NATO countries, Australia and Japan that will encourage government-to-government cooperative research and development, support joint ventures and teaming arrangements and facilitate a U.S. company's role in a cooperative project when covered by a government-to-government Memorandum of Understanding (MOU).

In implementing these initiatives, Part 124, 125, and 126 are being amended.

This amendment involves a foreign affairs function of the United States and therefore, is not subject to the procedures required by 5 U.S.C. 553 and 554. It is exempt from review under Executive Order 12866 but has been reviewed internally by the Department of State to ensure consistency with the purposes thereof. This rule does not require analysis under the Regulatory Flexibility Act or the Unfunded Mandates Reform Act. It has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Act of 1966. It will not have substantial direct effects on the States, the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with § 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant application of Executive Order Nos. 12372 and 13123. However, interested parties are invited to submit written comments to the Department of State, Office of Defense Trade Controls, ATTN: Regulatory Change, NATO, Australia and Japan, 13th Floor, H1304, 2401 E Street, NW., Washington, DC 20037. Such persons must be so registered with the Department of State's Office of Defense Trade Controls (DTC) pursuant to the registration requirements of § 38 of the Arms Export Control Act.

List of Subjects

22 CFR Part 124

Arms and munitions, Exports, Technical assistance.

22 CFR Part 125

Arms and munitions, Exports.

22 CFR Part 126

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, Part 124, 125 and 126, are being amended as follows:

PART 124—AGREEMENTS, OFF-SHORE PROCUREMENT AND OTHER DEFENSE SERVICES

1. The authority citation for part 124 continues to read as follows:

Authority: Sec. 2, 38, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); E.O. 11958, 42 FR 4311, 3 CFR 1977 Comp. p. 79; 22 U.S.C. 2658; Pub L. 105–261.

2. Section 124.2 is amended by adding paragraph (c) to read as follows:

§ 124.2 Exemptions for training and military service.

* * * * *

(c) NATO countries, Australia and Japan, in addition to the basic maintenance training exemption provided in § 124.2(a) and basic maintenance information exemption in § 125.4(b)(5), no technical assistance agreement is required for maintenance training or the performance of maintenance, including the export of supporting technical data, when the following criteria can be met:

(1) Defense services are for unclassified U.S.-origin defense articles lawfully exported or authorized for export and owned or operated by and in the inventory of NATO or the Federal Governments of NATO countries, Australia or Japan;

(2) This defense service exemption does not apply to any transaction involving defense services for which congressional notification is required in accordance with § 123.15 and § 124.11 of this subchapter.

(3) Maintenance training or the performance of maintenance must be limited to inspection, testing, calibration or repair, including overhaul, reconditioning and one-to-one replacement of any defective items, parts or components; and excluding any modification, enhancement, upgrade or other form of alteration or improvement that enhances the performance or capability of the defense article. This does not preclude maintenance training or the performance of maintenance that would result in enhancements or improvements only in the reliability or maintainability of the defense article, such as an increased mean time between failure (MTBF).

(4) Supporting technical data must be unclassified and must not include software documentation on the design or details of the computer software, software source code, design methodology, engineering analysis or manufacturing know-how such as that described in paragraphs (c)4)(i) through (c)(4)(iii) as follows:

(i) *Design Methodology,* such as: The underlying engineering methods and design philosophy utilized (*i.e.,* the ''why'' or information that explains the rationale for particular design decision, engineering feature, or performance requirement); engineering experience (*e.g.* lessons learned); and the rationale and associated databases (*e.g.* design allowables, factors of safety, component life predictions, failure analysis criteria) that establish the operational requirements (*e.g.,* performance, mechanical, electrical, electronic, reliability and maintainability) of a defense article.

(ii) *Engineering Analysis,* such as: Analytical methods and tools used to design or evaluate a defense article's performance against the operational requirements. Analytical methods and

tools include the development and/or use of mockups, computer models and simulations, and test facilities.

(iii) *Manufacturing Know-how,* such as: Information that provides detailed manufacturing processes and techniques needed to translate a detailed design into a qualified, finished defense article.

(5) This defense service exemption does not apply to maintenance training or the performance of maintenance and service or the transfer of supporting technical data for the following defense articles:

(i) All Missile Technology Control Regime Annex Items;

(ii) Firearms listed in Category I; and ammunition listed in Category III for the firearms in Category I;

(iii) Nuclear weapons strategic delivery systems and all components, parts, accessories and attachments specifically designed for such systems and associated equipment;

(iv) Naval nuclear propulsion equipment listed in Category VI(e);

(v) Gas turbine engine hot sections covered by Categories VI(f) and VIII(b);

(vi) Category VIII(f);

(vii) Category XII(c);

(viii) Chemical agents listed in Category XIV (a), biological agents in Category XIV (b), and equipment listed in Category XIV (c) for dissemination of the chemical agents and biological agents listed in Categories XIV (a) and (b);

(ix) Nuclear radiation measuring devices manufactured to military specifications listed in Category XIV(d);

(x) Category XV;

(xi) Nuclear weapons design and test equipment listed in Category XVI;

(xii) Submersible and oceanographic vessels and related articles listed in Category XX(a) through (d);

(xiii) Miscellaneous articles covered by Category XXI.

(6) *Eligibility Criteria for Foreign Persons.* Foreign persons eligible to receive technical data or maintenance training under this exemption are limited to nationals of the NATO countries, Australia or Japan.

PART 125—LICENSES FOR THE EXPORT OF TECHNICAL DATA AND CLASSFIED DEFENSE ARTICLES

3. The authority citation for part 125 continues to read as follows:

Authority: Sections 2 and 38, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778); E.O. 11958, 42 FR 4311, 3 CFR, 1977 Comp. p. 79; 22 U.S.C. 2658.

4. Section 125.4 is amended by revising paragraph (a) and by adding paragraph (c) to read as follows:

§ 125.4 Exemptions of general applicability.

(a) The following exemptions apply to exports of technical data for which approval is not needed from the Office of Defense Trade Controls. These exemptions, except for paragraph (b)(13) of this section, do not apply to exports to proscribed destinations under § 126.1 of this subchapter or for persons considered generally ineligible under § 120.1(c) of this subchapter. The exemptions are also not applicable for purposes of establishing offshore procurement arrangements or producing defense articles offshore (see § 124.13), except as authorized under § 125.4 (c). If § 126.8 of this subchapter requirements are applicable, they must be met before an exemption under this section may be used. Transmission of classified information must comply with the requirements of the National Industrial Security Program Operating Manual and the exporter must certify to the transmittal authority that the technical data does not exceed the technical limitation of the authorized export.

(b) * * *

(c) Defense services and related unclassified technical data are exempt from the licensing requirements of this subchapter, to nationals of NATO countries, Australia and Japan, for the purposes of responding to a written request from the Department of Defense for a quote or bid proposal. Such exports must be pursuant to an official written request or directive from an authorized official of the U.S. Department of Defense. The defense services and technical data are limited to those listed in paragraphs (c)(1), (c)(2), and (c)(3) and must not include those listed in paragraphs (c)(4), (c)(5), and (c)(6) which follow:

(1) *Build-to-Print.* ''Build-to-Print'' means that a foreign consignee can produce a defense article from engineering drawings without any technical assistance from a U.S. exporter. This transaction is based strictly on a ''hands-off'' approach since the foreign consignee is understood to have the inherent capability to produce the defense article and only lacks the necessary drawings. Supporting documentation such as acceptance criteria, and specifications, may be released on an as-required basis (*i.e.* ''must have'') such that the foreign consignee would not be able to produce an acceptable defense article without this additional supporting documentation. Documentation which is not absolutely necessary to permit manufacture of an acceptable defense article (*i.e.* ''nice to have'') is not considered within the boundaries of a ''Build-to-Print'' data package;

(2) *Build/Design-to-Specification.* ''Build/Design-to-Specification'' means that a foreign consignee can design and produce a defense article from requirement specifications without any technical assistance from the U.S. exporter. This transaction is based strictly on a ''hands-off'' approach since the foreign consignee is understood to have the inherent capability to both design and produce the defense article and only lacks the necessary requirement information;

(3) *Basic Research.* ''Basic Research'' means a systemic study directed toward greater knowledge or understanding of the fundamental aspects of phenomena and observable facts without specific applications towards processes or products in mind. It does not include ''Applied Research'' (*i.e.* a systemic study to gain knowledge or understanding necessary to determine the means by which a recognized and specific need may be met. It is a systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.);

(4) *Design Methodology,* such as: The underlying engineering methods and design philosophy utilized (*i.e.*, the ''why'' or information that explains the rationale for particular design decision, engineering feature, or performance requirement); engineering experience (*e.g.* lessons learned); and the rationale and associated databases (*e.g.* design allowables, factors of safety, component life predictions, failure analysis criteria) that establish the operational requirements (*e.g.*, performance, mechanical, electrical, electronic, reliability and maintainability) of a defense article. (Final analytical results and the initial conditions and parameters may be provided.)

(5) *Engineering Analysis*, such as: Analytical methods and tools used to design or evaluate a defense article's performance against the operational requirements. Analytical methods and tools include the development and/or use of mockups, computer models and simulations, and test facilities. (Final analytical results and the initial conditions and parameters may be provided.)

(6) *Manufacturing Know-how*, such as: information that provides detailed manufacturing processes and techniques needed to translate a detailed design into a qualified, finished defense article. (Information may be provided in a

build-to-print package that is necessary in order to produce an acceptable defense article.)

PART 126—GENERAL POLICIES AND PROVISIONS

5. The authority citation for Part 126 continues to read as follows:

Authority: Secs. 2, 38, 40, 42, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2780, 2791, and 2797); 22 U.S.C. 2778; E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp., p.79; 22 U.S.C. 2658; 22 U.S.C. 287c; E.O. 12918, 59 FR 28205, 3 CFR 1994 Comp., p 899.

6. Section 126.9 is revised to read as follows:

§ 126.9 Advisory opinions and related authorizations.

(a) Any person desiring information as to whether the Office of Defense Trade controls would be likely to grant a license or other approval for the export or approval of a particular defense article or defense service to a particular country may request an advisory opinion from the Office of Defense Trade Controls. These opinions are not binding on the Department of State and are revocable. A request for an advisory opinion must be made in writing and must outline in detail the equipment, its usage, the security classification (if any) of the articles or related technical data, and the country or countries involved. An original and seven copies of the letter must be provided along with seven copies of suitable descriptive information concerning the defense article or defense service

(b) *Related authorizations.* The Office of Defense Trade Controls may, as appropriate, in accordance with the procedures set forth in paragraph (a) of this section, provide export authorization, subject to all other relevant requirements of this subchapter, both for transactions that have been the subject of advisory opinions requested by prospective U.S. exporters, or for the Office's own initiatives. Such initiatives may cover pilot programs, or specifically anticipated circumstances for which the Office considers special authorizations appropriate.

7. Section 126.14 is added to read as follows:

§ 126.14. Special comprehensive export authorizations for NATO, Australia, and Japan.

(a) With respect to NATO members, Australia, and Japan, the Office of Defense Trade Controls may provide the comprehensive authorizations described below for circumstances where the full parameters of a commercial export endeavor including the needed defense exports can be well anticipated and described in advance, thereby making use of such comprehensive authorizations appropriate.

(1) *Major Project Authorization.* With respect to NATO members, Australia, and Japan, the Office of Defense Trade Controls may provide comprehensive authorizations for well circumscribed commercially developed ''major projects'', where a principal registered U.S. exporter/prime contractor identifies in advance the broad parameters of a commercial project including defense exports needed, other participants (e.g., exporters with whom they have ''teamed up'', subcontractors), and foreign government end users. Projects eligible for such authorization may include a commercial export of a major weapons system for a foreign government involving, for example, multiple U.S. suppliers under a commercial teaming agreement to design, develop and manufacture defense articles to meet a foreign government's requirements. U.S. exporters seeking such authorization must provide detailed information concerning the scope of the project, including other exporters, U.S. subcontractors, and planned exports (including re-exports) of defense articles, defense services, and technical data, and meet the other requirements set forth in paragraph (b) of this section.

(2) *Major Program Authorization.* With respect to NATO members, Australia, and Japan, the Office of Defense Trade Controls may provide comprehensive authorizations for well circumscribed commercially developed ''major program''. This variant would be available where a single registered U.S. exporter defines in advance the parameters of a broad commercial program for which the registrant will be providing all phases of the necessary support (including the needed hardware, tech data, defense services, development, manufacturing, and logistic support). U.S. exporters seeking such authorization must provide detailed information concerning the scope of the program, including planned exports (including re-exports) of defense articles, defense services, and technical data, and meet the other requirements set forth below in paragraph (b) of this section.

(3)(i) *Global Project Authorization.* With respect to NATO members, Australia and Japan, the Office of Defense Trade Controls may provide a comprehensive ''Global Project Authorization'' to registered U.S. exporters for exports of defense articles, technical data or defense services in support of government to government cooperative projects (covering research and development or production) with one of these countries undertaken pursuant to an agreement between the USG and the government of such country, or a memorandum of understanding between the Department of Defense and the country's Ministry of Defense.

(ii) A set of standard terms and conditions derived from and corresponding to the breadth of the activities and phases covered in such a cooperative MOU will provide the basis for this comprehensive authorization for all U.S. exporters (and foreign end users) identified by DoD as participating in such cooperative project. Such authorizations may cover a broad range of defined activities in support of such programs including multiple shipments of defense articles and technical data and performance of defense services for extended periods, and re-exports to approved end users.

(iii) Eligible end users will be limited to ministries of defense of MOU signatory countries and foreign companies serving as contractors of such countries.

(iv) Any requirement for non-transfer and use assurances from a foreign government may be deemed satisfied by the signature by such government of a cooperative agreement or by its ministry of defense of a cooperative MOU where the agreement or MOU contains assurances that are comparable to that required by a DSP–83 with respect to foreign governments and that clarifies that the government is undertaking responsibility for all its participating companies. The authorized non-government participants or end users (*e.g.*, the participating government's contractors) will still be required to execute DSP–83's.

(4) *Technical Data Supporting an Acquisition, Teaming Arrangement, Merger, Joint Venture Authorization.* With respect to NATO member countries, Australia and Japan, the Office of Defense Trade Controls may provide a registered U.S. defense company a comprehensive authorization to export technical data in support of the U.S. exporter's consideration of entering into a teaming arrangement, joint venture, merger, acquisition, or similar arrangement with prospective foreign partners. Specifically the authorization is designed to permit the export of a broadly defined set of technical data to qualifying well established foreign defense firms in NATO countries, Australia or Japan in order to better facilitate a sufficiently in depth

assessment of the benefits, opportunities and other relevant considerations presented by such prospective arrangements. U.S exporters seeking such authorization must provide detailed information concerning the arrangement, joint venture, merger or acquisition, including any planned exports of defense articles, defense services, and technical data, and meet the other requirements set forth in paragraph (b) of this section.

(b) *Provisions and Requirements for Comprehensive Authorizations.* Requests for the special comprehensive authorizations set forth in paragraph (a) of this section should be by letter addressed to the Office of Defense Trade Control. With regard to a commercial major program or project authorization, or technical data supporting a teaming arrangement, merger, joint venture or acquisition, registered U.S. exporters may consult the Director of the Office of Defense Trade Controls about eligibility for and obtaining available comprehensive authorizations set forth in paragraph (a) of this section or pursuant to § 126.9(b).

(1) Requests for consideration of all such authorizations should be formulated to correspond to one of the authorizations set out in paragraph (a) of this section, and should include:

(i) A description of the proposed program or project, including where appropriate a comprehensive description of all phases or stages; and

(ii) Its value; and

(iii) Types of exports needed in support of the program or project; and

(iv) Projected duration of same, within permissible limits; and

(v) Description of the exporter's plan for record keeping and auditing of all phases of the program or project; and

(vi) In the case of authorizations for exports in support of government to government cooperative projects, identification of the cooperative project.

(2) Amendments to the requested authorization may be requested in writing as appropriate, and should include a detailed description of the aspects of the activities being proposed for amendment.

(3) The comprehensive authorizations set forth in paragraph (a) of this section may be made valid for the duration of the major commercial program or project, or cooperative project, not to exceed 10 years.

(4) Included among the criteria required for such authorizations are those set out in Part 124, *e.g.,* §§ 124.7, 124.8 and 124.9, as well as §§ 125.4 (technical data exported in furtherance of an agreement) and 123.16 (hardware being included in an agreement). Provisions required will also take into account the congressional notification requirements in §§ 123.15 and 124.11 of the ITAR. Specifically, comprehensive congressional notifications corresponding to the comprehensive parameters for the major program or project or cooperative project should be possible, with additional notifications such as those required by law for changes in value or other significant modifications.

(5) All authorizations will be consistent with all other applicable requirements of the ITAR, including requirements for non-transfer and use assurances (see §§ 123.10 and 124.10), congressional notifications (*e.g.,* §§ 123.15 and 124.11), and other documentation (*e.g.,* §§ 123.9 and 126.13).

(6) Special auditing and reporting requirements will also be required for these authorizations. Exporters using special authorizations are required to establish an electronic system for keeping records of all defense articles, defense services and technical data exported and comply with all applicable requirements for submitting shipping or export information within the allotted time.

Dated: July 14, 2000.

Pamela L. Frazier,

Acting Assistant Secretary, Bureau of Political-Military Affairs, Department of State.

[FR Doc. 00–18530 Filed 7–20–00; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF STATE

Bureau of Political-Military Affairs

22 CFR Part 126

[Public Notice 3366]

Amendment to the International Traffic in Arms Regulation: FMS LOA Authorized Defense Services

AGENCY: Bureau of Political-Military Affairs, Department of State.

ACTION: Final rule.

SUMMARY: The International Traffic In Arms Regulations (ITAR), § 126.6, Foreign-owned military aircraft and naval vessels, and the Foreign Military Sales program is being amended to clarify the use of the exemption when providing defense services authorized by the Foreign Military Sales (FMS) Program.

EFFECTIVE DATE: September 1, 2000.

FOR FURTHER INFORMATION CONTACT: Rose Biancaniello, Deputy Director, Licensing, Office of Defense Trade Controls, Bureau of Political-Military Affairs, Department of State ATTN: Regulatory Change, Section 126.6 FMS Defense Service at (202) 663–2862 or FAX (202) 261–8264.

SUPPLEMENTARY INFORMATION: Section 126.6 currently provides for the export of defense services when authorized by the Foreign Military Sales (FMS) Program without a license or other approval. However, companies, lacking clear guidance often sought approval of the Office of Defense Trade Controls which delayed the provision of the service or frequently also entailed seeking assurances that the foreign government believed it had already provided to the USG. Thus, this amendment to § 126.6 which clarifies the exemption on the basis of specific criteria will assist registered defense firms by making it clear when to use the exemption to provide defense services authorized by the Department of Defense in an LOA.

This amendment involves a foreign affairs function of the United States and therefore, is not subject to the procedures required by 5 U.S.C. 553 and 554. It is exempt from review under Executive Order 12866 but has been reviewed internally by the Department of State to ensure consistency with the purposes thereof. This rule does not require analysis under the Regulatory Flexibility Act or the Unfunded Mandates Reform Act. It has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Act of 1966. It will not have substantial direct effects on the Nation, USG or any State, the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant application of Executive Order Nos. 12372 and 13123. However, interested parties are invited to submit written comments to the Department of State, Office of Defense Trade Controls, ATTN: Regulatory Change, FMS LOA Authorized Defense Services, 13th Floor, Room H1304, 2401 E Street, N.W., Washington, D.C. 20037. Such persons must be so registered with the Department of State's Office of Defense Trade Controls (ODTC) pursuant to the registration requirements of section 38 of the Arms Export Control Act.

List of Subjects in 22 CFR Part 126

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, title 22, chapter 1, subchapter M, part 126 is amended as follows:

PART 126—GENERAL POLICIES AND PROVISIONS

1. The authority citation for Part 126 continues to read as follows:

Authority: Secs. 2, 38, 40, 42, and 71, Pub.L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2780, 2791, and 2797); 22 U.S.C. 2778; E.O. 11958, 42 FR 4311; 3 CFR, 1977 Com., p. 79; 22 U.S.C. 2658; 22 U.S.C. 287c; E.E. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899.

2. Section 126.6 is revised to read as follows:

§ 126.6 Foreign-owned military aircraft and naval vessels, and the Foreign Military Sales program.

(a) A license from the Office of Defense Trade Controls is not required if:

(1) The article or technical data to be exported was sold, leased, or loaned by the Department of Defense to a foreign country or international organization pursuant to the Arms Export Control Act or the Foreign Assistance Act of 1961, as amended, and

(2) The article or technical data is delivered to representatives of such a country or organization in the United States; and

(3) The article or technical data is to be exported from the United States on a military aircraft or naval vessel of that government or organization or via the Defense Transportation Service (DTS).

(b) *Foreign military aircraft and naval vessels.* A license is not required for the entry into the United States of military aircraft or naval vessels of any foreign state if no overhaul, repair, or modification of the aircraft or naval vessel is to be performed. However, Department of State approval for overflight (pursuant to the 49 U.S.C. 1508) and naval visits must be obtained from the Bureau of Political-Military Affairs, Office of International Security Operations.

(c) *Foreign Military Sales Program.* A license from the Office of Defense Trade Controls is not required if the defense article or technical data or a defense service to be transferred was sold, leased or loaned by the Department of Defense to a foreign country or international organization under the Foreign Military Sales (FMS) Program of the Arms Export Control Act pursuant to an Letter of Offer and Acceptance (LOA) authorizing such transfer which meets the criteria stated below:

(1) Transfers of the defense articles, technical data or defense services using this exemption may take place only during the period which the FMS Letter of Offer and Acceptance (LOA) and implementing USG FMS contracts and subcontracts are in effect and serve as authorization for the transfers hereunder in lieu of a license. After the USG FMS contracts and subcontracts have expired and the LOA no longer serves as such authorization, any further provision of defense articles, technical data or defense services shall not be covered by this section and shall instead be subject to other authorization requirements of this subchapter; and

(2) The defense article, technical data or defense service to be transferred are specifically identified in an executed LOA, in furtherance of the Foreign Military Sales Program signed by an authorized Department of Defense Representative and an authorized representative of the foreign government, and

(3) The transfer of the defense article and related technical data is effected during the duration of the relevant Letter of Offer and Acceptance (LOA), similarly a defense service is to be provided only during the duration of the USG FMS contract or subcontract and not to exceed the specified duration of the LOA, and

(4) The transfer is not to a country identified in § 126.1 of this subchapter, and

(5) The U.S. person responsible for the transfer maintains records of all transfers in accordance with Part 122 of this subchapter, and

(6) For transfers of defense articles and technical data,

(i) The transfer is made by the relevant foreign diplomatic mission of the purchasing country or its authorized freight forwarder, provided that the freight forwarder is registered with the Office of Defense Trade Controls pursuant to Part 122 of this subchapter, and

(ii) At the time of shipment, the District Director of Customs is provided an original and properly executed DSP–94 accompanied by a copy of the LOA and any other documents required by U.S. Customs in carrying out their responsibilities. The Shippers Export Declaration or, if authorized, the outbound manifest, must be annotated ''This shipment is being exported under the authority of Department of State Form DSP–94. It covers FMS Case [insert case identification], expiration [insert date]. 22 CFR 126.6 applicable. The U.S. Government point of contact is , telephone number ,'' and

(iii) If, classified hardware and related technical data are involved the transfer must have the requisite USG security clearance and transportation plan and be shipped in accordance with the Department of Defense National Industrial Security Program Operating Manual, or

(7) For transfers of defense services:

(i) A contract or subcontract between the U.S. person(s) responsible for providing the defense service and the USG exists that:

(A) Specifically defines the scope of the defense service to be transferred;

(B) Identifies the FMS case identifier,

(C) Identifies the foreign recipients of the defense service

(D) Identifies any other U.S. or foreign parties that may be involved and their roles/responsibilities, to the extent known when the contract is executed,

(E) Provides a specified period of duration in which the defense service may be performed, and

(ii) The U.S. person(s) identified in the contract maintain a registration with the Office of Defense Trade Controls for the entire time that the defense service is being provided. In any instance when the U.S. registered person(s) identified in the contract employs a subcontractor, the subcontractor may only use this exemption when registered with DTC, and when such subcontract meets the above stated requirements, and

(iii) In instances when the defense service involves the transfer of classified technical data, the U.S. person transferring the defense service must have the appropriate USG security clearance and a transportation plan, if appropriate, in compliance with the Department of Defense National Industrial Security Program Operating Manual, and

(iv) The U.S. person responsible for the transfer reports the initial transfer, citing this section of the ITAR, the FMS case identifier, contract and subcontract number, the foreign country, and the duration of the service being provided to the Office of Defense Trade Controls using DTC's Direct Shipment Verification Program.

Dated: July 14, 2000.

Pamela L. Frazier,

Assistant Secretary (Acting), Bureau of Political-Military Affairs, U.S. Department of State.

[FR Doc. 00–18531 Filed 7–20–00; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

TRICARE; Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Nonavailability Statement Requirement for Maternity Care

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: This final rule implements Section 712(c) of the National Defense Authorization Act for Fiscal Year 2000 (Pub. L. No. 106–65), which requires that a nonavailability-of-health-care statement shall be required for a beneficiary not enrolled in TRICARE Prime for TRICARE cost-share of maternity care services related to outpatient prenatal, outpatient or inpatient delivery, and outpatient post-partum care subsequent to the visit which confirms the pregnancy. The Act reestablishes a requirement which was previously eliminated under the broad direction of the National Defense Authorization Act for FY 1997, section 734, which removed authority for nonavailability statements (NASs) for outpatient services. Therefore, the Act changes the provisions which require an NAS for inpatient delivery, but do not require an NAS for outpatient prenatal and post-partum care. The change will significantly contribute to continuity of care for maternity patients. In furtherance of that principle, and consistent with the previous policy, an NAS for maternity care shall not be required when a beneficiary has other health insurance for primary coverage.

EFFECTIVE DATE: This rule is effective October 5, 1999, the effective date of Section 712(c) of the National Defense Authorization Act for Fiscal Year 2000 (Pub. L. No. 106–65), which imposes the requirement.

ADDRESSES: TRICARE Management Activity, Medical Benefits and Reimbursement Systems, 16401 East Centretech Parkway, Aurora, CO 80011–9043.

FOR FURTHER INFORMATION CONTACT: Tariq Shahid, Medical Benefits and Reimbursement Systems, TRICARE Management Activity, telephone (303) 676–3801.

SUPPLEMENTARY INFORMATION:

I. Final Rule Provisions

This final rule implements section 712(c) of the National Defense Authorization Act for Fiscal Year 2000 (Pub. L. No. 106–65) which requires that a nonavailability-of-health-care statement shall be required for TRICARE/CHAMPUS cost-share of maternity care services related to outpatient prenatal, outpatient or inpatient delivery, and outpatient post-partum care subsequent to the visit which confirms the pregnancy. The nonavailability statement (NAS) requirement applies to non-enrolled TRICARE beneficiaries who live in a catchment area of a military treatment facility (MTF). Except for an emergency or when there is other primary health insurance coverage, these beneficiaries are required to obtain all maternity care from the MTF. If care is unavailable at the MTF, an NAS will be issued for the beneficiary. The Act changes the existing provisions which require an NAS for inpatient delivery but do not require an NAS for outpatient prenatal, outpatient delivery and post-partum care. The change will provide for continuity of care for maternity patients. Beneficiaries will need one NAS for the entire episode of maternity care which shall remain valid until 42 days following termination of the pregnancy. We published the interim final rule on December 23, 1999.

II. Public Comments

We provided a 60-day comment period on the interim final rule. We received no public comments, and no comments were received from other federal agencies with which we are required to coordinate.

III. Regulatory Procedures

Executive Order 12866 requires certain regulatory assessments for any significant regulatory action, defined as one which would result in an annual effect on the economy of $100 million or more, or have other substantial impacts. The Regulatory Flexibility Act (RFA) requires that each Federal agency prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This is not a significant regulatory action under Executive Order 12866 and has been reviewed by the Office of Management and Budget. In addition, this final rule will not significantly affect a substantial number of small entities. The changes set forth in the final rule are minor revisions to the existing regulation.

The final rule will not impose additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3511).

List of Subjects in 32 CFR Part 199

Claims, Handicapped, Health insurance, and Military personnel.

PART 199—[AMENDED]

Accordingly, 32 CFR 199 is amended as follows:

1. The authority citation for Part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. Chapter 55.

2. Section 199.4(a) is amended by revising paragraphs (a)(9) and (a)(9)(i)(B).

§ 199.4 Basic program benefits.

* * * * *

(a) * * *

(9) Nonavailability Statements within a 40-mile catchment area. In some geographic locations, it is necessary for CHAMPUS beneficiaries not enrolled in TRICARE Prime to determine whether the required medical care can be provided through an Uniformed Services facility. If the required care cannot be provided, the hospital commander, or designee, will issue a Nonavailability Statement (DD Form 1251). Except for emergencies, a Nonavailability Statement should be issued before medical care is obtained from a civilian source. Failure to secure such a statement may waive the beneficiary's rights to benefits under CHAMPUS.

(i) * * *

(B) For CHAMPUS beneficiaries who are not enrolled in TRICARE Prime, an NAS is required for services in connection with non-emergency inpatient hospital care and outpatient and inpatient maternity care if such services are available at a facility of the Uniformed Services located within a 40-mile radius of the residence of the beneficiary, except that an NAS is not required for services otherwise available at a facility of the Uniformed Services located within a 40-mile radius of the beneficiary's residence when another insurance plan or program provides the beneficiary primary coverage for the services. For maternity care, an NAS is required for services related to outpatient prenatal, outpatient or inpatient delivery, and outpatient post-partum care subsequent to the visit that confirms the pregnancy. The requirement for an NAS does not apply to beneficiaries enrolled in TRICARE Prime, even when those beneficiaries use the point-of-service option under § 199.17(n)(3).

* * * * *

Dated: July 17, 2000.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 00–18451 Filed 7–20–00; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP Western Alaska 00–010]

RIN 2115–AA97

Safety Zone; U. S. Marine Corps Water Jump, Resurrection Bay, Seward, Alaska

AGENCY: Coast Guard, DOT

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary 1100 yard radius safety zone around a point located at 60°02′28.7″N latitude, 149°23′02.8″W longitude in Resurrection Bay, Seward, AK. This safety zone is implemented to ensure the safety of approximately 25 U. S. Marine Corps personnel who will be jumping from a C–130 aircraft into the waters of Resurrection Bay at a time when this waterway will be extremely busy with commercial and recreational vessels. Entry into, transit through, anchoring or remaining in this zone is prohibited unless authorized by the Captain of the Port, Western Alaska, or his authorized representative.

DATES: This regulation is effective from 12:30 p.m. until 4:30 p.m. on July 20, 2000.

ADDRESSES: Comments should be mailed to Commanding Officer, Coast Guard Marine Safety Office Anchorage, 510 ''L'' Street, Suite 100, Anchorage, AK 99501. Comments received will be available for inspection and copying at Coast Guard Marine Safety Office Anchorage. Normal Office hours are 7:30 a.m. to 4 p.m., Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Mark McManus, USCG Marine Safety Office, Anchorage, at (907) 271–6762.

SUPPLEMENTARY INFORMATION:

Regulatory Information

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days after Federal Regulation publication. Publishing an NPRM and delaying its effective date would be contrary to the public interest since the scope of the activities requiring this safety zone, and other logistical details surrounding this port visit, were not finalized until a date fewer than 30 days prior to the project date. Furthermore, immediate action is necessary to provide for the safe transit of the vessel.

Although this rule is being published as a temporary final rule without prior notice, an opportunity for public comment is nevertheless desirable to ensure the rule is both reasonable and workable. Accordingly, persons wishing to comment may do so by submitting written comments to the office listed in **ADDRESSES** in this preamble. Those providing comments should identify the docket number for the regulation (COTP Western Alaska 00–010) and also include their name, addresses, and reason(s) for each comment presented. Based upon the comments received, the regulation may be changed.

The Coast Guard plans no public meeting. Persons may request a public meeting by writing the Marine Safety Office in Anchorage, Alaska at the address listed in **ADDRESSES** in this preamble.

Background and Purpose

Due to the fact that Resurrection Bay is a relatively narrow waterway, that commercial vessel traffic transits routinely through this area conducting business at the Port of Seward, and the large amount of recreational vessel traffic that utilize this waterway, the Coast Guard is establishing a 1100 yard radius safety zone to ensure the safety of 25 U.S. Marine Corps personnel that will be jumping into Resurrection Bay from a C–130 aircraft on July 20, 2000.

Discussion of the Regulation

The Coast Guard is establishing a temporary 1100 yard safety zone around a point located at 60°02′28.7″N latitude, 149°23′02.8″W longitude in Resurrection Bay, Seward, AK. This safety zone is implemented to ensure the safety of approximately 25 U. S. Marine Corps personnel who will be jumping from a C–130 aircraft into the waters of Resurrection Bay at a time when this waterway will be extremely busy with commercial and recreational vessels. The proposed safety zone is intended to become effective at 12:30 a.m. on July 20, 2000, and terminate at 16:30 p.m. on July 20, 2000. Entry into, transit through, anchoring or remaining in this zone is prohibited unless authorized by the Captain of the Port or his authorized representative.

Regulatory Evaluation

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

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this rule will have a significant economic impact on a substantial number of small entities. ''Small entities'' may include small businesses and not-for-profit organizations that are not dominant in their respective fields, and governmental jurisdictions with populations less than 50,000. Commercial and recreational vessel traffic will be able to transit into and out of the Port of Seward via the traffic lanes that will be open on the east and west sides of the safety zone area during the entire effective period of this regulation. For the same reasons set forth in the above Regulatory Evaluation, the Coast Guard certifies under 5 U.S.C. 605(b) that this rule is not expected to have a significant economic impact on any substantial number of entities, regardless of their size.

Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), the Coast Guard wants to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking process. If your small business or organization is affected by this rule and you have questions concerning its provisions or options for compliance, please contact Lieutenant Mark McManus, Coast Guard Marine Safety Office Anchorage, AK, at (907) 271–6762.

Collection of Information

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

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 13132 and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that, under Figure 2–1, paragraph 34(g) of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation.

Unfunded Mandates

Under the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), the Coast Guard must consider whether this rule will result in an annual expenditure by state, local, and tribal governments, in the aggregate of $100 million (adjusted annually for inflation). If so, the Act requires that a reasonable number of regulatory alternatives be considered, and that from those alternatives, the least costly, most cost-effective, or least burdensome alternative that achieves the objective of the rule be selected.

No state, local, or tribal government entities will be effected by this rule, so this rule will not result in annual or aggregate costs of $100 million or more. Therefore, the Coast Guard is exempt from any further regulatory requirements under the Unfunded Mandates Act.

List of Subjects in 33 CFR Part 165

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

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

PART 165—[AMENDED]

1. The authority citation for Part 165 reads as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.401–1, 6.04–6, and 160.5; 49 CFR 1.46.

2. A new temporary § 165.T17–010 is added to read as follows:

§ 165.T17–010 Safety Zone; U. S. Marine Corps Water Jump, Resurrection Bay, Seward, Alaska

(a) *Description.* The following area is a Safety Zone: All navigable waters within a 1100 yard radius around a point located at 60°02′28.7″N latitude, 149°23′02.8″W longitude in Resurrection Bay, Seward, AK.

(b) *Effective Dates.* This proposed regulation is effective at 12:30 p.m. on July 20, 2000, and terminates at 16:30 p.m. on July 20, 2000.

(c) *Regulations.* (1) The Captain of the Port means the Captain of the Port, Western Alaska. The Captain of the Port may authorize or designate any Coast Guard commissioned, warrant, or petty officer to act on his behalf.

(2) The general regulations governing safety zones contained in 33 CFR 165.23 apply. No person or vessel may enter, transit through, anchor or remain in this safety zone, with the exception of attending vessels, without first obtaining permission from the Captain of the Port, Western Alaska, or his on scene representative.

The U. S. Coast Guard Cutter *Mustang* will be enforcing the safety zone and can be reached on marine VHF channel 16. The Captain of the Port's representative can also be contacted by telephone at (907) 271–6700.

Dated: June 27, 2000

W.J. Hutmacher,

Captain, U.S. Coast Guard, Captain of the Port, Western Alaska.

[FR Doc. 00–18533 Filed 7–18–00; 8:45 am]

BILLING CODE 4910–15–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01–00–187]

RIN 2115–AA97

Safety Zone: Oil Spill Cleanup Zone, Middletown, Rhode Island

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone in the waters of Narragansett Bay shoreward of the area marked by a high flyer (flagged metal pole) at the westernmost end of Midway Pier in Portsmouth; southwest to a high flyer 250 yards west of McAllister Point; south to a high flyer at the first bend in the Coddington Cove Breakwater. The safety zone is needed to safeguard the public and pollution response personnel during oil cleanup operations. Entry into this zone is prohibited unless authorized by the Captain of the Port, Providence, Rhode Island.

EFFECTIVE DATES: This rule is effective from 3 p.m., Wednesday July 12, 2000, until 6 p.m. on Monday July 31, 2000.

ADDRESSES: You may mail comments and related material to Marine Safety Office Providence, 20 Risho Avenue, East Providence, Rhode Island 02914. The Prevention Department maintains the public docket for this rulemaking.

Comments and related material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at Marine Safety Office Providence between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LCDR James McLaughlin at Marine Safety Office Providence, (401) 435–2300.

SUPPLEMENTARY INFORMATION

Regulatory History

Pursuant to 5 U.S.C. 553, a notice of proposed rulemaking (NPRM) was not published for this regulation and good cause exists for making it effective less than 30 days after **Federal Register** publication. This temporary final rule establishes a safety zone around the cleanup operations being conducted after the spill of No. 6 oil from the barge Penn 460. The safety zone is needed to safeguard the public, and cleanup personnel, from the hazards associated with cleanup vessels and beach response personnel operating in the area. Any delay encountered in this regulation's effective date would be contrary to public interest since immediate action is needed to close portions of Narragansett Bay to protect the public and response personnel.

Background and Purpose

Barge Penn 460 experienced an oil spill of approximately 14,000 gallons of No. 6 oil on July 5, 2000. Due to heavy recreational traffic in vicinity of the spill, a safety zone is needed to ensure the safety of recreational traffic and response vessels and personnel. The exclusion of recreational traffic will minimize the risk of wake damage to response vessels and personnel, and will eliminate the risk of collision. Entry into this safety zone is prohibited unless authorized by the Captain of the Port (COTP), Providence, RI. A safety zone [CGD01–00–250] was previously established on Friday July 7, 2000, for this same event. This previous safety zone prohibited entry into the waters of Narragansett Bay within 500 yards of the shoreline from the base of the Coddington Cove, Middletown, Rhode Island, breakwater to the waterside end of the pier located 2,500 yards Northeast of Coddington Cove. However, the

Rhode Island Department of Health and Department of Environmental Management reopened a significant portion of the area to commercial fishing at 12:00 p.m. on July 12, 2000. This new safety zone prohibits entry into the area which remains closed to commercial fishing.

Regulatory Evaluation

This temporary final rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. The Office of Management and Budget has not reviewed it under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary. This safety zone prevents traffic from transiting in the immediate area of cleanup operations. This regulation will not be significant as all vessel traffic may safely pass around this safety zone, no commercial entities are located within the zone, a State of Rhode Island fisheries closure is in effect in this zone, and extensive maritime advisories will be made.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this proposal will have a significant economic impact on a substantial number of small entities. ''Small entities'' may include (1) small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields and (2) governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this final rule will not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

We have analyzed this action under E.O. 13132 and have determined that this rule does not have implications for federalism under that Order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those costs. This rule will not impose an unfunded mandate.

Taking of Private Property

This temporary rule would not effect a taking of private property or otherwise have taking implications under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This temporary rule meets applicable standards in section 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this temporary rule under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Environment

The Coast Guard has considered the environmental impact of these regulations and concluded that, under Figure 2–1, paragraph 34(g), of Commandant Instruction M16475.1C, this final rule is categorically excluded from further environmental documentation. A ''Categorical Exclusion Determination'' will be available in the docket for inspection or copying where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 165

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

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

PART 165—[AMENDED]

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6 and 160.5; 49 CFR 1.46. Section 165.100 is also issued under the authority of Sec. 311, Pub. L. 105–383.

2. Add temporary § 165.T01–187 to read as follows:

§ 165.T01–187 Safety Zone: Oil Spill Cleanup Zone, Middletown, Rhode Island.

(a) *Location.* All waters in Narragansett Bay shoreward of the area marked by a high flyer (flagged metal pole) at the westernmost end of Midway Pier in Portsmouth, RI; southwest to a high flyer 250 yards west of McAllister Point; south to a high flyer at the first bend in the Coddington Cove.

(b) *Effective Period.* This section is effective from 3 p.m. on Wednesday July 12, 2000, until 6 p.m. on Monday July 31, 2000.

(c) *Regulations.* (1) The general regulations governing safety zones contained in 33 CFR 165.23 apply.

(2) All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on-scene U.S. Coast Guard patrol personnel. The personnel comprise commissioned, warrant, and petty officers of the U.S. Coast Guard. Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed.

Dated: July 12, 2000.

Peter A. Popko,

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

[FR Doc. 00–18557 Filed 7–20–00; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD 01–00–186]

RIN 2115–AA97

Safety Zone: Village of Bellport Fireworks Display

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone for the Village of Bellport Fireworks Display to be held in Bellport Bay, Bellport, NY, on July 22, 2000. This action is needed to protect persons, facilities, vessels and others in the maritime community from the safety hazards associated with this fireworks display. Entry into this safety zone is prohibited unless authorized by the Captain of the Port.

DATES: This rule is effective from 8:30 p.m. on July 22, 2000, until 10 p.m., on July 23, 2000.

ADDRESSES: Documents relating to this temporary final rule are available for inspection or copying at U.S. Coast Guard Group/Marine Safety Office Long Island Sound, 120 Woodward Avenue, New Haven, CT 06512 between 8:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Chief Petty Officer C. D. Stubblefield, Command Center, Captain of the Port, Long Island Sound at (203) 468–4428.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a NPRM. The sponsor of the event did not provide the Coast Guard with the final details for the event in sufficient time to publish a NPRM or a final rule 30 days in advance. The delay encountered if normal rulemaking procedures were followed would effectively cancel the event. Cancellation of this event is contrary to the public interest since the fireworks display is for the benefit of the public.

Background and Purpose

The Village of Bellport, is sponsoring a 12 minute fireworks display in Bellport Bay, Bellport, NY. The safety zone will be in effect from 8:30 p.m. until 10:00 p.m., July 22, 2000. The safety zone covers all waters of Bellport Bay within a 600 foot radius of the fireworks launching barge which will be located in Bellport Bay, Bellport, NY, in approximate position; 40°44′58″N, 072°55′43″W, (NAD 1983). This zone is required to protect the maritime community from the safety dangers associated with this fireworks display. Entry into or movement within this zone will be prohibited unless authorized by the Captain of the Port or his on-scene representative.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979). The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This safety zone involves only a portion of Bellport Bay and entry into this zone will be restricted for only 90 minutes on July 22, 2000. Although this regulation prevents traffic from transiting this section of Bellport Bay, the effect of this regulation will not be significant for several reasons: the duration of the event is limited; the event is at a late hour; all vessel traffic may safely pass around this safety zone; and extensive, advance maritime advisories will be made.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit or anchor in a portion of Bellport Bay from 8:30 p.m. until 10:00 p.m. July 22, 2000. This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: The duration of the event is limited; the event is at a late hour; all vessel traffic may safely pass around this safety zone; and extensive, advance maritime advisories will be made.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

We have analyzed this rule under Executive Order 13132 and have determined that this rule does not have implications for federalism under that Order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government having first provided the funds to pay those unfunded mandate costs. This rule will not impose an unfunded mandate.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to

minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that under figure 2–1, paragraph (34)(g), of Commandant Instruction M16475.lC, this rule is categorically excluded from further environmental documentation. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying where indicated under **ADDRESSES.**

List of Subjects

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

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

PART 165—[AMENDED]

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6 and 160.5; 49 CFR 1.46. Section 165.100 is also issued under authority of Sec. 311, Pub. L. 105–383.

2. Add temporary § 165.T01–186 to read as follows:

§ 165.T01–186 The Village of Bellport Fireworks Display, Bellport, NY.

(a) *Location.* The safety zone includes all waters of Bellport Bay within a 600 foot radius of the launch barge located in Bellport Bay, Bellport, NY. in approximate position 40°44′58″ N, 072°55′43″ W (NAD 1983).

(b) *Effective date.* This section is effective on July 22, 2000 from 8:30 p.m. until 10 p.m., July 23, 2000.

(c)(1) *Regulations.* The general regulations covering safety zones contained in § 165.23 of this part apply.

(2) All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on scene patrol personnel. U.S. Coast Guard patrol personnel include commissioned, warrant, and petty officers of the Coast Guard. Upon being hailed by a U.S. Coast Guard Vessel via siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed.

Dated: July 10, 2000.

David P. Pekoske,

Captain, U.S. Coast Guard, Captain of the Port, Long Island Sound.

[FR Doc. 00–18556 Filed 7–20–00; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP San Juan 00–065]

RIN 2115–AA97

Safety Zone Regulation for San Juan Harbor, Puerto Rico

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone within a 1500 foot radius surrounding the drill boat *Apache* while it is engaged in drilling or blasting operations. The drill boat will operate at the entrance to San Juan Harbor, Puerto Rico. The safety zone is necessary to protect vessels and personnel in the vicinity of the drilling and blasting operations. Entry into this zone is prohibited, unless authorized by the Captain of the Port.

DATES: This rule is effective from 7 a.m., Atlantic Standard Time, on July 11, 2000, to 11:59 p.m., Atlantic Standard Time, October 31, 2000.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Robert Lefevers, Chief of Port Operations, Coast Guard Marine Safety Office San Juan, telephone (787) 706–2440.

ADDRESSES: Documents indicated in this preamble are available in the docket, are part of docket COTP San Juan 00–065, and are available for inspection or copying at the USCG Marine Safety Office, Rodriguez and Del Valle Building, 4th Floor, Calle San Martin, Road #2, Guaynabo, Puerto Rico, between the hours of 7:30 a.m. to 3:30 p.m., Monday through Friday, excluding federal holidays.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. It was impracticable to attempt to publish a NPRM for this situation due to the inherent difficulties in scheduling marine dredging operations, and the temporary nature of this regulation.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register** because the operational schedule for the drilling and blasting was not finalized until a June 21, 2000 meeting between the U.S. Coast Guard, Army Corps of Engineers and Contract Drilling and Blasting.

Background and Purpose

These regulations are needed to provide for the safety of life on navigable waters from hazards associated with drilling and blasting operations that will occur at the entrance to San Juan Harbor, Puerto Rico.

The drilling and blasting operations will be conducted to the west of the San Juan Harbor bar entrance channel, between buoys number 1 and number 4, in the approximate position of 18°28.3691′ N, 066°07.6889′ W. The drilling and blasting operations will occur outside of the navigation channel.

To further ensure the safety of life, the contractor conducting the drilling and blasting operations will, 15 minutes prior to any detonation, send two small boats outside the safety zone to advise mariners of the operation.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, l979), The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary as the operation will not significantly impede navigation and commercial activity due to the low frequency of occurrence and extremely short duration.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not

dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. The rule may affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit in a portion of San Juan Harbor from July 11, 2000 to October 31, 2000. This special local regulation will not have a significant economic impact on a substantial number of small entities because this rule will be in effect sporadically, and vessel traffic can pass safely around the regulated area.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub.L. 104–121), we want to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking process. If the rule would affect your small business, organization, or government jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** for assistance in understanding and participating in this rulemaking. We also have a point of contact for commenting on actions by employees of the Coast Guard. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3520).

Federalism

We have analyzed this rule under Executive Order 13132 and have determined that this rule does not have implications for federalism under that Order.

The Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those unfunded mandate costs. This rule will not impose an unfunded mandate.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or safety that may disproportionately affect children.

Environment

The Coast Guard has considered the environmental impact of this rule and concluded that under figure 2–1, paragraph 34(g) of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation because it is establishing a temporary safety zone.

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the Preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED AREAS AND LIMITED NAVIGATION AREAS

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

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

2. Temporary § 165.T00–065 is added to read as follows:

§ 165.T00–065 Safety Zone; San Juan Harbor, Puerto Rico.

(a) *Regulated Area.* A temporary safety zone is established within a 1500-foot radius surrounding the drill boat *Apache*, operating at the entrance to San Juan Harbor in the approximate position of 18° 28.3691′ N, 066° 07.6889′ W, when the vessel is conducting drilling or blasting.

(b) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into, anchoring, mooring or transiting in this zone is prohibited when the vessel *Apache* is displaying the flashing blue strobe light, unless authorized by the Coast Guard Captain of the Port.

(2) Notifications of blasting or drilling operations will be broadcast via VHF–FM radio Channel 16 beginning 2 hours prior to drilling or blasting operations.

(c) *Dates.* This section is effective at 7 a.m., Atlantic Standard Time, on July 11, 2000, and expires at 11:59 p.m., Atlantic Standard Time, October 31, 2000.

Dated: July 11, 2000.

J. Servidio,

Commander, U.S. Coast Guard, Captain of the Port, San Juan, Puerto Rico.

[FR Doc. 00–18555 Filed 7–20–00; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 184–0245a; FRL–6734–5]

Revisions to the California State Implementation Plan, Ventura County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve revisions to the Ventura County Air Pollution Control District's portion of the California State Implementation Plan (SIP). These revisions concern volatile organic compound (VOC) emissions from degreasers. We are approving local rules that regulate these emission sources under the Clean Air Act as amended in 1990 (CAA or the Act).

DATES: This rule is effective on September 19, 2000 without further notice, unless EPA receives adverse comments by August 21, 2000. If we receive such comment, we will publish a timely withdrawal in the **Federal Register** to notify the public that this rule will not take effect.

ADDRESSES: Mail comments to Andy Steckel, Rulemaking Office Chief (AIR–4), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

You can inspect copies of the submitted SIP revisions and EPA's technical support document (TSD) at our Region IX office during normal business hours. You may also see copies of the submitted SIP revisions at the following locations:

Environmental Protection Agency, Air Docket (6102), Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington DC 20460.

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812.

Ventura County Air Pollution Control District, 669 County Square Dr., 2nd Fl., Ventura, CA 93003–5417.

FOR FURTHER INFORMATION CONTACT: Yvonne Fong, Rulemaking Office (AIR–4), U.S. Environmental Protection Agency, Region IX, (415) 744–1199.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to EPA.

Table of Contents

I. The State's Submittal

A. What Rules Did the State Submit?

Table 1 lists the rules we are approving with the dates that they were adopted by the local air agency and submitted by the California Air Resources Board (CARB).

TABLE 1.—SUBMITTED RULES

Agency	Rule #	Rule Title	Adopted	Submitted
VCAPCD	74.6.1	Cold Cleaners	07/09/96	10/18/96
VCAPCD	74.6.2	Batch Loaded Vapor Degreasers	07/09/96	10/18/96
VCAPCD	74.6.3	Conveyorized Degreasers	07/09/96	10/18/96

On December 19, 1996, these rule submittals were found to meet the completeness criteria in 40 CFR part 51 appendix V, which must be met before formal EPA review.

B. Are There Other Versions of These Rules?

There are no previous versions of these rules in the SIP, although the VCAPCD adopted earlier versions of these rules on December 10, 1991, and CARB submitted them to us on June 19, 1992. While we can act on only the most recently submitted versions, we have reviewed materials provided with previous submittals.

C. What Is the Purpose of the Submitted Rules?

Rules 74.6.1, 74.6.2, and 74.6.3 set equipment and operating requirements for cold cleaners, batch loaded vapor degreasers, and conveyorized degreasers. These requirements ensure that these sources will be operated in a way which limits VOC emissions. The TSD has more information about these rules.

II. EPA's Evaluation and Action

A. How Is EPA Evaluating the Rules?

Generally, SIP rules must be enforceable (see section 110(a) of the Act), must require Reasonably Available Control Technology (RACT) for major sources in nonattainment areas (see section 182(a)(2)(A)), and must not relax existing requirements (see sections 110(l) and 193). The VCAPCD regulates an ozone nonattainment area (see 40 CFR part 81), so Rules 74.6.1, 74.6.2, and 74.6.3 must fulfill RACT.

Guidance and policy documents that we used to define specific enforceability and RACT requirements include the following:

1. Portions of the proposed post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044, November 24, 1987.

2. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations; Clarification to Appendix D of November 24, 1987 **Federal Register** Notice,'' (Blue Book), notice of availability published in the May 25, 1988 **Federal Register**.

3. The Control Technique Guideline (CTG) entitled, ''Control of Volatile Organic Emissions from Solvent Metal Cleaning'' (November 1977; EPA–450/2–77–022)

4. The California Air Resources Board (CARB) document entitled, ''Determination of Reasonably Available Control Technology and Best Available Control Technology for Organic Solvent Cleaning and Degreasing Operations'' (July 18, 1991).

B. Do the Rules Meet the Evaluation Criteria?

We believe these rules are consistent with the relevant policy and guidance regarding enforceability, RACT, and SIP relaxations. The TSD has more information on our evaluation.

C. Public Comment and Final Action

As authorized in section 110(k)(3) of the Act, EPA is fully approving the submitted rules because we believe they fulfill all relevant requirements. We do not think anyone will object to this, so we are finalizing the approval without proposing it in advance. However, in the Proposed Rules section of this **Federal Register**, we are simultaneously proposing approval of the same submitted rules. If we receive adverse comments by August 21, 2000, we will publish a timely withdrawal in the **Federal Register** to notify the public that the direct final approval will not take effect and we will address the comments in a subsequent final action based on the proposal. If we do not receive timely adverse comments, the direct final approval will be effective without further notice on September 19, 2000. This will incorporate these rules into the federally enforceable SIP.

III. Background Information

A. Why Were These Rules Submitted?

VOCs help produce ground-level ozone and smog, which harm human health and the environment. Section 110(a) of the CAA requires states to submit regulations that control VOC emissions. Table 2 lists some of the national milestones leading to the submittal of these local agency VOC rules.

TABLE 2.—OZONE NONATTAINMENT MILESTONES

Date	Event
March 3, 1978	EPA promulgated a list of ozone nonattainment areas under the Clean Air Act as amended in 1977. 43 FR 8964; 40 CFR 81.305.
May 26, 1988	EPA notified Governors that parts of their SIPs were inadequate to attain and maintain the ozone standard and requested that they correct the deficiencies (EPA's SIP-Call). See section 110(a)(2)(H) of the pre-amended Act.
November 15, 1990	Clean Air Act Amendments of 1990 were enacted. Pub. L. 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q.
May 15, 1991	Section 182(a)(2)(A) requires that ozone nonattainment areas correct deficient RACT rules by this date.

IV. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. This action merely approves state law as meeting federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that these rules will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because these rules approve pre-existing requirements under state law and do not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). For the same reason, these rules also do not significantly or uniquely affect the communities of tribal governments, as specified by Executive Order 13084 (63 FR 27655, May 10, 1998). These rules will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because they merely approve state rules implementing a federal standard, and do not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. These rules also are not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because they are not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rules in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. These rules do not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing these rules and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rules in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 19, 2000. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: June 28, 2000.

Nora L. McGee,

Acting Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

2. Section 52.220 is amended by adding paragraph (c)(241)(i)(C)(*2*) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(241) * * *

(i) * * *

(C) * * *

(*2*) Rules 74.6.1, 74.6.2, and 74.6.3, adopted on July 9, 1996.

* * * * *

[FR Doc. 00–18431 Filed 7–20–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 083–0243; FRL–6733–7]

Revisions to the California State Implementation Plan, El Dorado County Air Pollution Control District and Kern County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing limited approval and limited disapproval of revisions to the El Dorado County (EDCAPCD) Air Pollution Control District, and Kern County Air Pollution Control District (KCAPCD) portions of the California State Implementation Plan (SIP). The actions were proposed in the **Federal Register** on May 5, 1999, and March 22, 2000, respectively, and concern control of emissions of oxides of nitrogen (NO_X) from Industrial, Institutional, and Commercial Boilers, Steam Generators, and Process Heaters, and Stationary Piston Engines. Under authority of the Clean Air Act as amended in 1990 (CAA or the Act), this action simultaneously approves local rules that regulate these emission sources and directs California to correct rule deficiencies.

EFFECTIVE DATE: This rule is effective on August 21, 2000.

ADDRESSES: You can inspect copies of the administrative record for this action at EPA's Region IX office during normal business hours. You can inspect copies of the submitted SIP revisions at the following locations:

Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Environmental Protection Agency, Air Docket (6102), Ariel Rios Building, 1200 Pennsylvania Avenue, N.W., Washington D.C. 20460.

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812.

El Dorado County Environmental Management Department, Air Pollution Control District, 2850 Fairlane Court, Placerville, CA 95667, or

Kern County Air Pollution Control District, 2700 ''M'' Street, Suite 302, Bakersfield, CA 93301

FOR FURTHER INFORMATION CONTACT: Ed Addison, Rulemaking Office, AIR–4, Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901 Telephone: (415) 744–1160.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to EPA.

I. Proposed Action

On May 5, 1999 (64 FR 24119), and March 22, 2000 (65 FR 15287), respectively, EPA proposed a limited approval and limited disapproval of the following rules that were submitted for incorporation into the California SIP.

Local agency	Rule No.	Rule title	Adopted	Submitted
EDCAPCD	229	Industrial, Institutional, and Commercial Boilers, Steam Generators, and Process Heaters.	09/27/94	10/20/94
KCAPCD	427	Stationary Piston Engines (Oxides of Nitrogen)	07/2/98	08/21/98

We proposed a limited approval because we determined that these rules improve the SIP and are largely consistent with the relevant CAA requirements. We simultaneously proposed a limited disapproval because some rule provisions conflict with section 110 and part D of the Act. These provisions include the following:

- Alternate Emission Control Plan (AECP) in Section 229.3 (D) and Rule 427 Section VIII C.2.d.
- Compliance schedule in Section 229.4 (A) and Rule 427 Section VIII C.1.
- Heat input language in Section 229.3 (A).
- Flow rate meter language in Section 229.3 (C).
- Group testing of engines in Rule 427 Section VIII C.2.d.
- Exemption of engines between 25 and 250 bhp in Rule 427 Section V.

Our proposed action contains more information on the basis for this rulemaking and on our evaluation of the submittals.

II. Public Comments and EPA Responses

EPA's proposed action provided a 30-day public comment period. No comments were submitted regarding our proposed action on EDCAPCD Rule 229.

KCAPCD Rule 427: KCAPCD commented orally that EPA should not object to exempting engines between 50 and 250 bhp from NO_X emission limits or testing requirements. KCAPCD argued that these engines are not likely to emit greater than 50 tons/year of NO_X and are therefore not major sources subject to the RACT requirement in serious ozone nonattainment areas like Southeastern Kern County. EPA concurs with this comment and withdraws this as a basis for disapproving Rule 427 at this time. We note, however, that Southeastern Kern County may soon be reclassified as severe nonattainment and thus be subject to a 25 ton/year major source threshold. If and when that occurs, this exemption will need to be modified since engines smaller than 250 bhp are capable of emitting more than 25 tons/year NO_X.

III. EPA Action

No comments were submitted that change our assessment of the rules as described in our proposed action except for the comment discussed above. Therefore, as authorized in sections 110(k)(3) and 301(a) of the Act, EPA is finalizing a limited approval of the submitted rules. This action incorporates the submitted rules into the California SIP, including those provisions identified as deficient. As authorized under section 110(k)(3), EPA is simultaneously finalizing a limited disapproval of the rules. As a result, sanctions will be imposed unless EPA approves subsequent SIP revisions that correct the rules deficiencies within 18 months of the effective date of this action. These sanctions will be imposed under section 179 of the Act according to 40 CFR 52.31. In addition, EPA must promulgate a federal implementation plan (FIP) under section 110(c) unless we approve subsequent SIP revisions that correct the rules deficiencies within 24 months. Note that the submitted rules have been adopted by the El Dorado County Air Pollution Control District and Kern County Air Pollution Control District, and EPA's final limited disapproval does not prevent the local agency from enforcing them.

IV. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866, entitled ''Regulatory Planning and Review.''

B. Executive Order 13045

Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rules on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

The rules are not subject to Executive Order 13045 because they do not involve decisions intended to mitigate environmental health or safety risks.

C. Executive Order 13084

Under Executive Order 13084, Consultation and Coordination with Indian Tribal Governments, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation.

In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rules do not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to the rules.

D. Executive Order 13132

Executive Order 13121, entitled Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612, Federalism and 12875, Enhancing the Intergovernmental Partnership. Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

The rules will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely approves a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, the requirements of section 6 of the Executive Order do not apply to the rules.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply act on requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

EPA's disapproval of the state request under section 110 and subchapter I, part D of the Clean Air Act does not affect any existing requirements applicable to small entities. Any pre-existing federal requirements remain in place after this disapproval. Federal disapproval of the state submittal does not affect state enforceability. Moreover, EPA's disapproval of the submittal does not impose any new Federal requirements. Therefore, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.,* v. *U.S. EPA,* 427 U.S. 246, 255-66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal

governments, or to the private sector, result from this action.

G. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. The rules are not ''major'' rules as defined by 5 U.S.C. 804(2).

H. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

I. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 19, 2000. Filing a petition for reconsideration by the Administrator of the final rules does not affect the finality of the rules for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: June 7, 2000.

Felicia Marcus,

Regional Administrator, Region IX.

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

PART 52—[AMENDED]

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

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

2. Section 52.220 is amended by adding paragraphs (c) (203)(i)(A)(*2*) and (c) (230)(i)(C)(*2*) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(203) * * *

(i) * * *

(A) * * *

(*2*) Rule 229 adopted on September 27, 1994.

* * * * *

(230) * * *

(i) * * *

(C) * * *

(*2*) Rule 427 adopted on July 2, 1998.

* * * * *

[FR Doc. 00–18436 Filed 7–20–00; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

41 CFR Chapter 301

[FTR Amendment 93]

RIN 3090–AH27

Federal Travel Regulation; Maximum Per Diem Rates in Minnesota

AGENCY: Office of Governmentwide Policy, GSA.

ACTION: Final rule.

SUMMARY: This final rule amends the Federal Travel Regulation (FTR) Amendment 87, published in the **Federal Register** on Thursday, December 2, 1999 (64 FR 67670). In order to provide adequate per diem reimbursement for Federal employee travel in Duluth, Minnesota, the maximum lodging allowance is changed to reflect seasonal rates.

DATES: This final rule is effective July 21, 2000, and applies to travel performed on or after July 21, 2000.

FOR FURTHER INFORMATION CONTACT: Joddy Garner, Office of Governmentwide Policy, Travel and Transportation Management Policy Division, at 202–501–1538.

SUPPLEMENTARY INFORMATION:

A. Background

The General Services Administration (GSA), after an analysis of additional data, has determined that the current lodging allowance for Duluth, Minnesota, does not adequately reflect the cost of lodging in this area. To provide adequate per diem reimbursement for Federal employee travel for this area, the maximum lodging allowance is changed to reflect seasonal rates.

B. Regulatory Flexibility Act

This final rule is not required to be published in the **Federal Register** for notice and comment; therefore, the Regulatory Flexibility Act does not apply.

C. Executive Order 12866

GSA has determined that this rule is not a significant regulatory action for the purposes of Executive Order 12866 of September 30, 1993.

D. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the rule does not impose recordkeeping or information collection requirements, or the collection of information from offerors, contractors, or members of the public which require the approval of the Office of Management and Budget under 44 U.S.C. 501 *et seq.*

E. Small Business Regulatory Enforcement Fairness Act

This final rule is also exempt from congressional review prescribed under 5 U.S.C. 801 since it relates solely to agency management and personnel.

List of Subjects in 41 CFR Chapter 301

Government employees, Travel and transportation expenses.

For the reasons set forth in the preamble, under 5 U.S.C. 5701–5709, 41 CFR chapter 301 is amended as follows:

CHAPTER 301—TEMPORARY DUTY (TDY) TRAVEL ALLOWANCES

1. Appendix A to chapter 301 is amended by revising the entry in the table under the State of Minnesota, city of Duluth, St. Louis County. The page of the table beginning with Frankfort and ending with Gulfport, which includes the Duluth revision, reads as follows:

BILLING CODE 6820–34–M

Appendix A to Chapter 301—Prescribed Maximum per Diem Rates for Conus

* * * * * * *

Per diem locality:		Maximum lodging amount **(room rate only—no taxes)** (a)	+	M&IE rate (b)	=	Maximum per diem rate [4] (c)
Key city[1]	County and/or other defined location [2, 3]					
Frankfort	Benzie					
(June 1-September 30)		62		34		96
(October 1-May 31)		55		34		89
Gaylord	Otsego	68		38		106
Grand Rapids	Kent	60		34		94
Grayling	Crawford					
(June 1-September 30)		69		34		103
(October 1-May 31)		55		34		89
Holland	Ottawa					
(May 1-September 30)		79		34		113
(October 1-April 30)		59		34		93
Lansing	Ingham (except East Lansing)	61		34		95
Leland	Leelanau					
(June 1-September 30)		75		34		109
(October 1-May 31)		60		34		94
Mackinac Island	Mackinac					
(June 1-August 31)		165		46		211
(September 1-May 31)		130		46		176
Manistee	Manistee					
(June 1-September 15)		62		30		92
(September 16-May 31)		55		30		85
Midland	Midland	59		34		93
Mount Pleasant	Isabella	60		34		94
Muskegon	Muskegon	60		30		90
Ontonagon	Ontonagon	65		30		95
Petoskey	Emmet	60		38		98
Pontiac/Troy/Auburn Hills	Oakland and City limits of Auburn Hills (see Bay County)	93		38		131
Sault Ste Marie	Chippewa	60		34		94
South Haven	Van Buren	76		34		110
Traverse City	Grand Traverse					
(June 1-September 30)		110		42		152
(October 1-May 31)		60		42		102
	Macomb	83		34		117
MINNESOTA						
Anoka County	Anoka County	68		34		102
Dakota County	Dakota County	75		34		109
Duluth	St. Louis					
(June 1-October 31)		75		42		117
(November 1-May 31)		56		42		98
Minneapolis/St. Paul	Hennepin County and Fort Snelling Military Reservation and Navy Astronautics Group (Detachment BRAVO), Rosemount; and Ramsey County	91		46		137
Rochester	Olmsted	72		34		106
MISSISSIPPI						
Bay St. Louis	Hancock					
(May 1-September 30)		72		38		110
(October 1-April 30)		65		38		103
Biloxi	City limits of Biloxi (see Harrison County)	72		38		110
Gulfport	Harrison (except Biloxi)					

* * * * *

Dated: July 13, 2000.

David J. Barram,

Administrator of General Services.

[FR Doc. 00–18329 Filed 7–20–00; 8:45 am]

BILLING CODE 6820–34–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration (SAMHSA)

45 CFR Part 96

RIN 0930–AA04

Application Deadline for the Substance Abuse Prevention and Treatment (SAPT) Block Grant Program

AGENCY: HHS.

ACTION: Final Rule.

SUMMARY: On February 4, 2000, the Department of Health and Human Services (HHS) published a Notice of Proposed Rulemaking (NPRM) proposing a new submission date for its Substance Abuse Prevention and Treatment (SAPT) Block Grant program under section 1921 of the Public Health Service (PHS) Act which authorizes the Secretary to provide block grants to States for the purposes of prevention and treatment of substance abuse which includes alcohol and other drugs. The Secretary requested comments on the NPRM and gave 45 days for individuals to submit their comments to the Department. The Secretary has considered the comments received during the open comment period and has finalized the rule.

EFFECTIVE DATE: August 21, 2000.

FOR FURTHER INFORMATION CONTACT: Thomas M. Reynolds, Room 13C–20, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857 Tel. (301)443–0179.

SUPPLEMENTARY INFORMATION: The Department is finalizing the rule entitled ''Application Deadline for SAPT Block Grant Program,'' 45 CFR Part 96, which was published as a NPRM in the **Federal Register** on February 4, 2000 (65 FR 5474).

Background on the Notice of Proposed Rulemaking and Summary of Responses to Public Comment

A. Notice of Proposed Rulemaking (NPRM)

When SAMHSA first implemented the SAPT Block Grant program a primary concern was affording States sufficient time to develop the increased information required to apply for a grant under this program as compared to the generally less detailed application required under the predecessor Alcohol, Drug Abuse, and Mental Health Services Block Grant program administered by the Alcohol, Drug Abuse, and Mental Health Administration. This was accomplished by affording States the opportunity to submit their applications as late as March 31, fully six months into the Federal fiscal year (FFY) for which funding is requested (See 45 CFR 96.122(d)). This relatively late receipt date results in insufficient time to administer the SAPT Block Grant program in accordance with all the governing provisions of law. This is most noted under circumstances calling for the clarification of application data and, if necessary, the conduct of hearings in a timely manner and consistent with the requirements of section 1945(e) of the Public Health Service (PHS) Act.

States are now fully aware of the application requirements and can reasonably be expected to respond to an earlier submission date. Accordingly, starting with Federal fiscal year 2001, the Department proposed to establish a new date of October 1 of the Federal fiscal year for which Block Grant funding is being requested for receipt of applications for such funding. However, if a State determines that it will not be able to submit by October 1 either the report as required at 45 CFR 96.130(e) on Synar enforcement efforts and State success in reducing youth access to tobacco products during the preceding Federal fiscal year, or the information on maintaining State expenditures (MOE) during the preceding year as required at 45 CFR 96.134(d), the State, under the proposed rule, could request an extension of the due date(s) for a limited period, not to extend past December 31 of the Federal fiscal year for which application is made. The request for the extension would need to be signed by the official with the authority to apply for the grant or the Governor, and be submitted no later than September 1 of the prior Federal fiscal year. Under the proposed rule, the extension request must indicate for which requirement the extension is requested; include an explanation of why the State is unable to comply with the due date of October 1; state the date of submission the State is requesting; and discuss whether there are steps the State can take to avoid requiring an extension in future years. Extensions for the deadlines for these requirements are to be granted in writing by the SAMHSA official with delegated authority to grant the extension. All other components of the SAPT Block Grant application not covered by the extension are due by October 1 of the Federal fiscal year for which funds are being sought.

After considering the comments on the NPRM, HHS is finalizing the rule as proposed. Below is the Department's response to the comments to the proposed rule.

B. Public Comments and the Department's Responses

The Department received comments from 9 States and one national organization, the National Association of State Alcohol and Drug.

Abuse Directors (NASADAD), during the 45-day comment period. All written comments were reviewed and taken into consideration in the preparation of the final rule. The substantive concerns raised in the public comments and the Department's responses to the comments are set out below. Similar comments are considered together.

One commenter, the national organization, indicated that the proposed change will negatively impact half of the 60 SAPT Block Grant applicants. The commenter stated that while some States may be able to complete their applications earlier than others, this may be due to the fact that their State fiscal years, data collection, and reporting systems are more consistent with the Federal fiscal year, or because they have additional staff or resources to commit to the processes of planning, collecting and analyzing data, and reporting information. However, for the other half of the States that submit their application between October 1 and March 31, the proposed rule would create a hardship. Five other commenters expressed similar concerns related to their specific States, with one State commenting that the change to advance the application date should be delayed for at least one year.

SAMHSA has engaged in a number of interactions with the States regarding the proposed change in due date for the Block Grant application as follows:

Regional Team Building Workshops: The first formal discussions of the proposed change in the application due date were held at these regional workshops. Fifty-eight of 60 Single State Agency Directors and their Staff as well as NASADAD attended at least one of this series of meetings held in San Antonio, Texas (December 8–9, 1998), Hilton Head Island, South Carolina (March 2–3, 1999), Providence, Rhode Island (April 13–14, 1999), and Juneau, Alaska (May 25–26, 1999). Some States indicated that they would not be able to comply with the new due date

requirement unless they could delay reporting MOE and Synar information. As a result, SAMHSA decided to propose a 90-day extension for Synar and MOE data reporting.

State by State inquiry: In developing the proposed rule, SAMHSA queried the States in July 1999 as to their ability to meet the proposed deadline. All States responded that, while the change would pose some difficulty for some of them, they would be able to meet the deadline given the ability to receive extensions for the required Synar and MOE data. Although some States may need to make some changes in internal procedures, the Department believes the earlier application date is feasible, and the fact that we received few comments on this proposal reinforces our belief that States can adapt to the earlier due date.

NASADAD Annual Meeting: On June 5, 2000, SAMHSA staff discussed this issue with the States again at the NASADAD Leadership Forum in Reno, Nevada. The States responded that the task could be accomplished if the extensions were made available.

National Meeting: On June 22 and 23, 2000, at the Center for Substance Abuse Treatment's (CSAT) Fifth State Systems Development Program (SSDP), in Orlando, Florida, the Director of CSAT's Division of State and Community Assistance presented two workshops around Block Grant Administration issues in which most of the Single State Agency Directors participated. Again, the States responded that they can submit the application on October 1 if SAMHSA can provide the opportunity for an extension until December 31 for Synar or MOE reporting.

Two States also said that they would have difficulty because their public review and comment processes are currently (and have been since 1993) established around the March 31 deadline. It would, therefore, take time to change these long established procedures and mechanisms at the State level. The Department recognizes that these States will need to change these procedures but believes that the States and their constituent groups should be able to accommodate an October 1 deadline. Further, as we indicated in the NPRM, published in early February, States should be preparing to move toward an October 1 due date.

Commenters were concerned that the Block Grant applications and instructions have historically been received by the States from SAMHSA between May and September prior to the start of the Federal fiscal year for which they were applying. One State expressed concern but supported the rule change as long as this issue is addressed. We agree that the provision of application forms and instructions to the States so close to the next Federal fiscal year would not be appropriate with an October 1 deadline. SAMHSA has anticipated this problem, and consistent with one commenter's request that the application forms be available about six months prior to the due date, the FY 2001 Block Grant application forms and software were sent to all 60 Block Grant applicants by overnight mail on April 3, 2000. SAMHSA will continue this practice of providing sufficient lead time.

Two commenters indicated that recent changes, such as the requirement for multi-year reporting on the 16 Federal goals in the Federal fiscal year 2000 Block Grant application, have, in their view, added more work to complete the application. In turn, this increases the potential difficulty States will face in complying with the change in rule. However, the Department notes that the changes in the application simply consolidate previously existing reporting requirements into one place. These changes have been well received by most States that have discussed them with SAMHSA.

Another State indicated that the Block Grant Application System (BGAS) software distributed to the States is cumbersome and not always compatible with State software. The Department notes, however, that approximately 85 percent of States utilize the BGAS software in submitting their applications. Further, SAMHSA maintains a help desk during office hours to assist States in using the system and has provided successful on-site technical assistance to those having difficulty. SAMHSA will offer individual assistance to this commenter.

One State indicated that, although they have historically submitted their application in November, it would not have necessary MOE and Synar data available for the October due date. It should be noted that the Department has allowed for the opportunity for a State to seek an extension of the reporting date for this information until no later than December 31, which should accommodate this State's needs. With regard to the provision for an extension, a few States, and one in particular, stated a concern that the extension request provision is burdensome and unnecessary. Further, it was suggested that the due date not be changed, the due date be December 31, or that only a simple notification with the application should be required for granting an extension. We do not believe that the requirement to request an extension is unduly burdensome. States will, necessarily, have already considered their ability to submit a timely and complete application by the October 1 due date, and will be aware of the valid reasons why this is impossible. The requirement to submit an extension request is, therefore, simply a request to submit this reasoning in writing accompanied by a request for an extension. The suggestion that the due date not be changed from the current date is addressed elsewhere. The proposed alternative due date of December 31 would provide insufficient time to effectively address the needs we are addressing in this rule. Finally, the Department believes simply allowing an applicant to notify us that they will be taking until December 31 to submit an application component does not guarantee the level of attention by senior State officials which we believe essential to a process intended to assure extensions are an exception to normal practice. However, if a State wished to incorporate an extension request which fully complied with the requirements found in § 96.122(d) into its application, and it submitted that application no later than September 1 of the prior Federal fiscal year, it would be eligible for consideration as a validly submitted extension request.

Another commenter expressed concern that other required expenditure information will not be available by October 1. It should be noted, the application requires reporting on expenditures that occurred three years prior to the application submission, and it is the Department's belief that such expenditures data should be available to meet the October 1 due date.

Three commenters stated that the reporting requirements for the Block Grant application have expanded to require increased reporting which makes it more difficult to meet an October 1 due date. These changes include expansion of Synar reporting requirements, reporting on planned and actual requirements for the supplemental funding authorized by Pub. L. 104–121, the addition of Form 10 (State Use of Needs Assessment Information), and extensive treatment and prevention outcome measures. One State is concerned that the new Sections IV–A and IV–B, (Voluntary Treatment and Prevention Performance Measures), will become ''required'' at some point in the future. It should be noted that the reporting requirements related to Pub. L. 104–121 are minimal requirements necessary for reporting under the Block Grant, are time limited, and expire with the FFY 2001 application. Form 10 was added to correct a deficiency in reporting in previous applications and

was designed to require minimal increased effort. The voluntary reporting on outcome measures is the product of agreement and extensive consensus development with the States and the national organization, NASADAD. At this time, the reporting is voluntary and the measures are being further refined through the consensus process. Although there has been an increase in the reporting of data, the Department believes that these data can be reported by the October 1 due date.

Several commenters stated that the SAPT Block Grant application is already a complex document that requires substantial involvement from both program and fiscal staff to complete. They believe the estimate provided in the NPRM of 60 additional hours required for the annual reporting burden as a result of the changed receipt date may lead to a perception that the proposed change in rule will pose no difficulties for grant applicants. Some commenters stated that they believe the 60 hours is too low an estimate. The Department recognizes the complexity of the statutorily mandated reporting required by the Block Grant application. The Department also recognizes that the change in rule will require some adjustments in current practices. However, while changing the due date for submission of the SAPT Block Grant application, the Rule does not change the basic reporting requirements. Further, the Department believes that this change is necessary to meet its responsibilities under the Block Grant program in a timely manner. The comments regarding reporting burden are more fully discussed below in the ''Paperwork Reduction Act of 1995'' section.

Three commenters stated that SAMHSA has limited staff to review each of the 60 Block Grant applications and that even if all applications were received on October 1 they believe it would be difficult for the SAMHSA State Project Officers to review all 60 applications in a timely manner. It should be noted that SAMHSA, with NASADAD input, has instituted a rigorous SAPT Block Grant review and approval process and a complementary tracking system that holds SAMHSA State Project Officers accountable for a timely review of all Block Grants assigned to them. SAMHSA time lines are being adjusted to accommodate the change in rule.

Two commenters recommended staggering the submission dates based on either the State fiscal year or their Synar circumstances. However, given the significant variances in State fiscal years and Synar circumstances the Department has sought to establish a process that most of the States have indicated will work for them.

Three States and NASADAD expressed concerns related to the Synar reporting requirements and processes; these are fully discussed below.

One State expressed concern regarding what it viewed as constant delays in the Federal review process due to frequent requirements for revisions of the Synar portion of the Block Grant application. The Department is aware that reporting on Synar activities requires time and resources in order to ensure that all the necessary data are included in the final report for review and analysis. However, the expressed concern is only true for States whose initial submission did not meet application requirements. In an effort to streamline the review process, SAMHSA has centralized the responsibilities for monitoring State Synar activities in the Division of State and Community System Development, System Development Branch. This change was implemented during the Federal fiscal year 2000 reviews. The Department believes that the new review process will facilitate the Synar report reviews and reduce the amount of time it takes to approve these reports. We note, however, that some States have experienced delays in funding when they have not met their negotiated Synar retailer compliance rates. The Department hopes that with the earlier application due date decisions will be made earlier in the Federal fiscal year. Further, the earlier deadline will allow SAMHSA more time to work with the States that are having Synar compliance problems, resulting in earlier funding decisions.

Another State suggested that all States be required to develop a plan that would enable them to complete their Synar reporting requirements by the required October 1 deadline, thereby making it unnecessary to institute a process for granting extensions. SAMHSA believes that, given the fact that all but three States rely on youth for the conduct of the Synar inspections, and given the fact that the summer months are the time when most youth are available to participate in the Synar inspections, many States will not be able to complete the required number of inspections, analyze the survey data and report the results back to SAMHSA by October 1. These factors will likely result in a number of States needing extensions for submitting their Synar reports. While SAMHSA is not adopting the suggested requirement, we are willing to provide assistance and work with States that may choose this approach.

Another State's comment made reference to specific circumstances for that State that seem to pose difficulties with meeting the October 1 deadline for submitting the annual Synar report. SAMHSA understands this State's concerns and is willing to provide technical assistance to the State in order to assist with adjusting the State's time lines for completing annual Synar inspections (current deadline for completing all Synar inspections is September 30), and collecting and reporting Synar information. It is SAMHSA's intent to provide assistance to all States to support the timely submission of required Synar-related materials.

The comment from NASADAD regarding Synar reporting focused on a concern about delays experienced by some States in securing SAPT Block Grant funding even when they believe they are in compliance with Synar requirements. While it is SAMHSA's desire to issue SAPT Block Grant awards as promptly as possible, if it is determined during the initial review that a Synar report is not complete, the State is asked to submit additional information to complete it. SAMHSA is only able to perform a thorough review of a State's application and make a determination of compliance with the Synar requirements after it receives a complete report from the State. In order to assure timely review, SAMHSA has implemented internal procedures designed to streamline the review process, including the development of enhanced and improved Synar plan reviews. The change to an October 1 due date for the Block Grant application should further enhance Federal review and approval of the applications. The earlier date provides SAMHSA additional time to work with the States in completing full and accurate applications in accordance with the Block Grant requirements. It also affords SAMHSA and the Department the time necessary to provide States with due process in the event that a State's application indicates possible non-compliance with Block Grant requirements.

Economic Impact

This rule does not have cost implications for the economy of $100 million, or otherwise meet the criteria for a major rule under Executive Order 12291, and therefore does not require a regulatory impact analysis. Further, this regulation will not have a significant impact on a substantial number of small entities, and therefore does not require

a regulatory flexibility analysis under the Regulatory Flexibility Act of 1980.

Federalism Impact

As was detailed earlier in the preamble, SAMHSA consulted with the States concerning the proposed change in application due date. During 1998 and 1999, SAMHSA discussed the proposed change at several regional team building workshops. As a result of these meetings, SAMHSA decided to propose a 90-day extension for Synar and MOE reporting. Also, SAMHSA staff participated in two National meetings where the States responded that the proposed task could be accomplished if extensions were made available for reporting MOE and Synar data. Further, in developing the proposed rule, SAMHSA queried all the States and the States indicated that it would not be an undue hardship on them to meet this new requirement if there can be an extension when necessary until December 31 with regard to both maintenance of effort and Synar provisions.

The primary concern set forth by the national organization, NASADAD, focused on the ability to obtain the critical information required for the SAPT Block grant application that would permit its inclusion by the proposed October 1 due date. Also, the national organization noted that while some States may be able to complete their applications earlier than others, this may be due to the fact that their State fiscal years, data collection, and reporting systems are more consistent with the Federal fiscal year, or because they have additional staff or resources to commit to the processes of planning, collecting and analyzing data, and reporting information. As a consequence of the meetings discussed in detail earlier in the preamble, and above, as well as the discussions with SAMHSA regarding such areas as making the application guidance and software available at the earliest possible date, and that guidance would be provided to the States for use in applying for extensions for MOE and Synar reporting, the Department believes that these concerns of the national organization have been addressed. Further, since Section 96.122(d) allows for an extension with regard to the MOE and Synar reporting elements of the application, we do not believe that there is a significant Federalism impact.

Regulatory Evaluation

This proposal is not a significant regulatory action under Section 3(f) of the Executive Order 12866 and does not require an assessment of the potential costs and benefits under Section 6(a)(3) of that Order and has been exempted from review by the Office of Management and Budget under that Order.

Paperwork Reduction Act of 1995

This final rule contains information collection provisions which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA)(44 U.S.C. 3507(d)). The title, description and respondent description of the information collections are shown in the following paragraphs with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Application Deadline for SAPT Block Grant Program.

Description: The Secretary is issuing regulations to change the receipt date of SAPT Block Grant applications starting with the Federal Fiscal Year (FY) 2001 from March 31 to October 1. All elements of the application reporting requirements will be due October 1. However, States may request an extension of time for reporting State expenditures necessary to determine compliance with the Maintenance of Effort (MOE) requirement and/or to submit required Synar information for a period up to December 31. This change will allow HHS to review Block Grant applications and make Block Grant awards to all States earlier in the fiscal year. It will also provide additional time for sufficient planning in the event of any penalty actions that may be required, while recognizing the inability of some States to report the MOE and Synar data prior to December 31.

Description of Respondents: State and tribal governments.

In response to the Secretary's invitation in the NPRM to comment on the information collection requirements, three states and the national organization included comments on the response burden associated with the SAPT Block Grant application.

Comment: Two commenters indicated that the annual application is a complex submission that requires much more time to prepare than the 60 hours indicated.

Discussion: The current burden estimate for the annual application (approved under OMB control number 0930–0080) is 655 hours per State. The 120 hours of burden shown for the first year and the 60 hours for future years reflect only additional burden associated with the change in the due date. This rule does not change those basic reporting requirements. It does add one burden hour per State annually for the purpose of sending a letter requesting an extension of the due date for reporting maintenance of effort and/or Synar. The new burden estimate assumes, conservatively, that all States will submit such a request.

Change: None.

Comment: Two States commented that the burden associated with the change in due date is much more than the estimate of one hour per State.

Discussion: The Department recognizes the complexity of the statutorily mandated reporting required by the Block Grant application. This rule changes the due date for submission of the SAPT Block Grant application, but it does not change the basic reporting requirements for the SAPT Block Grant. There will be a need for some States to adjust their work schedules in order to submit the application by the new due date. However, because of the series of meetings and discussions with the national organization and its members, over the past two years, on the plan to change the due date, States have been aware of the planned change and have been planning for the transition. The additional burden hour per State estimated for the first year is in recognition of the transition.

Change: None.

Response burden estimate: Information collection language for the current rule is approved by OMB under control number 0930–0165 (Synar reporting requirements on youth access to tobacco) and control number 0930–0163 (for all other aspects of the annual application). The Substance Abuse Prevention and Treatment Block Grant Uniform Application format for FY 2000–FY 2002 is approved by OMB under control number 0930–0080. None of the specifics of these reporting requirements are being changed. Only the due date of the Uniform Application is impacted by this final rule.

At present, approximately half of all eligible Block Grant applicants routinely submit their Uniform Application for Block Grant funds on or before September 30 of the fiscal year preceding the fiscal year for which they are applying for funds. Approximately one half of all eligible applicants submit their uniform applications between October 1 and March 31 of the fiscal year for which block grant funds are being made available.

SAMHSA recognizes that the earlier receipt date will have an impact on the applicants, particularly those that have

typically submitted their Uniform Application after September 30. Since the contents of the Uniform Application are not changing, it is difficult to estimate the additional response burden and associated costs for the first year of this change of receipt date (no additional burden is estimated for this change for future years). Therefore, a nominal response burden for each applicant of one hour is provided. In addition, it is conservatively assumed that all applicants will request an extension of the MOE and Synar reporting, and one hour is estimated for preparation of such a request.

Thus, for the first year of implementation, total response burden is estimated at 120 hours. For subsequent years, the burden estimate is 60 hours.

ANNUAL REPORTING BURDEN

45 CFR citation and purpose	Number of respondents	Responses per respondent	Hours per response	Total hours
96.122(d) Due date for annual report	60	1	1	60
96.122(d) Extension requests associated with MOE and Synar	60	1	1	60
Total	60	.....	.....	120

Individuals and organizations may submit comments on these burden estimates or any other aspect of these information collection provisions, including suggestions for reducing the burden, and should direct them to: SAMHSA Reports Clearance Officer, Room 16–105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

The information collection provisions in this final rule have been approved under OMB control number 0930–0163. This approval expires February 28, 2001. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects in 45 CFR Part 96

Alcohol abuse, Alcoholism, Confidentiality, Drug abuse, Health records, Tobacco use by minors.

Dated: June 29, 2000.

Donna E. Shalala,

Secretary.

For the reasons set forth in the preamble, Subpart L of Part 96 of Title 45 of the Code of Federal Regulations is amended as follows:

PART 96—BLOCK GRANTS

1. The authority citation for Subpart L of Part 96 continues to read as follows:

Authority: 42 U.S.C. 300x–21 to 300x–35 and 300x–51 to 300x–64.

2. Section 96.122(d) is revised to read as follows:

§ 96.122 Application content and procedures.

* * * * *

(d) Beginning with the fiscal year 2001 application, the application (in substantial compliance with the statutory and regulatory provisions for the Block Grant) must be submitted no later than October 1 of the fiscal year for which Block Grant funding is being requested. The submission date for the report required by § 96.130(e) to be submitted with the application and/or the information required by § 96.134(b) may be extended for good cause shown in a request signed by the official authorized to apply for the Block Grant funding on behalf of the State, or the Governor. The State should request an extension for only the amount of time necessary. In no event will an extension be granted past December 31 of the fiscal year for which application is made. All requests to extend the due date must be submitted no later than September 1 of the prior fiscal year and addressed to the same address as specified for the grant application. Extension requests must state for which requirement an extension is sought, the date of submission sought, why the State is unable to meet the October 1 due date, and discuss if there are steps the State will be able to take to avoid requiring an extension in future years, or if not, why not. Extension requests complying with these requirements will be acted upon no later than September 20 of the fiscal year prior to the year for which application is to be made. Due date extensions regarding the § 96.130(e) report and regarding the § 96.134(d) information shall only be granted in writing. In order for an applicant to have complied with the requirements of section 1932(a)(1) of the Public Health Service Act (42 U.S.C. 300x–32(a)(2)), it is necessary that the components of the application have been submitted by the date indicated or as extended pursuant to this paragraph.

* * * * *

[FR Doc. 00–18316 Filed 7–20–00; 8:45 am]

BILLING CODE 4162–20–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1807, 1815, and 1825

Acquisition Planning

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: This final rule amends the NASA FAR Supplement (NFS) to: include additional circumstances when NASA field installations are required to identify certain acquisitions through the Master Buy Plan (MBP) process; add NASA's policy regarding the use of the structured approach for developing profit or fee when contracting with non-profit organizations which was mistakenly removed; and make editorial corrections and miscellaneous changes dealing with NASA internal and administrative matters.

EFFECTIVE DATE: July 21, 2000.

FOR FURTHER INFORMATION CONTACT: Bruce King, NASA Headquarters Office of Procurement, Program Operations Division (Code HS), Washington, DC 20546, (202) 358–0461, e-mail: *bruce.king@hq.nasa.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

Current Master Buy Plan (MBP) submission guidance does not address high value acquisitions from or through other government agencies and Chiles Act cooperative agreements, and any acquisition deemed to be of significant importance to the Agency regardless of its dollar value. This final rule provides that NASA field installations identify these acquisitions through the MBP process for possible Headquarters review and approval. The change to NASA's structured approach for developing a profit or fee objective (64 FR 51472–51476, September 23, 1999) mistakenly deleted NASA's policy

regarding the use of the structured approach for non-profit organizations and NASA's policy not to pay profit or fee on contracts with educational institutions. This final rule corrects this error by adding the previous language as section 1815.404–471–6. Additionally, editorial corrections and miscellaneous changes are made to correct the MBP format instructions, revise Internet reference citations, and correct the instructions for completing the Customs Form 7501, Entry Summary.

B. Regulatory Flexibility Act

NASA certifies that this rule will not have a significant economic impact on a substantial number of small business entities under the Regulatory Flexibility Act (5U.S.C. 601 *et seq.*) because it does not impose any new requirements.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the NFS do not impose any recordkeeping or information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subparts in 48 CFR Parts 1807, 1815, and 1825

Government procurement.

Tom Luedtke,

Associate Administrator for Procurement.

Accordingly, 48 CFR Parts 1807, 1815 and 1825 are amended as follows:

1. The authority citation for 48 CFR Parts 1807, 1815 and 1825 continues to read as follows:

Authority: 42 U.S.C. 2473(c)(1)

PART 1807—ACQUISITION PLANNING

2. In section 1807.103 revise paragraph (d)(iii)(E) to read as follows:

1807.103 Agency-head responsibilities.

(d) * * *

(iii) * * *

(E) From or through other Government agencies except when the value of the acquisition meets the Master Buy Plan threshold (see 1807.7101(a));

* * * * *

3. Amend section 1807.7000 by removing ''(http://ec.msfc.nasa.gov /hq/cci/first.html)'' and adding ''(*http://procurement.nasa.gov/cgi-bin/CCI/first.cgi*)'' in its place.

4. In section 1807.7101, revise paragraph (a) and add paragraphs (c)(3) and (c)(4) to read as follows:

1807.7101 Applicability.

(a) The Master Buy Plan applies to each negotiated acquisition, including supplemental agreements and acquisitions through or from other Government agencies, where the dollar value, including the aggregate amount of options, follow-on acquisitions, or later phases of multi-phase acquisitions, is expected to equal or exceed $50,000,000.

* * * * *

(c) * * *

(3) Any cooperative agreement notice where the total value (the Government's contribution plus the contribution of the recipient) of any resulting cooperative agreement is expected to equal or exceed $50,000,000.

(4) Any acquisition designated by NASA Headquarters regardless of its value.

* * * * *

5. In Table 1807–1, the second sentence of items (5)–(9) in the section titled ''Supplementary instructions by heading number'' is amended by removing the words ''column (8)'' and adding ''column (7)'' in its place.

PART 1815—CONTRACTING BY NEGOTIATION

6. Add section 1815.404–471–6 to read as follows:

1815.404–471–6 Modification to structured profit/fee approach for nonprofit organizations.

(a) The structured approach was designed for determining profit or fee objectives for commercial organizations. However, the structured approach must be used as a basis for arriving at profit/fee objectives for nonprofit organizations (FAR subpart 31.7), excluding educational institutions (FAR subpart 31.3), in accordance with paragraph (b) of this section. It is NASA policy not to pay profit or fee on contracts with educational institutions.

(b) For contracts with nonprofit organizations under which profit or fee is involved, an adjustment of up to 3 percent of the costs in Block 13 of NASA Form 634 must be subtracted from the total profit/fee objective. In developing this adjustment, it is necessary to consider the following factors:

(1) Tax position benefits;

(2) Granting of financing through letters of credit;

(3) Facility requirements of the nonprofit organization; and

(4) Other pertinent factors that may work to either the advantage or disadvantage of the contractor in its position as a nonprofit organization.

PART 1825—FOREIGN ACQUISITION

7. Revise section 1825.903 to read as follows:

1825.903 Exempted supplies.

(a) Through delegation from the Associate Administrator for Procurement, procurement officers are authorized to certify duty free entry for articles imported into the United States, if those articles are procured by NASA or by other U.S. Government agencies, or by U.S. Government contractors or subcontractors when title to the articles is or will be vested in the U.S. Government in accordance with the terms of the contract or subcontract. Procurement officers shall complete the certification set forth in 14 CFR 1217.104(a) or 1217.104(c) (http://www.access.gpo.gov/nara/cfr/cfr-retrieve.html#page1). Upon arrival of foreign supplies at a port of entry, the consignee, generally the commercial carrier or its agent (import broker), will file Customs Form 7501, Entry Summary. This form is available from Service Ports (http://www.customs.ustreas.gov/location/ports/index.htm) or from NASA Headquarters' forms library (https://extranet.hq.nasa.gov/nef/user/form_search.cfm). All duty-free certificates must be coordinated with the center Chief Counsel. Procurement officers must maintain a record of each certification and make this record available for periodic review by NASA Headquarters and the U.S. Customs Service.

[FR Doc. 00–18390 Filed 7–20–00; 8:45 am]

BILLING CODE 7510–01–U

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1827, 1835 and 1852

Submission of Final Reports under NASA Research and Development Contracts

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: This final rule revises the report submission requirements under NASA research and development (R&D) contracts and clarifies that contractors cannot release these final reports until NASA has completed its Document Availability Authorization (DAA) review and the availability of the report has been determined.

EFFECTIVE DATE: July 21, 2000.

FOR FURTHER INFORMATION CONTACT: Celeste Dalton, NASA Headquarters Office of Procurement, Contract Management Division (Code HK), Washington, DC, 20546, (202) 358–1645.

SUPPLEMENTARY INFORMATION:

A. Background

A proposed rule was published in the **Federal Register** on April 18, 2000 (65 FR 20791–92). No comments were received. This final rule adopts the proposed rule without change. NASA's Center for AeroSpace Information (CASI) serves as a repository of NASA scientific and technical information (STI). This includes information developed under NASA-sponsored research and development efforts. The NFS currently requires that copies of the final report and other progress reports under R&D contracts be submitted to CASI. The need for other progress reports no longer exists. Copies of only the final report required under an R&D contract must be submitted to CASI. Before NASA STI is made available, it is subject to a NASA Document Availability Authorization (DAA) review and release determination. Contractors cannot release final reports resulting from NASA R&D contracts until NASA has completed its Document Availability Authorization (DAA) review (NASA Form 1676).

B. Regulatory Flexibility Act

NASA certifies that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because it only affects small business entities whose R&D contracts required progress reporting.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the NFS do not impose any new record keeping or information collection requirements which require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Parts 1827, 1835 and 1852

Government procurement.

Tom Luedtke,

Associate Administrator for Procurement.

Accordingly, 48 CFR Parts 1827, 1835, and 1852 are amended as follows:

1. The authority citation for 48 CFR Parts 1827, 1835, and 1852 continues to read as follows:

Authority: 42 U.S.C. 2473 (c)(1).

PART 1827—PATENTS, DATA, AND COPYRIGHTS

2. Revise section 1827.406–70 to read as follows:

1827.406–70 Reports of work.

(a) When considered necessary for monitoring contract performance, contracting officers must require contractors to furnish reports of work performed under research and development contracts (fixed-price and cost reimbursement), interagency agreements, or in cost-reimbursement supply contracts. This purpose may be achieved by including the following general requirements, modified as needed to meet the particular requirements of the contract, in the section of the contract specifying data delivery requirements:

(1) *Monthly progress reports.* Reports should be in narrative form, brief, and informal. They should include a quantitative description of progress, an indication of any current problems that may impede performance, proposed corrective action, and a discussion of the work to be performed during the next monthly reporting period. (Normally, this requirement should not be used in contracts with nonprofit organizations.)

(2) *Quarterly progress reports.* In addition to factual data, these reports should include a separate analysis section interpreting the results obtained, recommending further action, and relating occurrences to the ultimate objectives of the contract. Sufficient diagrams, sketches, curves, photographs, and drawings should be included to convey the intended meaning.

(3) *Final report.* This report should summarize the results of the entire contract, including recommendations and conclusions based on the experience and results obtained. The final report should include tables, graphs, diagrams, curves, sketches, photographs, and drawings in sufficient detail to explain comprehensively the results achieved under the contract. The final report must comply with NPG 2200.2A, Guidelines for Documentation, Approval, and Dissemination of NASA Scientific and Technical Information.

(4) *Report Documentation Page.* The final report must include a completed Report Documentation Page, Standard Form (SF) 298 as the final page of the report.

(b) The contracting officer must consider the desirability of providing reports on the completion of significant units or phases of work, in addition to periodic reports and reports on the completion of the contract.

(c) *Submission of final report.* In addition to the original of the final report submitted to the contracting officer, contracts containing the clause at 1852.235–70, Center for AeroSpace Information—Final Scientific and Technical Reports (see 1835.070(a)), must require the concurrent submission of a reproducible copy and a printed or reproduced copy of the final report to the NASA Center for AeroSpace Information (CASI).

(d) *NASA review of final report.* When required by the contract, final reports submitted to NASA for review, shall be reviewed for technical accuracy, conformance with applicable law, policy and publication standards, and to determine the availability and distribution of NASA-funded documents containing scientific and technical information (STI) (NASA Form 1676, NASA Scientific and Technical Document Availability Authorization (DAA)). The final report must not be released outside of NASA until NASA's DAA review has been completed and the availability of the document has been determined. The document is considered available when it is accessible through CASI.

PART 1835—RESEARCH AND DEVELOPMENT CONTRACTING

3. In section 1835.070, revise paragraph (a) to read as follows:

1835.070 NASA contract clauses and solicitation provision.

(a) The contracting officer must insert the clause at 1852.235–70, Center for AeroSpace Information—Final Scientific and Technical Reports, in all research and development contracts, interagency agreements, and in cost-reimbursement supply contracts involving research and development work.

* * * * *

PART 1852—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

4. Revise section 1852.235–70 to read as follows:

1852.235–70 Center for AeroSpace Information—Final Scientific and Technical Reports.

As prescribed in 1835.070(a), insert the following clause:

Center for Aerospace Information—Final Scientific and Technical Reports July 2000

(a) The Contractor should register with and avail itself of the services provided by the NASA Center for AeroSpace Information

(CASI) (http://www.sti.nasa.gov) for the conduct of research or research and development required under this contract. CASI provides a variety of services and products as a central NASA repository of research information, which may enhance contract performance. The address is set out in paragraph (d) of this clause.

(b) Should the CASI information or service requested by the Contractor be unavailable or not in the exact form necessary by the Contractor, neither CASI nor NASA is obligated to search for or change the format of the information. A failure to furnish information shall not entitle the Contractor to an equitable adjustment under the terms and conditions of this contract.

(c) In addition to the final report, as defined at 1827.406–70(a)(3), submitted to the contracting officer, a reproducible copy and a printed or reproduced copy of the final report or data shall be concurrently submitted to: Center for AeroSpace Information (CASI), Attn: Document Processing Section, 7121 Standard Drive, Hanover, Maryland 21076–1320, Phone: 301–621–0390, FAX: 301–621–0134.

(d) The last page of the final report submitted to CASI shall be a completed Standard Form (SF) 298, Report Documentation Page. In addition to the copy of the final report, the contractor shall provide, to CASI, a copy of the letter transmitting the final report to NASA for its Document Availability Authorization (DAA) review.

(e) The contractor shall not release the final report, outside of NASA, until the DAA review has been completed by NASA and availability of the report has been determined.

(End of clause)

[FR Doc. 00–18388 Filed 7–20–00; 8:45 am]

BILLING CODE 7510–01–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 1842

Exemption of SBIR/STTR Phase II Contracts from Interim Past Performance Evaluations

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: This final rule revises the NASA FAR Supplement (NFS) to make interim past performance evaluations under FAR Part 42 optional for SBIR/STTR Phase II contracts.

EFFECTIVE DATES: July 21, 2000.

FOR FURTHER INFORMATION CONTACT: Paul Brundage, NASA Headquarters, Office of Procurement, Contract Management Division (Code HK), Washington, DC 20456–0001, (202) 358–0481, e-mail: pbrundage@hq.nasa.gov.

SUPPLEMENTARY INFORMATION:

A. Background

NASA centers have reported that interim evaluations on SBIR/STTR contracts are usually perfunctory and without substance because there is seldom anything to evaluate until contract completion. This final rule makes interim evaluations for SBIR/STTR Phase II contracts optional.

B. Regulatory Flexibility Act

NASA certifies that this final rule will not have a significant economic impact on a substantial number of small business entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because it only affects NASA's internal implementation of existing regulatory requirements.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the NFS do not impose any recordkeeping or information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

Lists of Subjects in 48 CFR Part 1842

Government procurement.

Tom Luedtke,

Associate Administrator for Procurement.

Accordingly, 48 CFR Part 1842 is amended as follows:

1. The authority citation for 48 CFR Part 1842 continues to read as follows:

Authority: 42 U.S.C. 2473(c)(1).

PART 1842—CONTRACT ADMINISTRATION AND AUDIT SERVICES

2. Revise section 1842.1502 to read as follows:

1842.1502 Policy.

(a) Within 60 days of every anniversary of the award of a contract having a term exceeding one year, contracting officers must conduct interim evaluations of performance on contracts subject to FAR subpart 42.15 and this subpart. On such contracts, both an interim evaluation covering the last period of performance and a final evaluation summarizing all performance must be conducted. However, interim past performance evaluations are optional for SBIR/STTR Phase II, procurements.

[FR Doc. 00–18389 Filed 7–20–00; 8:45 am]

BILLING CODE 7510–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 600 and 660

[Docket No. 991223347–9347; I.D. 071200C]

Fisheries off West Coast States and in the Western Pacific; Pacific Coast Groundfish Fishery; Trip Limit Adjustments

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

ACTION: Fishing restrictions; request for comments.

SUMMARY: NMFS announces changes to trip limits in the Pacific Coast groundfish fishery and the season dates for the limited entry, fixed gear sablefish fishery. These actions, which are authorized by the Pacific Coast Groundfish Fishery Management Plan (FMP), are intended to help the fisheries achieve optimum yield (OY).

DATES: Changes to management measures are effective 0001 hours local time (l.t.) July 18, 2000, except that changes to management measures for minor shelf rockfish and lingcod are effective 0001 hours l.t. August 1, 2000, unless modified, superseded, or rescinded. These changes are in effect until the effective date of the 2001 annual specifications and management measures for the Pacific coast groundfish fishery, which will be published in the **Federal Register**. Comments on this rule will be accepted through August 7, 2000.

ADDRESSES: Submit comments to William Stelle, Jr., Administrator, Northwest Region (Regional Administrator), NMFS, 7600 Sand Point Way NE., BIN C15700, Bldg. 1, Seattle, WA 98115–0070 or to Rodney McInnis, Acting Administrator, Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213.

FOR FURTHER INFORMATION CONTACT: Yvonne deReynier or Katherine King (Northwest Region, NMFS) 206–526–6140.

SUPPLEMENTARY INFORMATION: The following changes to current management measures were recommended by the Pacific Fishery Management Council (Council,) in consultation with the States of Washington, Oregon, and California, at its June 27–30, 2000, meeting in Portland, OR. Pacific coast groundfish landings will be monitored throughout

the year, and further adjustments to the trip limits will be made as necessary to stay within the OYs and allocations announced in the annual specifications and management measures for the groundfish fishery, published in the **Federal Register** (65 FR 221, January 4, 2000, as amended at 65 FR 17805, April 5, 2000; 65 FR 25881, May 4, 2000; 65 FR 31283, May 17, 2000; and 65 FR 33423, May 23, 2000). Unless otherwise specified, these changes are effective through October 31, 2000. At its September meeting, the Council will consider whether changes recommended for August through October should apply also to the November and December fishing periods. If the Council does not recommend changes at that meeting, the trip limits that have already been published for those periods (January 4, 2000, 65 FR 221; May 17, 2000, 65 FR 31283) will remain in effect.

Yellowtail Rockfish Taken in Limited Entry Trawl Fisheries for Flatfish; New Trip Limit for Arrowtooth Flounder

At the June 27–30, 2000, Council meeting, the Council and its advisory entities heard testimony from commercial trawlers that the current combination of yellowtail rockfish and flatfish landings limits and gear requirements were resulting in yellowtail rockfish discard. Under year 2000 management measures, most flatfish taken with small footrope trawl (8 inches, 20 cm, or less in diameter) have no landings limits. Historically, landings for most flatfish have not been restricted because the fisheries have not achieved the acceptable biological catches for those species. To protect non-flatfish species associated with targeted flatfish on the continental shelf, the 2000 management measures encouraged use of small footrope trawls by prohibiting flatfish landings (except Dover and rex soles) taken with large footrope trawl (greater than 8 inches, 20 cm, in diameter). In May, the limits were modified to allow 400 lb (181 kg) of flatfish per trip (excluding Dover and rex soles) with large footrope trawls.

Landings of yellowtail rockfish are lower than expected for this fishery. Yellowtail rockfish may not be landed by vessels fishing with large footrope trawl, and the small footrope bottom trawl limits has been at 1,500 lb (680 kg) per month since the beginning of the year. This is a low limit for this relatively abundant species, which was set to protect overfished species that associate with yellowtail rockfish. By contrast, midwater trawl limits for yellowtail rockfish were higher, at 10,000 lb (4,536 kg) per 2-month period in January through April and at 30,000 lb (13,608 kg) per 2-month period, May through October; overfished species are not vulnerable to midwater trawl gear.

During the summer months, yellowtail rockfish tend to move away from their rockier habitats and associate more closely with flatfish. This seasonal migration, in combination with a low yellowtail rockfish small footrope trawl limit, has resulted in yellowtail rockfish discards for fishers targeting both flatfish and yellowtail rockfish. Trawlers currently use small footrope bottom trawl gear to target the more liberal flatfish limits, but may keep only 1,500 lb (680 kg) of incidentally caught yellowtail rockfish. Any incidentally caught yellowtail rockfish above the 1,500 lb (680 kg) limit is discarded. Trawlers may switch to midwater gear to directly target yellowtail, so as to achieve the 30,000 lb (13,608 kg) landings limit.

To make yellowtail rockfish and flatfish management more consistent with natural catch association patterns and to reduce discards of yellowtail rockfish taken with small footrope bottom trawl gear, the Council recommended a new ''per trip'' limit for yellowtail rockfish taken with small footrope bottom trawl gear equivalent to the sum of 33 percent (by weight) of all flatfish except arrowtooth flounder, plus 10 percent (by weight) of arrowtooth flounder, not to exceed 7,500 lb (3,402 kg,) per trip and not to exceed 30,000 lb (13,608 kg) per 2-month period. This limit prevents direct yellowtail targeting with small footrope bottom trawl gear by restricting all bottom trawl landings of yellowtail rockfish to vessels that also land flatfish. This change is expected to reduce yellowtail rockfish discard by making the management measures more reflective of summer groundfish catch associations while discouraging fishing patterns that would take overfished species. With these protections, the Council could justify recommending an increase in the small footrope trawl 2-month cumulative limit to the same level as the current midwater trawl limit.

In a separate action, the Council recommended increasing the arrowtooth flounder large footrope bottom trawl per trip limit from 400 lb (181 kg) to 5,000 lb (2,268 kg) to accommodate incidental catch in the deeper water fisheries for sablefish, Dover sole, and thornyheads, primarily on the continental slope. Arrowtooth flounder are not a high-value species, and this limit is not expected to increase targeted effort on that species.

Limited Entry Fixed Gear and Open Access Minor Nearshore Rockfish

Minor nearshore rockfish landings in both the limited entry fixed gear and open access fisheries have been low during the first half of 2000. The best available information at the June Council meeting indicated that limited entry fixed gear fisheries had landed 5.2 percent of the allocation for that fishery north of 40°10′ N. lat. and 13.2 percent of the allocation for that fishery south of 40°10′ N. lat. through May 31, 2000. Similarly, the best available information at that meeting also indicated that open access fisheries had landed 14.5 percent of the allocation for that fishery north of 40°10′ N. lat. and 6.4 percent of the allocation for that fishery south of 40°10′ N. lat. To allow fisheries access to these stocks without exceeding 2000 OYs, the Council recommended significant increases to the minor nearshore rockfish landings limits for these two fisheries.

North of 40°10′ N. lat. and starting with the July-August period, the limited entry minor nearshore rockfish fixed gear limit increases from 3,000 lb (1,361 kg) to 5,000 lb (2,268 kg) per 2-month period, and the sublimit for minor nearshore rockfish other than blue or black rockfish increases from 1,400 lb (635 kg) to 1,800 lb (816 kg.) South of 40°10′ N. lat. and starting with the July-August period, the limited entry minor nearshore rockfish fixed gear limit increases from 1,300 lb (590 kg) to 2,000 lb (907 kg) per 2-month period. North of 40°10′ N. lat. and starting with the July-August period, the open access minor nearshore rockfish limit would double from 1,500 lb (680 kg) to 3,000 lb (1,361 kg) per 2-month period, and the sublimit for minor nearshore rockfish other than blue or black rockfish increases from 700 lb (318 kg) to 900 lb (408 kg.) South of 40°10′ N. lat. and starting with the July-August period, the open access minor nearshore rockfish limit doubles from 800 lb (363 kg) to 1,600 lb (726 kg) per 2-month period. With the new management strategies implemented in 2000, it is difficult to predict the effect on industry. Increases in the nearshore rockfish limits increase the risk of reaching an allocation or OY before the end of the year and may result in early closures of the minor nearshore rockfish fishery in the north.

Limited Entry Trawl and Fixed Gear Minor Shelf Rockfish South of 40°10′ N. lat.

The limited entry minor shelf rockfish landings for trawl and fixed gear south of 40°10′ N. lat. were slow in January–April partly because fixed gear shelf

rockfish landings were closed south of 36° N. lat. in January–February, and closed between 40°10′ N. lat. and 36° N. lat. in March–April. Shelf rockfish landings rose in May, and by the end of May the fleet had taken 5.0 percent of the limited entry minor shelf rockfish allocation. Although the overall minor shelf rockfish landings are low, the Council had concerns about shelf rockfish fisheries intercepting bocaccio, an overfished stock. Bocaccio is managed under an overfished species rebuilding plan and is caught incidentally in commercial and recreational fisheries targeting many other different species.

The best available information at the June 2000 Council meeting indicated that the recreational fisheries have exceeded the 45 mt of bocaccio estimated for recreational landings in 2000. In order to protect bocaccio from excess incidental harvest in the commercial fishery, the Council recommended decreasing the limited entry minor shelf rockfish monthly limit for both trawl and fixed gear from 1,000 lb (454 kg) to 500 lb (227 kg) per month effective August 1, 2000. (An earlier effective date would not reduce fishing mortality because most fishers would have taken the July limit of 1,000 lb (454 kg) before this notice would take effect.)

Recreational bocaccio landings occur almost exclusively in California. The State has agreed to ask its Fish and Game Commission, which sets recreational fishing policies in State waters (0–3 nm offshore), to make inseason changes that further reduce recreational fishing pressure on overfished species (bocaccio, lingcod, canary rockfish, cowcod). This may include prohibiting landings of bocaccio taken in State waters for the remainder of 2000. The Council also asked NMFS to coordinate with the State of California to implement consistent changes to recreational rockfish fishery management measures in Federal waters (3–200 nm offshore).

Limited Entry Trawl and Fixed Gear, and Open Access Minor Slope Rockfish South of 40°10′ N. lat.

As with nearshore and shelf rockfish, minor slope rockfish landings south of 40°10′ N. lat. have been slow in the first half of 2000. The best available information at the June Council meeting indicated that limited entry fisheries south of 40°10′ N. lat. had landed 10.1 percent of slope rockfish set aside for those fisheries and that open access fisheries had landed only 1.0 percent of their minor slope rockfish allocation through the end of May 2000. Given these low landings rates, the Council recommended increasing cumulative landings limits to levels that would allow higher landings without jeopardizing overfished and depleted stocks. The Council recommended increasing the limited entry minor slope rockfish cumulative landings limit for both trawl and fixed gear south of 40°10′ N. lat. from 5,000 lb (2,268 kg) to 7,000 lb (3,175 kg) per 2-month period. The Council also recommended increasing the open access, minor slope rockfish cumulative landings limit south of 40°10′ N. lat. from 500 lb (227 kg) to 1,000 lb (454 kg) per 2-month period.

Open Access Fishery for Lingcod to Close August 1, 2000

The best available information at the June Council meeting indicated that the open access fishery will achieve its lingcod allocation before the end of July. This fishery was closed January through April and was scheduled to be closed in November and December, following a 400 lb (181 kg) monthly cumulative limit in May through October 2000. Lingcod is an overfished species managed under a rebuilding plan. To eliminate further open access lingcod landings for the rest of the year, the Council recommended closing open access lingcod landings from August 1 through the end of the year. This closure also applies to vessels in the pink shrimp trawl fishery.

Limited Entry, Fixed Gear and Open Access Daily Trip Limit Fisheries for Sablefish North of 36° N. lat.

Daily trip limit sablefish landings in both the 2000 limited entry fixed gear and the open access fisheries have been relatively low through the spring months. The best available information at the June Council meeting indicated that limited entry fixed gear fisheries had landed 11.9 percent of the sablefish set aside for small daily landings and that the open access fisheries had landed 7.0 percent of their sablefish allocation, both of which are taken under the small landings limit of 300 lb (136 kg) per day. To allow fisheries access to sablefish allocations during the more active summer fishing months, the Council recommended increasing the sablefish 2-month cumulative landings limits for both limited entry and open access fisheries north of 36° N. lat. from 2,400 lb (1,089 kg) to 3,300 lb (1,497 kg.) The 300 lb (136 kg) per day landings limit would remain in effect.

Limited Entry, Fixed Gear, Regular Sablefish Fishery

At its June 2000 meeting, the Council considered season structure options for the 2000 limited entry, fixed gear regular sablefish fishery. For 2000, the Council recommended that the regular season begin on August 6, 2000, at noon l.t. and last for 9 days, ending at noon on August 15, 2000. There will be no limited entry, daily trip limit fishery for sablefish taken with fixed gear during the regular season. During the regular season, each vessel with a limited entry permit and a sablefish endorsement that is registered for use with that vessel may land up to the cumulative trip limit for the tier to which the permit is assigned. The Council recommended the following tier limits: Tier 1, 81,000 lb (36,741 kg); Tier 2, 37,000 lb (16,783 kg); Tier 3, 21,000 lb (9,525 kg). These tier limits are expected to keep the overall fleet landings from exceeding the 2065.5 mt of sablefish available to this fishery.

The pre-season and post-season closures described for this fishery at 50 CFR 660.323 (a)(2) will be in effect. The pre-season closure will begin on August 4, 2000, at noon l.t., last for 48 hours, and end when the regular season begins on August 6, 2000, at noon l.t. During the pre-season closure, sablefish taken with fixed gear in the limited entry or open access fisheries north of 36° N. lat. may not be retained or landed. Also during the pre-season closure, all fixed gear used to take and retain groundfish must be out of the water. The post-season closure will begin when the regular season ends on August 15, 2000, at noon l.t., last for 30 hours, and end on August 16, 2000, at 1800 hours l.t. No sablefish taken with fixed gear north of 36° N. lat. during the post-season closure may be retained. Sablefish taken and retained during the regular season may be possessed and landed during the post-season closure, and gear may remain in the water during the post-season closure. However, during the post-season closure, fishers may not set or pull from the water fixed gear used to take and retain groundfish.

Fixed Gear Permit Transfers

Under 50 CFR 660.333, limited entry permits may not be transferred more than once every 12 months, and permit transfers are effective only on the first date of a major cumulative limit period. Each year, the major cumulative limit periods are defined in the annual specifications and management measures according to when the Council schedules its cumulative limit periods for the majority of the groundfish fleet. In 1999 and prior years, trawl and fixed gear landings limit periods have been the same for most species. However, the 2000 annual specifications and management measures set separate cumulative limit periods and

cumulative landings limits for limited entry trawl gear and for fixed gear.

Under 50 CFR 660.333, limited entry permits may not be transferred more than once every 12 months, and permit transfers are effective only on the first date of a major cumulative limit period. Each year, the major cumulative limit periods are defined in the annual specifications and management measures according to when the Council schedules its cumulative limit periods for the majority of the groundfish fleet. In 1999 and prior years, trawl and fixed gear landings limit periods have been the same for most species. However, the 2000 annual specifications and management measures set separate cumulative limit periods and cumulative landings limits for limited entry trawl gear and for fixed gear.

In July 1999, about 20 fixed gear permit holders transferred their permits so that the transfers would be effective in time for the August 1999 regular sablefish fishery. Changes to the major cumulative landings limits periods in 2000 meant that the first start date of a major cumulative limit period after July 1, 2000, was September 1, 2000. Thus, permit holders constrained by the regulatory restriction of one transfer every 12 months who had last transferred their permits in July 1999 would have missed the August 2000 fixed gear regular sablefish season, described above. The restriction that requires that permit transfers become effective on the first date of a major cumulative limit period would have prevented these permit holders from transferring their permits until September 1, 2000. Several of these permit holders testified at the June 2000 Council meeting that without changes to these restrictions, they would not be able to participate in the primary sablefish fishery. For participants in this fishery, this opportunity is often a significant portion of their annual incomes. To ensure that these 20 permit holders have the opportunity to transfer their permits and to participate in the regular fixed gear sablefish fishery, the Council recommended at its June 2000 meeting that a major cumulative trip limit period be added at August 1, 2000, for limited entry fixed gear fisheries, for purposes of allowing permit transfers in 2000. This added major cumulative limit period start date reflects the primarily month-long cumulative limit periods for limited entry fixed gear fisheries. The regulatory restriction that limited entry permit transfers may not occur more than once every 12 months would not be altered by this change to major cumulative limit start dates.

NMFS Actions

For the reasons stated here, NMFS concurs with the Council's recommendations and announces the following changes to the 2000 annual management measures (65 FR 221, January 4, 2000, as amended at 65 FR 17805, April 5, 2000, 65 FR 25881, May 4, 2000, 65 FR 31283, May 17, 2000, and 65 FR 33423, May 23, 2000) as follows:

In Section IV, paragraph (15), under A. *General Definitions and Provisions*, and paragraph (2)(b)(i); under B. *Limited Entry Fishery*, are revised; under C. *Trip Limits in the Open Access Fishery*, a new paragraph (3)(a)(ii)(C) is added; and Tables 3, 4, and 5 are revised to read as follows:

IV. NMFS Actions

* * * * *

A. General Definitions and Provisions

* * * * *

(15) *Permit transfers.* Limited entry permit transfers are to take effect only on the first day of a major cumulative limit period (50 CFR 660.333(c)(1)), which in 2000 are January 1, March 1, May 1, July 1, September 1, and November 1, and are delayed by 15 days (starting on the 16th of a month) for the ''B'' platoon. For limited entry fixed gear (longline and pot) permits, August 1 is also the first day of a major cumulative limit period.

* * * * *

B. Limited Entry Fishery

* * * * *

BILLING CODE 3510–22–F

Table 3. 2000 Trip Limits 1/ and Gear Requirements 2/ for Limited Entry Trawl Gear

Read Section IV. A. NMFS Actions before using this table.

line	Species/groups	JAN-FEB	MAR-APR	MAY-JUN	JUL-AUG	SEP-OCT	NOV-DEC
1	**Minor slope rockfish**						
2	North	3,000 lb / 2 months		5,000 lb / 2 months			1,500 lb / month
3	South	3,000 lb / 2 months		May-Jun, 5,000 lb / 2 months; Jul-Oct, 7,000 lb / 2 months			1,500 lb / month
4	**Splitnose**-South	8,500 lb / 2 months		14,000 lb / 2 months			4,000 lb / month
5	**POP**-North	500 / month		2,500 lb / month			500 lb / month
6	**Sablefish**	7,000 lb / 2 months; 22-inch size limit 3/		10,000 lb / 2 months; 22-inch size limit 3/			3,500 lb / month ; 22-inch size limit 3/
7	**Longspine thornyhead**	12,000 lb / 2 months		4,000 lb / 2 months			6,000 lb / month
8	**Shortspine thornyhead**	3,000 lb / 2 months		1,000 lb / 2 months			1,500 lb / month
9	**Dover sole**	55,000 lb / 2 months		20,000 lb / 2 months			20,000 lb/ month
10	**Arrowtooth flounder**	10,000 lb / trip		Small footrope: May-Oct, no pound limit 2/; Large footrope: May-Jun, in "other flatfish" limit; Jul-Oct, 5,000 lb/trip			10,000 lb / trip
11	**Petrale sole**	No restriction	Small footrope required	Small footrope--No pound limit; Large footrope--Included in "other flatfish" trip limit 2/			No restriction
12	**Rex sole**	No limit					
13	**Other flatfish 4/**	Small footrope--No pound limit; Large footrope--400 lb per trip 2/					
14	**Whiting shoreside 5/**	20,000 lb / trip before primary season		Primary season			20,000 lb / trip after primary season
15							
16	**Use of small footrope bottom trawl or midwater trawl required for landing all the following species: 6/**						
17	**Minor Shelf rockfish**						
18	North	300 lb / month		1,000 lb / month			300 lb / month
19	South	500 lb / month		May-Jul, 1,000 lb / month; Aug-Oct, 500 lb / month			500 lb / month
20	**Canary rockfish**	100 lb / month		300 lb / month			100 lb / month
21	**Widow rockfish**						
22	mid-water trawl	30,000 lb / 2 months		30,000 lb / 2 months			30,000 lb / 2 months
23	small footrope trawl	1,000 lb / month		1,000 lb / month			1,000 lb / month
24	**Yellowtail**-North 7/						
25	mid-water trawl	10,000 lb / 2 months		30,000 lb / 2 months			10,000 lb / 2 months
26	small footrope trawl	1,500 lb / month		May-Jun, 1,500 lb / month. Jul-Oct, per trip limit is sum of 33 percent (by weight) of all flatfish except arrowtooth flounder, plus 10 percent (by weight) of arrowtooth flounder; not to exceed 7,500 lb/trip, and 30,000 lb/2 months. Yellowtail rockfish may not be landed without flatfish.			1,500 lb / month
27	**Bocaccio**-South 7/	300 lb / month		500 lb / month			300 lb / month
28	**Chilipepper**-South 7/						
29	mid-water trawl	25,000 lb / 2 months		25,000 lb / 2 months			25,000 lb / 2 months
30	small footrope trawl	7,500 lb / 2 months		7,500 lb / 2 months			7,500 lb / 2 months
31	**Cowcod** - South 7/	1 fish per landing		1 fish per landing			1 fish per landing
32	**Minor Nearshore rockfish**						
33	North and South	200 lb / month		200 lb / month			200 lb / month
34	**Lingcod**	CLOSED		400 lb / month; 24-inch size limit 8/			CLOSED

1/ Trip limits apply coastwide unless otherwise specified. North means 40°10' N.lat. to the US-Canada border. "South" means 40°10' N.lat. to the US-Mexico border. 40°10' N.lat. is about 20 nm south of Cape Mendocino CA.

2/ Gear requirements and prohibitions are explained at paragraph IV.A.(14).

3/ No more than 500 lb/trip of sablefish smaller than 22 inches (56 cm) total length, which counts toward cumulative limit.

4/ Other flatfish means all flatfish at 50 CFR 660.302 except those in this Table 3 with a trip limit (excludes rex sole and arrowtooth flounder.)

5/ The whiting "per trip" limit in the Eureka area inside 100 fm is 10,000 lb / trip throughout the year (See IV.B.(3)(c)).

6/ Small footrope trawl means a bottom trawl net with a footrope no larger than 8 inches (20 cm) in diameter. Midwater gear also may be used; the footrope must be bare. See paragraph IV.A.(14).

7/ Yellowtail rockfish and POP in the south and bocaccio, chilipepper, and cowcod rockfishes in the north are included in the trip limits for minor shelf rockfish in the appropriate area (Table 2).

8/ Lingcod must be greater than or equal to 24 inches (61 cm) total length. See IV.A.(6).

To convert pounds to kilograms, divide by 2.20462, the number of pounds in one kilogram.

Table 4. 2000 Trip Limits 1/ for Limited Entry Fixed Gear

Read Section IV. A. NMFS Actions before using this table.

line	Species/groups	JAN-FEB	MAR-APR	MAY-JUN	JULY-AUG	SEP-OCT	NOV-DEC
1	**Minor slope rockfish**						
2	North	3,000 lb / 2 months		5,000 lb / 2 months			1,500 lb / month
3	South	3,000 lb / 2 months		May-Jun, 5,000 lb / 2 months; Jul-Oct, 7,000 lb / 2 months			1,500 lb / month
4	**Splitnose-South**	8,500 lb/2 mo.		14,000 lb / 2 months			4,000 lb / month
5	**POP-North**	500 lb / month		2,500 lb / month			500 lb / month
6	**Sablefish** (daily trip limit fishery) 2/						
7	North of 36 ° N. lat.	300 lb/day, 2,100 lb/2 mo OR 1 landing between 300 lb and 600 lb/ week, less than 1,800 lb/2 mo		May-Jun, 300 lb/day, 2,400 lb/2 mo; Jul-Oct, 300 lb/day, 3,300 lb/2 mo			300 lb / day, 2,400 lb / 2 months
8	South of 36 ° N. lat.	350 lb/day or 1 landing above 350 lb/week, up to 1,050 lb					
9	**Longspine thornyhead**	12,000 lb / 2 months		4,000 lb / 2 months			6,000 lb / month
10	**Shortspine thornyhead**	1,000 lb / month		1,000 lb / month			1,000 lb / month
11	**Dover sole**	55,000 lb / 2 months		20,000 lb / 2 months			20,000 / month
12	**Arrowtooth flounder**	10,000 lb / trip		No restriction			10,000 lb / trip
13	**Petrale sole**	No restriction		No restriction			No restriction
14	**Rex sole**	No restriction		No restriction			No restriction
15	**Other flatfish 3/**	No restriction		No restriction			No restriction
16	**Shoreside whiting 4/**	20,000 lb / trip		Open			20,000 lb / trip
17	**Minor shelf rockfish**						
18	North	300 lb / month		1,000 lb / month			300 lb / month
19	South	500 lb / month 5/		May-Jul, 1,000 lb/month; Aug-Oct, 500 lb/month			500 lb / month
20	**Canary-Coastwide**						
21	North	100 lb / month		300 lb / month			100 lb / month
22	South	100 lb / month 5/		300 lb / month			100 lb / month
23	**Widow rockfish-Coastwide:**						
24	North	3,000 lb / month		3,000 lb / month			3,000 lb / month
25	South	3,000 lb/month 5/		3,000 lb / month			3,000 lb / month
26	**Yellowtail-North 6/**	1,500 lb / month		1,500 lb / month			1,500 lb / month
27	**Bocaccio-South 6/**	300 lb/ month 5/		500 lb / month			300 lb / month
28	**Chilipepper-South 6/**	2,000 lb /month 5/		2,000 lb / month			2,000 lb / month
29	**Cowcod - South 6/**	1 fish per landing 5/					
30	**Minor nearshore rockfish**						
31	North 7/ 8/	2,400 lb/2 months, of which no more than 1,200 lb may be species other than black or blue rockfish		May-Jun, 3,000 lb/2 months, of which no more than 1,400 lb may be species other than black or blue rockfish; Jul-Oct, 5,000 lb/2 months of which no more than 1,800 lb may be species other than black or blue rockfish			3,000 lb/2 months, of which no more than 1,400 lb may be species other than black or blue rockfish
32	South	1,000 lb / 2 months 5/		May-Jun, 1,300 lb/2 months;			1,300 lb / 2 months
33				Jul-Oct, 2,000 lb/2 months			
34	**Lingcod 8/**	CLOSED		400 lb / month			CLOSED

1/ Trip limits apply coastwide unless otherwise specified. North means 40°10' N.lat. to the US-Canada border. South means 40 10' N. lat. to the US-Mexico border.

2/ The sablefish size limit applies only during the "regular" and "mop-up" seasons north of 36° N. lat. See IV.B.(2).

3/ Other flatfish means all flatfish listed at 50 CFR 660.302 except those in this Table 4 with a trip limit.

4/ The whiting "per trip" limit in the Eureka area for catch inside 100 fathoms is 10,000 lb / trip throughout the year.

5/ South of 40°10' N. lat., minor shelf and minor nearshore rockfish, as well as canary, widow, bocaccio, chilipepper, and cowcod were managed with area closures in Jan-Apr. In Jan-Feb, limited entry fixed gear fisheries for these species were closed south of 36° N. lat., yet open with limits shown between 40°10' N. lat. and 36° N. lat. In Mar-Apr, these fisheries were closed between 40°10' N. lat and 36° N. lat., yet open with limits shown in waters south of 36° N. lat. "Closed" means it is prohibited to take and retain, possess, or land the designated species in the time or area indicated (see IV.A.(7)).

6/ Yellowtail rockfish and POP in the south and bocaccio, chilipepper, and cowcod rockfishes in the north are included in trip limits for minor shelf rockfish (Table 2).

7/ The "per trip" limit for black rockfish off Washington also applies. See paragraph IV.B.(4).

8/ The size limit for lingcod is 24 inches (61 cm) in the north and 26 inches (66 cm) in the south, total length.

To convert pounds to kilograms, divide by 2.20462, the number of pounds in one kilogram.

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(2) * * *

(b) * * *

(i) *Regular season*. The regular season will begin at 12 noon l.t. on August 6, 2000, and end at noon on August 15, 2000. Pre-season and post-season closures described at 50 CFR 660.323(a)(2) are in effect. The pre-season closure will begin at 12 noon l.t. on August 4, 2000, and end when the regular season begins, at 12 noon l.t. on August 6, 2000. The post-season closure will begin when the regular season ends at noon (local time) on August 15, 2000, and end at 1800 hours (local time) on August 16, 2000. During the regular season, each vessel with a limited entry permit with a sablefish endorsement that is registered for use with that vessel may land up to the cumulative trip limit for the tier to which the permit is assigned. For 2000, the following tier limits are in effect: Tier 1, 81,000 lb (36,741 kg); Tier 2, 37,000 lb (16,783 kg); Tier 3, 21,000 lb (9,525 kg).

* * * * *

C. Trip Limits in the Open Access Fishery

Table 5. 2000 Trip Limits 1/ for All Open Access Gear except Exempted Trawl Gear Engaged in Fishing for Pink Shrimp

Read Section IV. A. NMFS Actions before using this table.

line	Species/groups	JAN-FEB	MAR-APR	MAY-JUN	JULY-AUG	SEP-OCT	NOV	DEC
1	**Minor slope rockfish**							
2	North	500 lb / 2 months		500 lb / 2 months			500 lb / 2 months	
3	South	500 lb / 2 months		May-Jun, 500 lb / 2 months; Jul-Oct, 1,000 lb / 2 months			500 lb / 2 months	
4	**Splitnose**-South	200 lb / month		200 lb / month			200 lb / month	
5	**POP**--North	100 lb / month		100 lb / month			100 lb / month	
6	**Sablefish 2/**							
7	North of 36°	300 lb / day, but no more		May-Jun, 300 lb / day, 2,400 lb 2 months			300 lb / day, but no more	
8		than 2,100 lb / 2 months		Jul-Oct, 300 lb / day, 3,300 lb / 2 months			than 2,400 lb / 2 months	
9	South of 36°	350 lb / day		350 lb / day			350 lb / day	
10	**Thornyheads (longspine and shortspine combined)**							
11	North of Pt. Conception	CLOSED 3/		CLOSED			CLOSED	
12	South of Pt. Conception	50 lb / day		50 lb / day			50 lb / day	
13	**Arrowtooth**	200 lb / month		200 lb / month			200 lb / month	
14	**Dover sole**	(included in "other" flatfish limit)						
15	**Petrale sole**	(included in "other" flatfish limit)						
16	**Nearshore flatfish**	(included in "other" flatfish limit)						
17	**"Other" flatfish 4/**	300 lb / month		300 lb / month			300 lb / month	
18	**Shoreside whiting**	300 lb / month		300 lb / month			300 lb / month	
19	**Minor shelf rockfish**							
20	North	100 lb / month		100 lb / month			100 lb / month	
21	South	200 lb/ month 5/		200 lb / month			200 lb / month	
22	**Canary**							
23	North	50 lb / month		50 lb / month			50 lb / month	
24	South	50 lb / month 5/		50 lb / month			50 lb / month	
25	**Widow**							
26	North	3,000 lb / month		3,000 lb / month			3,000 lb / month	
27	South	3,000 lb / month 5/		3,000 lb / month			3,000 lb / month	
28	**Yellowtail**-North 6/	100 lb / month		100 lb / month			100 lb / month	
29	**Bocaccio** - South 6/	200 lb / month 5/		200 lb / month			200 lb / month	
30	**Chilipepper**-South 6/	2,000 lb / month 5/		2,000 lb / month			2,000 lb / month	
31	**Cowcod** - South 6/	1 fish per landing 5/		1 fish per landing			1 fish per landing	
32	**Minor nearshore rockfish**							
33	North 7/8/	1,000 lb / 2 months, of which no more than 500 lb may be species other than black or blue rockfish		May-Jun, 1,500 lb/2 mo, of which no more than 700 lb may be species other than black or blue rockfish; 2,500 lb/2 mo; Jul-Oct, 3,000 lb/2 mo, of which no more than 900 lb may be species other than black or blue rockfish			1,00 lb / 2 months, of which no more than 00 lb may be species other than black or blue rockfish	
34	South	550 lb / 2 months 5/		May-Jun, 800 lb/2 months;			800 lb / 2 months	
35				Jul-Oct, 1,600 lb / 2 months				
36	**Lingcod 9/**	CLOSED		May-Jul, 400 lb/month; Aug-Oct, CLOSED.			CLOSED	

1/ Trip limits apply coastwide unless otherwise specified. North means 40°10' N. lat. to the US-Canada border. "South" means 40°10' N. lat. to the US-Mexico border.

2/ There is no size limit for sablefish taken and retained with nontrawl gear in the open access fishery. See IV.B.2.

3/ Closed means it is prohibited to take and retain, possess, or land the species in the time or area indicated (see IV.A.(7)).

4/ Other flatfish means all flatfish listed at 50 CFR 660.302 except those in this Table 5 with a trip limit.

5/ South of 40° 10' N. lat., minor shelf and nearshore rockfish, as well as canary, widow, bocaccio, chilipepper, and cowcod were managed with area closures in Jan-Apr. In Jan/Feb, open access fisheries for these species were closed south of 36° N. lat., yet open with limits shown between 40° 10' N. lat. and 36° N. lat. In Mar/Apr these fisheries were closed between 40° 10' N. lat. and 36° N. lat., and open with limits shown in waters south of 36° N. lat. (see IV.A.(7)).

6/ Yellowtail rockfish and POP in the south and bocaccio, chilipepper, and cowcod rockfishes in the north are included in the trip limits for minor shelf rockfish in the appropriate area (Table 2).

7/ The "per trip" limit for black rockfish off Washington also applies. See paragraph IV.B.(4).

8/ Provisions for landing groundfish in Pacific City, OR are found at paragraph IV.C.(4).

9/ The size limit for lingcod is 24 inches (61 cm) in the north and 26 inches (66 cm) in the south, total length (May through July.)

To convert pounds to kilograms, divide by 2.20462, the number of pounds in one kilogram.

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(3) * * *

(a) * * *

(ii) * * *

(C) August 1–December 31, 2000: closed.

Classification

These actions are authorized by the regulations implementing the FMP and the annual specifications and management measures and by the emergency rule published at 65 FR 221 (January 4, 2000) and are based on the most recent data available. The aggregate data upon which these actions are based are available for public inspection at the office of the Administrator, Northwest Region, NMFS (see **ADDRESSES**) during business hours.

NMFS finds good cause to waive the requirement to provide prior notice and comment on this action pursuant to 5 U.S.C. 553(b)(B) because providing prior notice and opportunity for comment would be impracticable. It would be impracticable because the current cumulative limit period began on July 1, 2000, and affording additional notice and opportunity for public comment would impede the due and timely execution of the agency's function of managing fisheries to achieve OY. The increases to trip limits and the addition of a major cumulative limit period for fixed gear relieve burdens on the public. In addition, the affected public had the opportunity to comment on these actions at the June 27–30, 2000, Council meeting. This action should be implemented as close as possible to the beginning of the cumulative trip limit period to avoid confusion and provide fishers the opportunity to achieve the increased trip limits and arrange for permit transfers. The reduced limits and closures that take effect August 1 are intended to prevent overfishing or to protect overfished species. For these reasons, good cause exists to waive the 30-day delay in effectiveness.

These actions are taken under the authority of 50 CFR 660.323(b)(1) and are exempt from review under Executive Order 12866.

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

Dated: July 18, 2000.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 00–18534 Filed 7–18–00; 8:45 am]

BILLING CODE 3510–22–F

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 000706201–0201–01; I.D. 060700A]

RIN 0648–AO00

Fisheries of the Exclusive Economic Zone Off Alaska; Removal of Vessel Moratorium of the GOA and BSAI

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

ACTION: Final rule; technical amendment.

SUMMARY: NMFS issues a final rule to remove the obsolete text implementing the Vessel Moratorium Program (VMP), which expired on December 31, 1999, and was replaced by the License Limitation Program (LLP). In addition, several paragraphs in the regulations are revised to account for the removal of the moratorium text. These revisions are necessary to remove obsolete text, clarify and simplify existing text, promote compliance with the regulations, and facilitate enforcement efforts. This action is intended to further the goals and objectives of the Federal fishery management programs for crab groundfish fisheries off Alaska.

DATES: Effective July 21, 2000.

FOR FURTHER INFORMATION CONTACT: Patsy A. Bearden, 907–586–7228.

SUPPLEMENTARY INFORMATION:

Background

NMFS manages the groundfish fisheries in the Exclusive Economic Zone (EEZ) off Alaska and the crab fisheries in the EEZ of the Bering Sea and Aleutian Islands area according to fishery management plans (FMPs) prepared by the North Pacific Fishery Management Council (Council) under the authority of the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C., 1801 *et seq.* The FMPs are implemented by regulations at 50 CFR part 679. General regulations that also pertain to these fisheries appear in subpart H of 50 CFR part 600.

NMFS published a final rule in the **Federal Register** on August 10, 1995, (60 FR 40763) implementing the VMP and, on January 25, 1999 (64 FR 3651), published a final rule extending the program for 1 year. The VMP expired on December 31, 1999, when it was succeeded by the LLP, which became effective on January 1, 2000. This technical amendment is designed to remove obsolete regulatory text that implemented the VMP without making any substantive change in the LLP implementing regulations or other rules.

The changes implemented with this rule in each section are described as nfollows.

Purpose and Scope (§ 679.1)

Paragraph (c) is removed and reserved because it is no longer effective.

Definitions (§ 679.2)

Definitions of terms that were relevant only to the VMP are removed. Some defined terms that also are used in existing and currently effective regulations are revised or renumbered to remove only the parts of the definitions that were applicable to the VMP. Terms and their definitions that are removed by this action are ''Lost or destroyed vessel,'' ''Moratorium crab species,'' ''Moratorium groundfish species,'' ''Moratorium species,'' ''Moratorium qualification,'' ''Original qualifying LOA,'' ''Original qualifying vessel,'' and ''Qualifying period.'' Definitions of terms that are revised or renumbered by this action are ''Catcher/processor,'' ''Catcher vessel,'' ''Directed fishing,'' ''Maximum LOA (MLOA),'' ''Person,'' and ''Reconstruction.''

Permits (§ 679.4)

Criteria required for a VMP permit specified at § 679.4(c) are no longer effective and are removed by this action. Paragraph (c) is reserved to maintain the designation sequence of the succeeding paragraphs. Some of these VMP permit criteria were integrated into the LLP and were referenced in the LLP qualification requirements at § 679.4(k). Hence, this action revises regulations implementing the LLP at § 679.4(k)(4) to add specified VMP qualification criteria that are included in the LLP licensing criteria previously included only by reference.

Prohibitions (§ 679.7)

Paragraphs (d)(13) and (14) in § 679.7 are revised by substituting the term ''license limitation groundfish'' for the term ''moratorium groundfish species.'' This change is made necessary by the substitution of the LLP for the VMP. Also in paragraph (e) of this section, the heading and text are removed and the paragraph reserved. Although paragraph (e) did not explicitly expire with the VMP, its continued existence no longer is necessary and could be confusing if it were not removed.

Western Alaska Community Development Quota Program (CDQ) (§ 679.30)

A reference in paragraph (a)(5)(i)(A)(*1*) of this section to catcher vessels and catcher/processors that could be exempt from the VMP is revised to reference the same exemption provided under the LLP. Although the Council originally recommended that this exemption for specific CDQ vessels be transferred to the LLP, more recently, it recommended its deletion because it is no longer necessary. Removing the CDQ exemption is beyond the scope of this action and will be included in a future proposed rule.

Classification

Because this technical amendment makes only minor, non-substantive changes to an existing rule, NMFS finds that there is good cause to waive the requirement to provide notice and an opportunity for public comment, pursuant to authority set forth at 5 U.S.C. 553(b)(B), as such procedures are unnecessary. For the same reasons, NMFS finds good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effective date.

Because prior notice, delayed effectiveness and opportunity for public comment are not required for this final rule by U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

List of Subjects in 50 CFR Part 679

Alaska, Fisheries, Recordkeeping and reporting requirements.

Dated: July 9, 2000.

Penelope D. Dalton,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set forth in the preamble, 50 CFR part 679 is amended as follows:

PART 679—FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA

1. The authority citation for 50 CFR part 679 continues to read as follows:

Authority: 16 U.S.C. 773 *et seq.*, 1801 *et seq.*, and 3631 *et seq.*

§ 679.1 [Amended]

2. In § 679.1, paragraph (c) is removed and reserved.

3. In § 679.2, definitions for the terms ''Lost or destroyed vessel (applicable through December 31, 1998),'' ''Moratorium crab species (applicable through December 31, 1999),'' ''Moratorium groundfish species (applicable through December 31, 1999),'' ''Moratorium qualification (applicable through December 31, 1999),'' ''Moratorium species,'' ''Original qualifying LOA (applicable through December 31, 1999),'' ''Original qualifying vessel (applicable through December 31, 1999),'' ''Qualifying period (applicable through December 31, 1999),'' and ''Reconstruction (applicable through December 31, 1999)'' are removed, definitions for the terms ''Catcher/processor,'' ''Catcher vessel'' ''Directed fishing,'' ''Maximum LOA (MLOA)'', and ''Person,'' are revised, and a new definition of ''Reconstruction'' is added to read as follows:

§ 679.2 Definitions.

* * * * *

Catcher/processor means:

(1) *With respect to groundfish recordkeeping and reporting*, a vessel that is used for catching fish and processing that fish.

(2) *With respect to subpart E of this part*, a processor vessel that is used for, or equipped to be used for, catching fish and processing that fish.

* * * * *

Catcher vessel means a vessel that is used for catching fish and that does not process fish on board.

* * * * *

Directed fishing means:

(1) *With respect to groundfish recordkeeping and reporting*, any fishing activity that results in the retention of an amount of a species or species group on board a vessel that is greater than the maximum retainable bycatch amount for that species or species group as calculated under § 679.20.

(2) *With respect to license limitation groundfish species*, directed fishing as defined in paragraph (1) of this definition, or, with respect to license limitation crab species, the catching and retaining of any license limitation crab species.

(3) (*Applicable through July 20, 2000*) *With respect to the harvest of groundfish by AFA catcher/processors and AFA catcher vessels*, any fishing activity that results in the retention of an amount of a species or species group on board a vessel that is greater than the maximum retainable bycatch amount for that species or species group as calculated under § 679.20.

* * * * *

Maximum LOA (MLOA) means, with respect to the groundfish and crab license limitation program, the LOA of the vessel on June 24, 1992, unless the vessel was less than 125 ft (38.1 m) on June 24, 1992, then 1.2 times the LOA of the vessel on June 24, 1992, or 125 ft (38.1 m), whichever is less. However, if the vessel was under reconstruction on June 24, 1992, then the basis for the MLOA will be the LOA of the vessel on the date that reconstruction was completed and not June 24, 1992. The following exceptions apply regardless of how the MLOA was determined.

(1) If the vessel's LOA on June 17, 1995, was less than 60 ft (18.3 m), or if the vessel was under reconstruction on June 17, 1995, and the vessel's LOA on the date that reconstruction was completed was less than 60 ft (18.3 m), then the vessel's MLOA cannot exceed 59 ft (18 m).

(2) If the vessel's LOA on June 17, 1995, was greater than or equal to 60 ft (18.3 m) but less than 125 ft (38.1 m), or if the vessel was under reconstruction on June 17, 1995, and the vessel's LOA on the date that reconstruction was completed was greater than or equal to 60 ft (18.3 m) but less 125 ft (38.1 m), then the vessel's MLOA cannot exceed 124 ft (37.8 m).

(3) If the vessel's LOA on June 17, 1995, was 125 ft (38.1 m) or greater, then the vessel's MLOA is the vessel's LOA on June 17, 1995, or if the vessel was under reconstruction on June 17, 1995, and the vessel's LOA on the date that reconstruction was completed was 125 ft (38.1 m) or greater, then the vessel's MLOA is the vessel's LOA on the date reconstruction was completed.

* * * * *

Person means:

(1) *For IFQ and CDQ Programs and General Usage* the term ''person'' means any individual who is a citizen of the United States or any corporation, partnership, association, or other entity (or its successor-in-interest), regardless of whether organized or existing under the laws of any state, who is a U.S. citizen.

(2) *For High Seas Salmon Fishery permits* issued under § 679.4(h), the term ''person'' excludes any nonhuman entity.

* * * * *

Reconstruction means a change in the LOA of the vessel from its original qualifying LOA.

* * * * *

4. In § 679.4, paragraph (c) is removed and reserved, and paragraphs (k)(4)(i)(A)(*3*), (k)(4)(i)(B)(*3*), and (k)(5)(i)(B) are revised to read as follows:

§ 679.4 Permits.

* * * * *

(k) * * *
(4) * * *
(i) * * *
(A) * * *

(*3*) January 1, 1988, through June 17, 1995, provided that, during the period January 1, 1988, through February 9, 1992, the vessel made a legal landing of any king or Tanner crab species harvested in the Bering Sea and Aleutian Islands Area, and, during the period February 10, 1992, through December 11, 1994, made a legal landing of any groundfish species harvested in the GOA or BSAI using trawl gear or a legal landing harvested in the GOA or BSAI of any groundfish species using longline gear, except sablefish landed using fixed gear.

(B) * * *

(*3*) January 1, 1988, through June 17, 1995, provided that, during the period January 1, 1988, through February 9, 1992, the vessel made a legal landing of any king or Tanner crab species harvested in the Bering Sea and Aleutian Islands Area, and during the period February 10, 1992, through December 11, 1994, made a legal landing of any groundfish species harvested in the GOA or BSAI using trawl gear or a legal landing of any groundfish species harvested in the GOA or BSAI using longline gear, except sablefish landed using fixed gear.

* * * * *

(5) * * *
(i) * * *

(B) At least one documented harvest of any amount of crab species must have been made from a vessel between January 1, 1988, and December 31, 1994, providing that, during the period January 1, 1988, through February 9, 1992, the vessel for which the documented harvest was made also made a legal landing of any groundfish species harvested in the GOA or BSAI with any authorized gear, except sablefish caught with fixed gear, and, during the period February 10, 1992, through December 11, 1994, made a legal landing of any king or Tanner crab species harvested in the Bering Sea and Aleutian Islands Area.

* * * * *

5. In § 679.7, paragraphs (d)(13) and (d)(14) are revised to read as set forth below and paragraph (e) is removed and reserved:

§ 679.7 Prohibitions.

* * * * *

(d) * * *

(13) For the operator of a catcher vessel, catch, retain on board, or deliver groundfish CDQ species together with license limitation groundfish.

(14) For the operator of a catcher/processor, catch groundfish CDQ species together with license limitation groundfish in the same haul, set, or pot.

* * * * *

6. In § 679.30, paragraph (a)(5)(i)(A)(*1*) is revised to read as follows:

§ 679.30 General CDQ regulations

(a) * * *

(5) * * *

(i) * * *

(A) * * *

(*1*) *Information required for all vessels.* A list of the name, Federal fisheries permit number (if applicable), ADF&G vessel number, LOA, gear type, and vessel type (catcher vessel, catcher/processor, or mothership). For each vessel, report only the gear types and vessel types that will be used while CDQ fishing. Any CDQ vessel that is exempt from license limitation requirements under § 679.4(k)(2)(iv) of this part must be identified as such.

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[FR Doc. 00–18564 Filed 7–20–00; 8:45 am]
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Proposed Rules

Federal Register
Vol. 65, No. 141
Friday, July 21, 2000

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

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

7 CFR Part 4280

Notice of Public Meeting on the Rural Economic Development Loan and Grant Program Proposed Rule

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice of public meeting.

SUMMARY: This Notice announces a Public Meeting on the Rural Economic Development Loan and Grant Program. On December 15, 1999, (64 FR 69937), the Agency published a proposed rule on the Rural Economic Development Loan and Grant Program. The public comment period on the proposed rule was extended through February 14, 2000. During the comment period, the Agency received 28 written comments. The Agency has decided to conduct a single meeting on this proposed rule. The intent of the meeting is to allow the Agency to listen to oral presentations from the general public on the proposed rule.

DATES: The meeting, which is open to the general public, will be conducted on August 2, 2000. The meeting will begin at 9:00 a.m. and conclude no later than 12:00 noon.

ADDRESSES: The meeting will be held in the Jefferson Auditorium, U.S. Department of Agriculture, South Building, 1400 Independence Avenue, SW., Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: If you wish to make an oral presentation, please contact Cheryl Thompson, Rural Development, U.S. Department of Agriculture, via fax on (202) 692–0013 or send an e-mail message to *cthompso@rus.usda.gov* at least three (3) business days before the hearing. Please indicate any special needs. You should receive a confirmation by telephone or e-mail that the Agency has received your request.

The Agency will listen to each presentation at the hearing. If a large number of participants desires to make presentations, a time limitation will be imposed on each presentation. Since this is a listening session and the rule is still being developed, Agency officials will not be responding to the comments during the hearing. The Agency will respond to the comments made at the hearing in the preamble to the final rule as part of the rule-making process under the Administrative Procedures Act. Since the Agency received written comments on the rule during the comment period, the Agency will not be accepting additional written comments on the proposed rule. The presentation may not include questions for other attendees of the general public or Agency officials, nor may it address comments to other attendees of the general public. If you have questions about the meeting or proposed rule, you may contact Mark Wyatt, Specialty Lenders Division, Rural Business-Cooperative Service, U.S. Department of Agriculture, STOP 3225, 1400 Independence Ave. SW, Washington, DC 20250–3225, Telephone (202) 720–2383 or e-mail *mwyatt@rus.usda.gov.*

Dated: July 13, 2000.

Wilbur T. Peer,

Acting Administrator, Rural Business-Cooperative Service.

[FR Doc. 00–18324 Filed 7–20–00; 8:45 am]

BILLING CODE 3410–XY–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–CE–29–AD]

RIN 2120–AA64

Airworthiness Directives; The New Piper Aircraft, Inc. Models PA–31, PA–31–300, PA–31–325, PA–31–350, PA–31P, PA–31T, PA–31T1, PA–31T2, PA–31T3, and PA–31P–350 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to supersede three existing airworthiness directives (AD's) that apply to certain The New Piper Aircraft, Inc. (Piper) Models PA–31, PA–31–300, PA–31P, PA–31T, and PA–31T1 airplanes. These AD's currently require you to repetitively inspect and/or modify the elevator structure. The proposed AD would: initially retain the inspection and modification requirements that are currently required; add certain other airplane models to the AD applicability; and require a modification at a certain time period, as terminating action for the currently required repetitive inspections. This action coincides with the Federal Aviation Adminstration's policy of incorporating modifications, when available, that will terminate the need for repetitive inspections. The actions specified by the proposed AD are intended to continue to detect and correct damage to the elevator structure. A damaged elevator structure could lead to reduced or loss of control of the airplane.

DATES: The Federal Aviation Administration (FAA) must receive any comments on this rule on or before September 8, 2000.

ADDRESSES: Submit comments in triplicate to FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 99–CE–29–AD, 901 Locust, Room 506, Kansas City, Missouri 64106. You may get the service information referenced in the proposed AD from The New Piper Aircraft, Inc., Customer Services, 2926 Piper Drive, Vero Beach, Florida 32960. You may examine this information at FAA.

FOR FURTHER INFORMATION CONTACT: William O. Herderich, Aerospace Engineer, FAA, Atlanta Aircraft Certification Office, One Crown Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia 30349; telephone: (770) 703–6084; facsimile: (770) 703–6097; e-mail: william.o.herderich@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

How do I comment on this AD? We invite your comments on the proposed rule. You may submit whatever written data, views, or arguments you choose. You need to include the rule's docket number and submit your comments in triplicate to the address specified under the caption **ADDRESSES.** We will consider all comments received on or before the closing date specified above, before acting on the proposed rule. We may change the proposals contained in this notice in light of the comments received.

How can we communicate more clearly with you? The FAA is reviewing the writing style we currently use in regulatory documents, in response to the Presidential memorandum of June 1, 1998. That memorandum requires federal agencies to communicate more clearly with the public. We are interested in your comments on the ease of understanding this document, and any other suggestions you might have to improve the clarity of FAA communications that affect you. You can get more information about the Presidential memorandum and the plain language initiative at *http://www.faa.gov/language/.*

The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of the proposed rule that might necessitate a need to modify the proposed rule. You may examine all comments we receive. We will file a report in the Rules Docket that summarizes each FAA contact with the public that concerns the substantive parts of this proposal.

How can I be sure FAA receives my comment? If you want us to acknowledge the receipt of your comments, you must include a self-addressed, stamped postcard. On the postcard, write ''Comments to Docket No. 99–CE–29–AD.'' We will date stamp and mail the postcard back to you.

Discussion

Has FAA taken any action to this point? The following AD's currently require you to repetitively inspect and/or modify the elevator structure on certain Piper Models PA–31, PA–31–300, PA–31P, PA–31T, and PA–31T1 airplanes.

—AD 70–26–06, Amendment 39–1132, which requires you to repetitively inspect the elevator structure on Piper Models PA–31 and PA–31–300 airplanes, serial numbers 31–2 through 31–694. The AD requires you to modify the elevator structure if cracks are found;

—AD 76–03–01, Amendment 39–2505, which requires you to modify the elevator structure on Piper Models PA–31T airplanes, serial numbers 31T–7400002 through 31T–7620007. This AD requires you to inspect the elevator support and replace any defective parts on Piper Model PA–31T airplanes, serial numbers 31T–7400002 through 31T–7520020, 31T–7520022 through 31T–7520038; and 31T–7520040 through 31T–760012; and

—AD 80–02–15, Amendment 39–3676, which requires you to inspect and alter the elevator structure and replace any defective parts on Piper Model PA–31P airplanes, serial numbers 31P–1 through 31P–7730012; Model PA–31T airplanes, serial numbers 31T–7400002 through 31T–7920075; and Model PA–31T1 airplanes, serial numbers 31T–7804001 through 31T–7904036 and 31T–7904038 through 31T–7904044.

What has happened to necessitate further AD action? Piper has informed FAA of reports of damage in the elevator structure area on additional airplanes. These are Piper Models PA–31–325, PA–31–350, PA–31T3, and PA–31P–350 airplanes.

On December 24, 1996, FAA issued a special airworthiness information bulletin (SAIB) to encourage compliance with new service information related to the elevator structure on the above-referenced airplanes. We continue to receive reports of damage in the elevator structure area on these airplanes.

Relevant Service Information

Is there service information that applies to this subject? Piper has issued the following:

—Service Bulletin No. 323, dated September 21, 1970;

—Service Bulletin No. 897B, Date: July 15, 1997; and

—Service Bulletin No. 1008, Date: September 30, 1997.

What are the provisions of these service bulletins? These service bulletins specify and include procedures for the following:

Service bulletin	Applies to	Specifies and includes procedures for	Other information
Piper Service Bulletin No. 323	Certain Piper Models PA–31 and PA–31–300 airplanes.	Inspecting replacing the rudder and elevator spars and elevator butt ribs. Modifying the rudder and elevator spar assemblies through new rudder and elevator spar hinges.	Procedures for installing the new rudder and elevator spar hinges are included in Piper Kit No. 760 465.
Piper Service Bulletin No. 897B	Certain Piper Models PA–31P, PA–31T, PA–31T1, PA–31T2, and PA–31T3 airplanes.	Incorporating an elevator butt rib refinement kit, Piper part number 766–219.	The intent of this service bulletin is met when Piper Service Bulletin 897A is accomplished.
Piper Service Bulletin No. 1008	Certain Piper Models PA–31, PA–31–300, PA–31–325, PA–31–350, PA–31P–350 airplanes.	Incorporating an elevator butt rib refinement kit, Piper part number 766–642.	You must have accomplished actions of Piper Service Bulletin 323; and Piper Service Bulletin 998 or 998A prior to or in conjunction with accomplishing Piper Service Bulletin No. 1008.

The FAA's Determination and an Explanation of the Provisions of the Proposed AD

What has FAA decided? After examining the circumstances and reviewing all available information related to the incidents described above, including the relevant service information, we have determined that:

—an unsafe condition is likely to exist or develop on Piper Models PA–31, PA–31–300, PA–31–325, PA–31–350, PA–31P, PA–31T, PA–31T1, PA–31T2, PA–31T3, and PA–31P–350 of the same type design;

—the actions of the above-referenced service bulletins should be accomplished on the affected airplanes; and

—AD action should be taken to detect and correct damage to the elevator structure. A damaged elevator structure could lead to reduced or loss of control of the airplane.

What are the provisions of the proposed AD? The proposed AD would supersede AD 70–26–06, AD 76–03–01, and AD 80–02–15, with a new AD that would:

—initially retain the inspection and modification requirements that are currently required;

—add certain other airplane models to the AD applicability; and
—require a modification at a certain time period, as terminating action for the currently required repetitive inspections.

Does this proposed AD follow FAA's aging commuter-class aircraft policy? The actions proposed in this NPRM are consistent with FAA's aging commuter aircraft policy, which briefly states that, when a modification exists that could eliminate or reduce the number of required critical inspections, the modification should be incorporated. This policy is based on our determination that reliance on critical repetitive inspections on airplanes utilized in commuter service carries an unnecessary safety risk when a design change exists that could eliminate or, in certain instances, reduce the number of those critical inspections. In determining what inspections are critical, we consider (1) the safety consequences of the airplane if the known problem is not detected by the inspection; (2) the reliability of the inspection such as the probability of not detecting the known problem; (3) whether the inspection area is difficult to access; and (4) the possibility of damage to an adjacent structure as a result of the problem.

The alternative to modifying the elevator structure on the affected airplanes would be to require you to repetitively inspect this area for the life of the airplane.

Cost Impact

How many airplanes does this proposed AD impact? We estimate that 2,344 airplanes in the U.S. registry would be affected by the proposed AD.

What is the cost impact of the proposed modification for affected airplanes on the U.S. Register? We estimate that it would take approximately 20 workhours per airplane to accomplish the proposed modification, at an average labor rate of $60 an hour. Parts to accomplish the proposed modification cost approximately $600 per airplane.

Based on these figures, FAA estimates the cost to accomplish the proposed modification at $4,219,200, or $1,800 per airplane.

What is the cost impact of the proposed inspections for affected airplanes on the U.S. Register? We estimate that it would take approximately 8 workhours per airplane to accomplish each proposed inspection, at an average labor rate of $60 an hour. Based on these figures, FAA estimates the cost to accomplish each proposed inspection at $480 per airplane. Accomplishment of the proposed modification would eliminate the need for the proposed inspections.

Regulatory Impact

How does this AD impact relations between Federal and State governments? The proposed regulations would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have determined that this proposed rule would not have federalism implications under Executive Order 13132.

How does this AD involve a significant rule or regulatory action? For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if put into effect, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. We have placed a copy of the draft regulatory evaluation prepared for this action in the Rules Docket. You may obtain a copy of it by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. FAA amends Section 39.13 by removing Airworthiness Directive (AD) 70–26–06, Amendment 39–1132; AD 76–03–01, Amendment 39–2505; and AD 80–02–15, Amendment 39–3676, and by adding a new AD to read as follows:

The New Piper Aircraft, Inc.: Docket No. 99–CE–29–AD; Supersedes AD 70–26–06, Amendment 39–1132; AD 76–03–01, Amendment 39–2505; and AD 80–02–15, Amendment 39–3676.

(a) *What airplanes are affected by this AD?* This AD affects the following airplanes, certificated in any category:

(1) Part I of this AD: Inspection, replacement, and installation as specified in Piper Service Bulletin No. 323, dated September 21, 1970:

Models: PA–31 and PA–31–300—Serial Numbers: 31–2 through 31–694.

(2) Part II of this AD: Modification as specified in Piper Service Bulletin No. 897B, Date: July 15, 1997:

Models: PA–31P—Serial Numbers 31P–1 through 31P–7730012.

PA–31T—31T–7400002 through 31T–8120104.

PA–31T1—31T–7804001 through 31T–8304003, and 31T–1104004 through 31T–1104017.

PA–31T2—31T–8166001 through 31T–8166076, and 31T–1166001 through 31T–1166008.

PA–31T3—31T–8275001 through 31T–8475001 and 31T–5575001.

(3) Part III of this AD: Modification as specified in Piper Service Bulletin No. 1008, Date: September 30, 1997:

Models: PA–31, PA–31–300, and PA–31–325—Serial Numbers: 31–2 through 31–8312019.

PA–31–350—31–5001 through 31–8452021.

PA–31–350—31–8253001 through 31–8553002.

PA–31P–350—31P–8414001 through 31P-8414050.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the above airplanes on the U.S. Register must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to detect and correct damage to the elevator structure. A damaged elevator structure could lead to reduced or loss of control of the airplane.

(d) *What must I do to address this problem?* To address this problem, you must accomplish the following actions:

(1) Part I of this AD: For the airplane models and serial numbers listed in paragraph (a)(1) of this AD, accomplish the actions in the following chart:

Action	Compliance time	Service information	Other information
(i) Initially inspect the rudder and elevator spars and elevator butt ribs for cracks.	(i) Within 100 hours time-in-service (TIS) after the last inspection required by AD 70–26–06, and thereafter at intervals not to exceed 100 hours TIS until Piper Elevator and Rudder Hinge Installation Kit No. 760 465 is incorporated.	Do this inspection in accordance in accordance with the instructions in Piper Service Bulletin No. 323, dated September 21, 1970.	This inspetion is retained from AD 70–26–06.
(ii) If cracks are found in the elevator structure during any inspection required by this portion of the AD, replace the cracked part, and either continue to reinspect or incorporate Kit No. 760 465.	Prior to further flight after the inspection where the cracks were found.	(A) Do the inspections in accordance with the instructions in Piper Service Bulletin No. 323, dated September 21, 1970; OR (B) Do the kit incorporation in accordance with the instructions to Piper Elevator and Rudder Hinge Installation Kit No. 760 465, Revised October 25, 1989..	
(iii) Incorporate Piper Elevator and Rudder Hinge Installation Kit No. 760 465.	Upon accumulating 2,000 hours TIS on the airplane or within the next 100 hours TIS after the effective date of this AD, whichever occurs later.	Do this kit incorporation in accordance with the instructions to Piper Elevator and Rudder Hinge Installation Kit No. 760 465, Revised October 25, 1989.	

(2) Part II of this AD: For the airplane models and serial numbers listed in paragraph (a)(2) of this AD, accomplish the actions in the following chart:

Action	Compliance time	Service information	Other information
(i) Modify the elevator trim tab system and elevator control tube, through the incorporation of Piper Kit No. 760 989.	Upon accumulating 2,000 hours TIS or within 100 hours TIS after the effective date of this AD, whichever occurs later.	Do this modification in accordance with the instructions to Piper Kit No. 760 989, as referenced in Piper Service Bulletin No. 477A, dated November 3, 1975.	(A) This modification is retained from AD 76–03–01, and applies to Piper Model PA–31T airplanes, serial numbers 31T–400002 through 31T–7620012. (B) Unless already accomplished credit may be taken for this portion of the AD if the airplane is in compliance with the actions of AD 76–03–01.
(ii) Incorporate Elevator Butt Rib Reinforcement Kit, Piper Part Number 766–219.	Upon accumulating 2,000 hours TIS or within the next 100 hours TIS after the effective date of this AD, whichever occurs later.	Do this kit incorporation in accordance with the instructions to Elevator Butt Rib Reinforcement Kit, Piper Part Number 766–219, as referenced in Piper Service Bulletin No. 897B, Date: July 15, 1997.	Reinforcement Kit, Piper Part Number 766–219, may have been incorporated as specified in Piper Service Bulletin 897A. If so, unless already accomplished credit may be taken for this portion of the AD.

(3) Part III of this AD: For the airplane models and serial numbers listed in paragraph (a)(3) of this AD, accomplish the actions in the following chart:

Action	Compliance time	Service information	Other information
(i) Incorporate Elevator Butt Rib Refinement Kit, Piper Part Number 766–642.	Upon accumulating 2,000 hours TIS or within the next 100 hours TIS after the effective date of this AD, whichever occurs later.	Do this kit incorporation in accordance with the instructions to Elevator Butt Rib Refinement Kit, Piper Part Number 766–642, as specified in Piper Service Bulletin No. 1008, Date: September 30, 1997.	(A) If AD 99–12–05, Amendment 39–11189 (63 FR 31687, June 14, 1999), applies to one of the above-referenced airplanes, then the actions of AD 99–12–05 must be accomplished prior to incorporating Elevator Butt Rib Refinement Kit, Piper Part Number 766–642. (B) No credit toward this AD is given for accomplishing the actions of Piper SB 864.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Atlanta Aircraft Certification Office (ACO), approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Atlanta ACO.

(3) Alternative methods of compliance that were approved in accordance with any of the following airworthiness directives (all superseded by this action) are not considered approved for this AD:

(i) AD 70–26–06, Amendment 39–1132;

(ii) AD 76–03–01, Amendment 39–2505; and

(iii) AD 80–02–15, Amendment 39–3676.

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

(f) *Where can I get information about any already-approved alternative methods of compliance?* You can contact William O. Herderich, Aerospace Engineer, FAA, Atlanta Aircraft Certification Office, One Crown Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia 30349; telephone: (770) 703–6084; facsimile: (770) 703–6097; e-mail: william.o.herderich@faa.gov.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *How do I get copies of the documents referenced in this AD?* You may obtain copies of the documents referenced in this AD from The New Piper Aircraft, Inc., Customer Services, 2926 Piper Drive, Vero Beach, Florida 32960. You may examine this service information at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

(i) *Does this AD action affect any existing AD actions?* This amendment supersedes the following AD actions:

(1) AD 70–26–06, Amendment 39–1132;

(2) AD 76–03–01, Amendment 39–2505; and

(3) AD 80–02–15, Amendment 39–3676.

Issued in Kansas City, Missouri, on July 17, 2000.

Marvin R. Nuss,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–18524 Filed 7–20–00; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–CE–69–AD]

RIN 2120–AA64

Airworthiness Directives; The New Piper Aircraft, Inc. (Formerly Piper Aircraft Corporation) PA–31 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Supplemental notice of proposed rulemaking (NPRM); Reopening of the comment period.

SUMMARY: This document proposes to revise an earlier proposed airworthiness directive (AD) that would apply to The New Piper Aircraft, Inc. (Piper) PA–31 series airplanes. The earlier NPRM would have superseded AD 80–26–05, which requires you to repetitively inspect the main landing gear (MLG) inboard door hinges and attachment angles for cracks on the affected airplanes, and requires you to replace any cracked MLG inboard door hinge or attachment angle. The earlier NPRM proposed to require you to inspect the original design MLG inboard door hinge assemblies for cracks; and replace the original design MLG inboard door hinge assemblies with parts of improved design either immediately (cracks) or at a certain time period (no cracks). This supplemental NPRM results from reports of cracks in the improved design MLG inboard door hinge assemblies on the affected airplanes. We are revising the NPRM to propose inspections on the improved design parts as well as the original design parts. The actions specified by the proposed AD are intended to detect and correct cracked MLG inboard door hinge assemblies. These cracked door hinge assemblies could result in the MLG becoming jammed with consequent loss of control of the airplane during landing operations.

DATES: The Federal Aviation Administration (FAA) must receive comments on or before September 8, 2000.

ADDRESSES: Submit comments in triplicate to FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 96–CE–69–AD, 901 Locust, Room 506, Kansas City, Missouri 64106.

You may get the service information referenced in the proposed AD from The New Piper Aircraft, Inc., Customer Services, 2926 Piper Drive, Vero Beach, Florida 32960. You may examine this information at FAA.

FOR FURTHER INFORMATION CONTACT: William O. Herderich, Aerospace Engineer, FAA, Atlanta Aircraft Certification Office, One Crown Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia 30349; telephone: (770) 703–6084; facsimile: (770) 703–6097; e-mail: william.o.herderich@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

How do I comment on the proposed AD? The FAA invites comments on this proposed rule. You may submit whatever written data, views, or arguments you choose. You need to include the rule's docket number and submit your comments in triplicate to the address specified under the caption **ADDRESSES.** The FAA will consider all comments received on or before the closing date. We may amend the proposed rule in light of comments received. Factual information that supports your ideas and suggestions is extremely helpful in evaluating the effectiveness of the proposed AD action and determining whether we need to take additional rulemaking action.

Are there any specific portions of the AD I should pay attention to? The FAA is re-examining the writing style we currently use in regulatory documents, in response to the Presidential memorandum of June 1, 1998. That memorandum requires federal agencies to communicate more clearly with the public. We are interested in your comments on whether the style of this document is clearer, and any other suggestions you might have to improve the clarity of FAA communications that affect you. You can get more information about the Presidential memorandum and the plain language initiative at http://www.plainlanguage.gov.

The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of the proposed rule that might suggest a need to modify the rule. You may examine all comments we receive before and after the closing date of the rule in the Rules Docket. We will file a report in the Rules Docket that summarizes each FAA contact with the public that concerns the substantive parts of the proposed AD.

How can I be sure FAA receives my comment? If you want us to acknowledge the receipt of your comments, you must include a self-addressed, stamped postcard. On the postcard, write ''Comments to Docket

No. 96–CE–69–AD.'' We will date stamp and mail the postcard back to you.

Discussion

Has FAA taken any action to this point? On December 1, 1995, FAA issued a proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to certain Piper PA–31 series airplanes. This proposal was published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on December 7, 1995 (60 FR 62774), and proposed to supersede AD 80–26–05, Amendment 39–3994. The NPRM proposed to:

—Retain the requirement of repetitively inspecting the MLG inboard door hinge assemblies for cracks, and replacing any cracked MLG inboard door hinge assembly; and

—Require incorporating a MLG inboard door hinge assembly of improved design (part number (P/N) 47529–32) or FAA-approved equivalent part number, as terminating action for the repetitive inspection requirement.

Accomplishment of the proposed inspections would have been required in accordance with Piper Service Bulletin (SB) No. 682, dated July 24, 1980.

Was the public invited to comment on the NPRM? The FAA invited interested persons to participate in the making of this amendment. Due consideration was given to the one comment received.

What issue did this comment address? The comment received on the NPRM contained information that the improved design MLG inboard door hinge assemblies, P/N 47529–32, are also susceptible to fatigue cracking, and that installing this assembly should not eliminate the need for the repetitive inspections currently required by AD 80–26–05. The commenter stated that its airplane fleet has experienced three failures and three incidents related to fatigue cracking of the P/N 47529–32 hinge assemblies.

What action did FAA take? We conducted a review of the manufacturer's service history and service difficulty reports in FAA's database associated with the P/N 47529–32 MLG inboard door hinge assembly. Based on a review of this information, including the information received from the commenter, we determined that more information and analysis were needed before mandating MLG inboard door hinge assembly replacements through an AD.

We then issued an advance notice of proposed rulemaking (ANPRM) on February 11, 1997. The ANPRM was published in the **Federal Register** on February 19, 1997 (62 FR 7375). The purpose of the ANPRM was to encourage interested persons to provide information that describes what they consider the best action (if any) for FAA to take regarding the P/N 47529–32 MLG inboard door hinge assembly issue. The FAA also withdrew the NPRM. We received no information or comments regarding the ANPRM.

We then re-evaluated the information in our service difficulty database. The database, at that time, contained 10 reports of failure or cracks found in the MLG inboard door hinge assembly on the affected airplanes. The commenter to the original NPRM had submitted six of these reports. Three of these six incident reports were specifically attributed to the original MLG inboard door hinge assemblies and three to the improved design MLG inboard door hinge assemblies. The four reports that others submitted do not specifically identify whether the original MLG inboard door hinge assemblies were installed or the improved design assemblies were installed. Since the incidents occurred on high service time airplanes and since there is no AD action mandating the installation of the improved-design MLG inboard door hinge assemblies, we presumed that the original hinge assemblies were installed.

The FAA then reviewed the three incident reports on the improved design MLG inboard door hinge assemblies and, along with the National Transportation Safety Board (NTSB), performed extensive testing and analysis of the improved design MLG inboard door hinge assemblies. Based on this review, testing, and analysis, we determined that:

—The incidents were isolated and that mandating repetitive inspections was not needed when the P/N 47529–32 MLG inboard door hinge assemblies are installed; and

—AD action should be taken to eliminate the repetitive short-interval inspections that AD 80–26–05 requires and to prevent separation of a MLG door from the airplane caused by a cracked inboard door hinge assembly.

On October 14, 1997, FAA issued an NPRM to address these issues. The NPRM was published in the **Federal Register** on October 21, 1997 (62 FR 54595).

What has happened to justify this AD action? Since issuance of the NPRM, we have received additional reports of cracks in the MLG inboard door hinge assemblies. The reports reference incidents on both the original design assemblies and the improved design hinges. As of the issue date of this document, we have reports of the following:

—27 reports of cracked improved design MLG inboard door hinge assemblies; and

—41 reports of cracked original design MLG inboard door hinge assemblies.

The FAA's Determination

What has FAA decided? After careful review of all available information related to the subject presented above, we have determined that:

—Both the improved design and original design MLG inboard door hinge assemblies on the PA–31 series airplanes are susceptible to cracking; and

—AD action should be taken to detect and correct cracked MLG inboard door hinge assemblies.

The Supplemental NPRM

How will the changes to the NPRM impact the public? Proposing inspections on airplanes with the improved design MLG inboard door hinge assemblies as well as the original design assemblies presents actions that go beyond the scope of what was already proposed. Therefore, we are issuing a supplemental NPRM and reopening the comment period to allow the public additional time to comment on the proposed AD.

What are the provisions of the supplemental NPRM? The supplemental NPRM would apply to all PA–31 series airplanes and would require you to accomplish the following:

—Repetitively inspect the MLG inboard door hinge assemblies (regardless of part number); and

—Immediately replace any cracked MLG inboard door hinge assembly with a new MLG inboard door hinge assembly, Piper part number (P/N) 47529–32 (or FAA-approved equivalent part number).

What document should I use to accomplish these actions? Piper Service Bulletin No. 682, dated July 24, 1980, includes all the procedures necessary to accomplish the actions proposed in this supplemental NPRM.

Cost Impact

How many airplanes does the proposed AD impact? The FAA estimates that 2,344 airplanes in the U.S. registry would be affected by the proposed AD.

What would it cost me to accomplish each proposed inspection? We estimate that it would take approximately 2 workhours per airplane to accomplish each proposed inspection, at an average

labor rate of $60 an hour. Based on these figures, FAA estimates the total cost impact of each proposed inspection on U.S. operators at $281,280, or $120 per airplane.

What would it cost me to replace a cracked assembly? We estimate 2 workhours to replace a cracked MLG inboard door hinge assembly. A replacement assembly costs approximately $270. We estimate a total cost of $390 to replace a cracked MLG inboard door hinge assembly.

Regulatory Impact

How does this AD impact various entities? The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposed rule would not have federalism implications under Executive Order 13132.

How does this AD involve a significant rule or regulatory action? The FAA has determined that the proposed action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if adopted, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. We have placed a copy of the draft regulatory evaluation prepared for this action in the Rules Docket. You may obtain a copy of it at the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. FAA amends Section 39.13 by removing Airworthiness Directive (AD) 80–26–05, Amendment 39–3994, and by adding a new AD to read as follows:

The New Piper Aircraft, Inc. (formerly Piper Aircraft Corporation): Docket No. 96–CE–69–AD, Supersedes AD 80–26–05, Amendment 39–3994.

(a) *What airplanes are affected by this AD?* This AD affects the following airplane models and serial numbers, certificated in any category:

Models	Serial numbers
PA–31	31–2 through 31–900 and 31–7300901 through 31–8312019.
PA–31–300 ..	31–2 through 31–900 and 31–7300901 through 31–8312019.
PA–31–350 ..	31–5001 through 31–5004 and 31–7305005 through 31–8553002.
PA–31–325 ..	31–7400990, 31–7512001 through 31–8312019.
PA–31P	31P–1 through 31P–109 and 31P–7300110 through 31P–7730012.
PA–31T	31T–7400002 through 31T–8120104.
PA–31T1	31T–7804001 through 31T–8104073; 31T–8104101; 31T–8304001 through 31T–8304003; and 31T–1104004 through 31T–1104017.
PA–31T2	31T–8166001 through 31T–8166076, and 31T–1166001 through 31T–1166008.
PA–31T3	31T–8275001 through 31T–8475001, and 31T–5575001.
PA–31P–350	31P–8414001 through 31P–8414050.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the above airplanes on the U.S. Register must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to detect and correct cracked main landing gear (MLG) inboard door hinge assemblies. This could result in the MLG becoming jammed with consequent loss of control of the airplane during landing operations.

(d) *What must I do to address this problem?* To address this problem, you must accomplish the following:

Action	Compliance time	Procedures
(1) Inspect all hinges and hinge attachment angles in the MLG inboard door hinge assembly.	(i) For airplanes with any MLG inboard door hinge assembly that is not made of steel: At the next inspection required by AD 80–26–05 or within the next 100 hours time-in-service (TIS) after the effective date of this AD, whichever occurs first, and thereafter at intervals not to exceed 100 hours TIS. (ii) For airplanes with any MLG inboard door hinge assembly that is made of steel (*i.e.,* Piper part number 47529–32): Upon accumulating 2,000 hours TIS on the MLG inboard door hinge assembly, and thereafter at intervals not to exceed 2,000 hours TIS.	Accomplish in accordance with the INSTRUCTIONS section of Piper Service Bulletin No. 682, dated July 24, 1980.
(2) Replace any cracked MLG inboard door hinge assembly with a Piper part number 47529–32 assembly (or FAA-approved part number).	Prior to further flight after the inspection required by this AD. The repetitive inspection requirement of this AD is still required for airplanes incorporating these replacement assemblies. Inspect upon accumulating 2,000 hours TIS on the new assembly, and thereafter at 2,000-hour TIS intervals.	Accomplish in accordance with the INSTRUCTIONS section of Piper Service Bulletin No. 682, dated July 24, 1980.

(e) *Can I comply with this AD in any other way?*

(1) You may use an alternative method of compliance or adjust the compliance time if:

(i) Your alternative method of compliance provides an equivalent level of safety; and

(ii) The Manager, Atlanta Aircraft Certification Office (ACO), approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Atlanta ACO, One Crown Center,

1895 Phoenix Boulevard, suite 450, Atlanta, Georgia 30349.

(2) Alternative methods of compliance approved in accordance with AD 80–26–05 (superseded by this action) are not considered approved as alternative methods of compliance with this AD.

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

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact William O. Herderich, Aerospace Engineer, FAA, Atlanta Aircraft Certification Office, One Crown Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia 30349; telephone: (770) 703–6084; facsimile: (770) 703–6097; e-mail: william.o.herderich@faa.gov.

(g) *What if I need to fly the airplane to another location to comply with this AD?* FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *How do I get copies of the documents referenced in this AD?* You may obtain copies of the documents referenced in this AD from The New Piper Aircraft, Inc., 2926 Piper Drive, Vero Beach, Florida 32960. You may examine these documents at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

(i) *Does this AD action affect any existing AD actions?* This amendment supersedes AD 80–26–05, Amendment 39–3994.

Issued in Kansas City, Missouri, on July 17, 2000.

Marvin R. Nuss,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–18525 Filed 7–20–00; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD05–00–031]

RIN 2115–AE46

Special Local Regulations for Marine Events; Sharptown Outboard Regatta, Nanticoke River, Sharptown, Maryland

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish temporary special local regulations for the Sharptown Outboard Regatta, to be held on the waters of the Nanticoke River between Maryland S.R. 313 bridge at Sharptown, Maryland and Nanticoke River Light 43 (LLN–24175). These special local regulations are necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in portions of the Nanticoke River during the event.

DATES: Comments and related material must reach the Coast Guard on or before August 21, 2000.

ADDRESSES: You may mail comments and related material to Commander (Aoax), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704–5004, or deliver them to the same address between 9 a.m. and 2 p.m., Monday through Friday, except Federal holidays. Comments and materials received from the public as well as documents indicated in this preamble as being available in the docket, are part of this docket and are available for inspection or copying at Commander (Aoax), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704–5004, between 9 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Chief Warrant Officer R. Houck, Marine Events Coordinator, Commander, Coast Guard Activities Baltimore, 2401 Hawkins Point Road, Baltimore Maryland, 21226–1791, telephone number (410) 576–2674.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking (CGD05–00–031), indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. The comment period for this regulation is 30 (thirty) days. This time period is adequate since the event is well publicized in the local maritime community. If you would like to know that your comments reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not plan to hold a public meeting. But you may submit a request for a meeting by writing to Commander (Aoax), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704–5004, explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The North-South Racing Association will sponsor the Sharptown Outboard Regatta on September 23 and September 24, 2000. The event will consist of 60 hydroplanes and runabouts conducting a high speed competitive race on the waters of the Nanticoke River between Maryland S.R. 313 bridge at Sharptown, Maryland and Nanticoke River Light 43 (LLN–24175). A fleet of spectator vessels is anticipated for the event. Due to the need for vessel control during the races, vessel traffic will be temporarily restricted to provide for the safety of participants, spectators and transiting vessels.

Discussion of Proposed Rule

The Coast Guard will establish temporary special local regulations on specified waters of the Nanticoke River. The regulated area will include waters of the Nanticoke River between Maryland S.R. 313 bridge at Sharptown, Maryland and Nanticoke River Light 43 (LLN–24175). The temporary special local regulations will be effective from 10 a. m. to 7 p.m. on September 23 and September 24, 2000, and will restrict general navigation in the regulated area during the event. Except for participants in the Sharptown Outboard Regatta and persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area.

Regulatory Evaluation

This proposed rule is not a ''significant regulatory action'' under

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

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Although this proposed regulation will prevent traffic from transiting a portion of the Nanticoke River during the event, the effect of this regulation will not be significant due to the limited duration that the regulated area will be in effect and the extensive advance notifications that will be made to the maritime community via the Local Notice to Mariners, marine information broadcasts, and area newspapers, so mariners can adjust their plans accordingly.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), we considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

Although this proposed regulation will prevent traffic from transiting a portion of the Nanticoke River during the event, the effect of this regulation will not be significant because of the limited duration that the regulated area will be in effect and the extensive advance notifications that will be made to the maritime community via the Local Notice to Mariners, marine information broadcasts, and area newspapers, so mariners can adjust their plans accordingly.

If you think that your business, organization or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this proposed rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Commander (Aoax), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704–5004.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

We have analyzed this proposed rule under Executive Order 13132 and have determined that this rule does not have implications for federalism under that Order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those costs. This proposed rule will not impose an unfunded mandate.

Taking of Private Property

This proposed rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Environment

We prepared an ''Environmental Assessment'' in accordance with Commandant Instruction M16475.1C, and determined that this rule will not significantly affect the quality of the human environment. The ''Environmental Assessment'' and ''Finding of No Significant Impact'' is available in the docket where indicated under **ADDRESSES**.

List of Subjects

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

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

PART 100—[AMENDED]

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

Authority: 33 U.S.C. 1233 through 1236; 49 CFR 1.46 and 33 CFR 100.35.

2. Add temporary § 100.35–T05–031 to read as follows:

§ 100.35–T05–031 Special Local Regulations for Marine Events; Sharptown Outboard Regatta, Nanticoke River, Sharptown, Maryland

(a) *Definitions*—(1) *Regulated Area.* All waters of the Nanticoke River, near Sharptown, Maryland, between Maryland S.R. 313 bridge and Nanticoke River Light 43 (LLN–24175), bounded by a line drawn between the following points: southeasterly from latitude 38°32′47″ N, longitude 075°43′15″ W, to latitude 38°32′42″ N, longitude 75°43′09″ W, thence northeasterly to latitude 38°33′07″ N, longitude 075°42′27″ W, thence northwesterly to latitude 38°33′10″ N, longitude 75°42′46″ W, thence southwesterly to latitude 38°32′47″ N, longitude 75°43′15″ W. All coordinates reference Datum NAD 1983.

(2) *Coast Guard Patrol Commander.* The Coast Guard Patrol Commander is a commissioned, warrant, or petty officer of the Coast Guard who has been designated by the Commander, Coast Guard Activities Baltimore.

(3) *Official Patrol.* The Official Patrol is any vessel assigned or approved by Commander, Coast Guard Activities Baltimore with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

(4) *Participating Vessels.* Participating vessels include all vessels participating in the Sharptown Outboard Regatta under the auspices of the Maine Event

Application submitted by the North-South Racing Association Inc., and approved by the Commander, Fifth Coast Guard District.

(b) *Special Local Regulations*—(1) Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area.

(2) The operator of any vessel in this area shall:

(i) Stop the vessel immediately when directed to do so by any official patrol.

(ii) Proceed as directed by any official patrol.

(c) *Effective Dates.* The regulated area is effective from 10 a.m. on September 23, 2000, until 7 p.m. September 24, 2000.

Dated: July 14, 2000.

T. C. Paar,

Captain, U.S. Coast Guard, Acting Commander, Fifth Coast Guard District.

[FR Doc. 00–18559 Filed 7–20–00; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD11–00–007]

RIN 2115–AE84

Regulated Navigation Area; San Pedro Bay, California

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to revise the regulated navigation area for San Pedro Bay, California. Due to the port expansion projects underway in the Ports of Los Angeles and Long Beach, the Coast Guard conducted a Port Access Route Study (PARS). The PARS notice of study results, published in the **Federal Register** on May 19, 2000, recommended, among other things, changes to the San Pedro Bay regulated navigation area (RNA). In general, the Coast Guard is proposing to expand the RNA to the south approximately 2.2 nm. The proposed changes to the RNA boundaries would coincide with the boundaries of the Precautionary Area, essentially making the two boundaries the same. The Coast Guard is also proposing minor changes to some vessel operational procedures and requirements to reflect the necessary modifications with respect to traffic management due to the port construction and expansion projects.

DATES: Comments must be received on or before September 5, 2000.

ADDRESSES: Comments should be mailed to Commander (Pmc-3), USCG PACAREA/D11, Bldg 50–6, Coast Guard Island, Alameda, CA 94501–5100. The comments and other materials referenced in this proposed rule will be available for inspection and copying at the Marine Safety Office. Normal office hours are between 7:30 a.m. and 4 p.m., Monday through Friday, except holidays. Comments may also be hand delivered to this address.

FOR FURTHER INFORMATION CONTACT: Lieutenant Patricia Springer, Chief Vessel Traffic Management Section, 11th Coast Guard District, telephone (510) 437–2951.

SUPPLEMENTARY INFORMATION:

Request for Comments

Interested persons are invited to participate in this proposed rulemaking by submitting written views, data or concerns to the office listed under **ADDRESSES** in this preamble. Persons submitting comments should include their names and addresses, identify the docket number for the regulations (CGD11–00–007), the specific section of the proposal to which their comments apply, and give reasons for each comment.

The regulations may be changed in light of the comments received. All comments received before the expiration of the comment period will be considered before final action is taken on this proposal. No public hearing is planned, however, one may be held if written requests for a hearing are received and it is determined that the opportunity to make oral presentations will aid in the rule making process.

Definitions

The following definitions should help you review this document:

Precautionary area means a routing measure comprising an area within defined limits where ships must navigate with particular caution and within which the direction of traffic flow may be recommended.

Traffic lane means an area within defined limits in which one-way traffic is established.

Traffic Separation Scheme or TSS means a routing measure aimed at the separation of opposing streams of traffic by appropriate means and by the establishment of traffic lanes.

Vessel routing system means any system of one or more routes or routing measures aimed at reducing the risk of casualties; it includes traffic separation schemes, two-way routes, recommended tracks, areas to be avoided, inshore traffic zones, roundabouts, precautionary areas, and deep-water routes.

Background and Purpose

In 1999, the Coast Guard conducted a Port Access Route Study (PARS), which we announced in a document published in the **Federal Register** on March 11, 1999 (63 FR 12140). A PARS was needed to evaluate the effects of port improvement projects for the ports of Los Angeles and Long Beach on navigational safety and vessel traffic management efficiency, and to recommend any necessary changes to existing routing measures. The Coast Guard completed the study in July 1999 and announced the results of this study in a Notice published in the **Federal Register** on May 19, 2000 (65 FR 31856). Among other things, this study recommended modifications to the precautionary areas, existing TSS's, and aids to navigation.

Major port improvement projects for the Ports of Los Angeles and Long Beach have taken place. These projects include the following:

Lengthening of the Los Angeles Approach Channel to extend approximately 3.5 nautical miles beyond the Los Angeles breakwater;

Deepening of the Los Angeles Approach Channel to a project depth of 81 feet;

Shift of the Long Beach Approach to a 355 degrees True inbound course; and

Deepening of the Long Beach Approach Channel to a project depth of 69 feet.

Fill and construction activities within the Los Angeles/Long Beach Harbors and development of a shallow water habitat have constricted the amount of room available for small commercial and recreational traffic to maneuver within the Outer Harbor, Middle, and Long Beach breakwaters. This has the effect of concentrating traffic flows and placing small marine traffic more directly in competition with deep draft traffic for use of the Precautionary Area.

During the PARS, the Coast Guard consulted with Federal and State agencies and solicited the views of representatives of the maritime community, port and harbor authorities or associations, environmental groups and other interested parties. The Coast Guard also considered previous studies and experience in the areas of vessel traffic management, navigation, ship handling, and the effects of weather, and review prior analyses of the traffic density. In particular, the Coast Guard reviewed the results of a 1982 LA/LB Port Access Route Study (47 FR 27430, June 24, 1982) and a 1995 Port Access

Route Study (61 FR 55248, October 25, 1996) which focused on vessel traffic management measures along the California coast from San Francisco to Los Angeles.

Three comment letters were received and indicated strong overall support for the PARS recommendations. To enhance navigational safety and vessel traffic management efficiency, the study recommended three changes to the existing vessel routing and traffic management measures.

1. Expand the Existing LA/LB Precautionary Area

The study found that the existing Precautionary Area should be expanded to provide enhanced navigational safety in light of the pending and planned improvements to the port facilities and navigational channels previously discussed. The port improvements discussed above will allow even larger vessels to call on Los Angeles and Long Beach. These larger, less maneuverable ships will be constrained to the channels. The study also noted that the current practice of freighters, tankers, tugs and barges, fishing boats and pleasure craft converging in the Precautionary Area would continue to present hazards for all mariners.

Expansion of the existing Precautionary Area should result in several positive impacts for safe navigation. First, the expanded Precautionary Area should give vessels of all types, sizes, and drafts more time and room to maneuver in their approach to or departure from the ports. Second, by this rulemaking, the Commander, Eleventh Coast District, is proposing modifications to the San Pedro Bay RNA, promulgated at 33 CFR 165.1109, to geographically match the expanded Precautionary Area. When specified categories of vessels enter the RNA, they are required to slow. This allows more time for vessel traffic management, e.g. queuing of vessels arriving and departing during peak periods and coordinating passing arrangements. Finally, the expanded Precautionary Area should be well adapted to the lengthened Los Angeles entrance channel.

2. Relocate the Western and Southern TSSs

The study found that the existing western and southern TSSs do not yield safe or practical approaches to the improved Long Beach and Los Angeles entrance channels. The study recommended a shift of the western TSS to the south and a shift of the southern TSS to the west. The Eleventh Coast Guard District's Aids to Navigation Division (oan) is developing a separate rulemaking to address changes to the TSSs.

3. Modifications to Aids to Navigation

The PARS solicited specific recommendations regarding the aids to navigation design for the lengthened approach channels to Los Angeles and Long Beach, CA. Specific recommendations included adding, deleting, relocating and upgrading the existing buoys in these channels. The Commander, Eleventh Coast Guard District will review these recommendations and make final decisions concerning Los Angeles-Long Beach aids to navigation in light of the Coast Guard's waterways analysis management system (WAMS). Specific questions on WAMS should be directed to the Eleventh Coast Guard District's points of contact listed in **FOR FURTHER INFORMATION CONTACT**.

Discussion of Regulation

Modifications to the RNA. The Commander, Eleventh Coast Guard District is proposing modifications to the San Pedro Bay RNA. As previously discussed, one proposed change will make the RNA geographically the same as the precautionary area.

A Precautionary Area is an internationally recognized routing measure comprising an area within defined limits where ships must navigate with particular caution. By itself, a precautionary area does not impose specific maneuvering requirements on vessels.

A Regulated Navigation Area (RNA) is a regulatory measure that defines an area, in which the Coast Guard has imposed specific vessel operating requirements because of the existence of hazardous conditions. Due to the quantity of vessel traffic and diversity of types of vessels transiting the approach to Los Angeles and Long Beach harbors, the Coast Guard thinks that the general guidance of a Precautionary Area is insufficient to ensure safe transit of the area. Therefore, in addition to establishing the Precautionary Area, the Coast Guard is also establishing an RNA, which covers the same area of waters and includes specific vessel operating procedures.

This proposed rulemaking will also address vessel operating requirements; vessel size, speeds, draft limitations; operating conditions; and pilot boarding areas.

Below is a summary of the specific changes to the RNA:

- The southern boundary of the RNA will be moved to the south approximately 2.2 nautical miles (nm) to align with the new western traffic separation scheme. The southeastern corner of the RNA will be shifted to the west approximately 1.8 nm on a bearing on 220 degrees T from the easterly most point of the existing Precautionary Area, to align with the new southern traffic separation scheme (The changes to the traffic separation schemes are the subject of a separate rulemaking to be published in the future).
- The Los Angeles Pilot Area will be expanded approximately 0.4 nm to the south-southeast.
- The Long Beach Pilot Area will be expanded approximately 1.7 nm to the south.
- A Deep Water Traffic lane approximately 3.27 nm long will be established in the Los Angeles approach channel.
- A Deep Water Traffic Lane approximately 1.9. nm long will be established in the Long Beach approach channel.
- A Deep Water Pilot Area will be established just south of the Los Angeles Deep Water Traffic Lane. It will be centered on position 33°39′00″ N, 118°13'11.6''W, approximately 0.5 nm south of the southern terminus of the Los Angeles Channel and will be 1.0 nm in diameter.

The proposed amendment to the RNA would expand the size of the RNA and change certain operating procedures for vessels transiting the RNA. The Ports of Los Angeles and Long Beach are conducting significant alterations to their port complex and waterway layout. These changes include lengthening and deepening of both approach channels to the Federal Breakwater. The lengthened approach channels will extend beyond the western traffic lane that joins the existing Precautionary Area. Without changes to the traffic lanes, the precautionary area and the RNA, these lengthened channels would create vessel traffic management problems and increase the risk of collision to vessels operating in the area. The Los Angeles-Long Beach Harbor Safety Committee provided a detailed recommendation to the PARS recommending expansion of the size of the Precautionary Area and concurrently expanding the RNA to cover the entire Precautionary Area.

The existing RNA only extends out to approximately 3 (nm) offshore and covers roughly half of the existing Precautionary Area. Navigable waters, for the purposes of the Ports and Waterways Safety Act (33 U.S.C. 1222), were extended from 3nm to 12nm by section 301 of the Coast Guard Authorization Act of 1998 and Presidential Proclamation 5928,

allowing the Coast Guard to establish RNAs in areas outside of 3nm.

The location, size and shape of the Pilot Areas for the harbors are also being changed due to the lengthening and deepening of the harbor entrance channels. Pilot Areas are designated waters where ships maneuver to embark or disembark a pilot. Pilot Area regulations are in place to allow this transfer to occur safely and without interference from other vessel traffic. The Long Beach Pilot Area will be expanded to the south approximately 1.6 nm to encompass the entire length of the newly deepened channel. Enlarging this pilot area will allow the pilots to board inbound vessels further offshore in order to guide the ships through the channel. The Los Angeles Pilot Area will also be extended to the south-southeast by approximately 0.4nm. The expanded Los Angeles Pilot Area will not cover the entire length of the newly deepened channel as it is expected that only those vessels with a draft greater than 50 feet will need to use the entire length of the channel. Lesser draft vessels may enter and depart the channel closer to the Los Angeles Harbor entrance and will embark and disembark their pilot there.

The newly lengthened and deepened Los Angeles and Long Beach approach channels will be designated Deep Water Traffic Lanes. When a vessel drawing more than 50 feet is using the Deep Water Traffic Lane, other vessels will not be allowed to enter the traffic lane. A Deep Water Pilot Area will be established at the southern end of the Los Angeles Deep Water Traffic Lane to afford pilots an area to board vessels with drafts greater than 50 feet. A deep water pilot area is not considered necessary for the Long Beach entrance.

Regulatory Evaluation

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

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this proposed rule will have a significant economic impact on a substantial number of small entities. ''Small entities'' may include small businesses and not-for-profit organizations that are not dominant in their respective fields, and governmental jurisdictions with populations less than 50,000. For the same reasons set forth in the above Regulatory Evaluation, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule is not expected to have a significant economic impact on any substantial number of entities, regardless of their size.

Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), the Coast Guard wants to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rule making process. If your small business or organization is affected by this proposed rule and you have questions concerning its provisions or options for compliance, please contact Lieutenant Patricia Springer at the address indicated under **ADDRESSES.**

Collection of Information

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

Federalism

The Coast Guard has analyzed this proposed regulation under the principles and criteria contained in Executive Order 13132 and has determined that this proposed regulation does not have federalism implications under that Order.

Environmental Assessment

The Coast Guard has considered the environmental impact of this proposed regulation and concluded that under Chapter 2.B.2. of Commandant Instruction M16475.1C, Figure 2–1, paragraph (34)(g), it will have no significant environmental impact and it is categorically excluded from further environmental documentation.

Unfunded Mandates

Under the Unfunded Mandates Reform Act of 1995 (Public Law 104–4), the Coast Guard must consider whether this proposed rule will result in an annual expenditure by state, local, and tribal governments, in the aggregate of $100 million (adjusted annually for inflation). If so, the Act requires that a reasonable number of regulatory alternatives be considered, and that from those alternatives, the least costly, most cost-effective, or least burdensome alternative that achieves the objective of the rule be selected.

No state, local, or tribal government entities will be affected by this proposed rule, so this proposed rule will not result in annual or aggregate costs of $100 million or more. Therefore, the Coast Guard is exempt from any further regulatory requirements under the Unfunded Mandates Act.

Taking of Private Property

This proposed rule will not effect a taking of private property or otherwise have taking implications under this Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in section 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This proposed rule does not concern an environmental risk to safety disproportionately affecting children.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reports and recordkeeping requirements, Vessels, Waterways.

Proposed Regulation

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR Part 165 as follows:

PART 165—[AMENDED]

1. The authority citation for 33 CFR Part 165 continues to read as follows:

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

2. Revise § 165.1109 to read as follows:

§ 165.1109 San Pedro Bay, California—Regulated navigation area.

(a) *Applicability.* This section applies to all vessels unless otherwise specified.

(b) *Deviations.* The Captain of the Port of Los Angeles-Long Beach or his or her

designated representative may authorize a deviation from the requirements of this regulation when it is deemed necessary in the interests of safety.

(c) *Location.* (1) The following is a regulated navigation area: The waters of San Pedro Bay encompassed by the following geographic coordinates:

From Point Fermin Light (33°42′18″ N, 118°17′36″ W) thence allow the shoreline to the San Pedro Breakwater, thence along the San Pedro Breakwater and the Middle Breakwater (following the COLREGS Demarcation Lines) to the Long Beach Channel Entrance Light 2 (33°43′24″ N, 118°10′48″ W), thence southeast to (33°37′42″ N, 118°06′36″ W), thence southwesterly to (33°35′30″ N, 118°08′48″ W), thence west to (33°35′30″ N, 118°17′36″ W), thence north to the point of origin. [All datum: NAD 1983]

(2) The San Pedro Bay RNA consists of the following defined sub-areas:

(i) *The Los Angeles Pilot Area.* This area is enclosed by a line beginning at the Los Angeles Light (33°42′30″ N, 118°15′06″ W), thence east to Los Angeles Main Light Channel Entrance Light 2 (33°42′42″ N, 118°14′12″ W), thence southeasterly to (33°41′17″ N, 118°13′30″ W), thence southwesterly to (33°40′51″ N, 118°14′53″ W), thence north to the point of origin.

(ii) *The Long Beach Pilot Area.* This area is enclosed by a line beginning at Long Beach Light (33°43′24″ N, 118°11′12″ W), thence east to Long Beach Channel Entrance Light 2 (33°43′24″ N, 118°10′48″ W), thence south-southeasterly to (33°41′30″ N, 118°10′13″ W), thence south to (33°40′31″ N, 118°10′13″ W), thence west to (33°40′31″ N, 118°11′49″ W), thence north to (33°41′30″ N, 118°11′49″ W), thence north-northeasterly to the point of origin.

(iii) *The Los Angeles Deep Water Traffic Lane.* This area is bounded by a line beginning at (33°42′28″ N, 118°14′56.9″ W) thence easterly to (33°42′33.4″ N, 118°14′45″ W), thence southeasterly to (33°39′29″ N, 118°13′19.4″ W), thence westerly to (33°39′25.1″ N, 118°13′33″ W), thence northerly to the point of origin.

(iv) *The Long Beach Deep Water Traffic Lane.* This area is bounded by a line beginning at (33°43′25.5″ N, 118°11′09″ W) thence east to (33°43′23.3″ N, 118°10′54.1″ W), thence south to (33°41′30.8″ N, 118°10′42.6″ W), thence west to (33°41′30″ N, 118°10′57″ W), thence north to the point of origin.

(v) *The Los Angeles Deep Water Pilot Area.* A circular area of 1.0 nm diameter centered on (33°39′00″ N, 118(13′11.6″ W).

(d) *General regulations.* The following regulations contained in paragraphs (d)(1) through (d)(3) of this section apply to power driven vessels of 1600 or more gross tons, a towing vessel of 8 meters (approximately 26 feet) or over in length engaged in towing, or vessels of 100 gross tons and upward carrying one or more passengers for hire:

(1) A vessel shall not exceed a speed of 12 knots through the water within the RNA.

(2) A vessel navigating within the RNA, shall have its engine(s) ready for immediate maneuver and shall operate its engine(s) in a control mode and on fuel that will allow for an immediate response to any engine order, ahead or astern, including stopping its engine(s) for an extended period of time.

(3) A vessel navigating within the RNA shall maintain a minimum separation from other vessels of at least 0.25 nm.

(e) *Specific regulations.* [All Datum: NAD 1983]

(1) *Los Angeles Pilot Area.* (i) No vessel may enter the Los Angeles Pilot Area unless it is entering or departing Los Angeles Harbor entrance (Angels Gate).

(ii) Vessels entering the Los Angeles Pilot Area shall pass directly through without stopping or loitering except as necessary to embark or disembark a pilot.

(2) *Long Beach Pilot Area.* (i) No vessel may enter the Long Beach Pilot Area unless it is entering or departing Long Beach Harbor entrance (Queens Gate).

(ii) Vessels entering the Long Beach Pilot Area shall pass directly through without stopping or loitering except as necessary to embark or disembark a pilot.

(iii) Every vessel shall leave Long Beach Approach Lighted Whistle Buoy ''LB'' to port when entering and departing Long Beach Channel and departing vessels shall pass across the southern boundary of the Long Beach Pilot Area.

(3) *Los Angeles and Long Beach Deep Water Traffic Lanes.* When a vessel of 50 foot draft or greater is using the Los Angeles or Long Beach Deep Water Traffic Lane no other vessel shall enter the deep water traffic lane if it will result in a meeting, crossing or overtaking situation.

(4) *Los Angeles Deep Water Pilot Area.* When a vessel of 50 foot draft or greater is embarking or disembarking a pilot in the Los Angeles Deep Water Pilot Area no other vessel shall enter the Deep Water Pilot Area.

(5) *Commercial Anchorage G Area.* No vessel may enter the waters between Commercial Anchorage G and the Middle Breakwater as defined by an area enclosed by the by a line beginning at Los Angeles Main Channel Entrance Light 2 (33°42′42″ N, 118°14′42″ W), thence east along the Middle Breakwater to Long Beach Light (33°43′24″ N, 118°11′12″ W), thence south to (33° 43′05.3″ N, 118°11′15.3″ W), thence westerly to (33°43′05.3″ N, 118°12′15.7″ W), thence southwesterly parallel to the breakwater to (33°42′25.9″ N, 118°14′18.0″ W, thence to the point or origin, unless such vessel is:

(i) In an emergency;

(ii) Proceeding to anchor in or departing Commercial Anchorage G;

(iii) Standing by with confirmed pilot boarding arrangements; or,

(iv) Engaged in towing vessels to or from Commercial Anchorage G, or to or from the waters between Commercial Anchorage G and the Middle Breakwater.

Dated: July 6, 2000.

C.D. Wurster,

Acting Captain, U.S. Coast Guard, Commander, Coast Guard Pacific Area, Acting.

[FR Doc. 00–18313 Filed 7–20–00; 8:45 am]

BILLING CODE 4910–15–U

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

36 CFR Part 1191

[Docket No. 98–5]

RIN 3014–AA16

Americans With Disabilities Act Accessibility Guidelines; Recreation Facilities

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Availability of draft final guidelines summary and informational meetings.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (Access Board) has placed in the docket for public review and comment a summary of recommendations made by an ad hoc committee of the Access Board for final accessibility guidelines on recreation facilities. The summary placed in the docket reflects the ad hoc committee's consideration of comments on a proposed rule and information gathered at meetings sponsored by the committee. Comments will be accepted on the summary and the Access Board will consider those comments before it votes on a final rule. The Access Board will hold informational meetings to

discuss the summary on the dates and at the locations noted below.

DATES: Comments on the summary must be received by September 19, 2000. The Access Board will hold informational meetings on the summary on August 21–22, 2000 from 8:30 a.m. to 5:30 p.m. and on September 6–7, 2000 from 8:30 a.m. to 5:30 p.m.

ADDRESSES: Comments should be sent to the Office of Technical and Information Services, Architectural and Transportation Barriers Compliance Board, 1331 F Street NW., suite 1000, Washington, DC 20004–1111. Please identify comments as pertaining to this notice of availability. Comments will be available for inspection at the above address from 9:00 a.m. to 5:00 p.m. on regular business days. The informational meeting on August 21–22, 2000 will be held at the Hilton Garden Inn, 815 14th Street, NW in Washington, DC. The informational meeting on September 6–7, 2000 will be held at the Holiday Inn Golden Gateway, 1500 Van Ness Avenue in San Francisco, CA.

FOR FURTHER INFORMATION CONTACT: Bill Botten, Office of Technical and Information Services, Architectural and Transportation Barriers Compliance Board, 1331 F Street, NW., suite 1000, Washington, DC 20004–1111. Telephone number (202) 272–5434 extension 136 (Voice); (202) 272–5449 (TTY). These are not toll-free numbers. Electronic mail address: botten@access-board.gov.

SUPPLEMENTARY INFORMATION: In 1993, the Architectural and Transportation Barriers Compliance Board (Access Board) established an advisory committee of 27 members to make recommendations on guidelines for recreation facilities. The Recreation Access Advisory Committee met from July 1993 to May 1994 and submitted a report to the Board, ''Recommendations for Accessibility Guidelines: Recreational Facilities and Outdoor Developed Areas''. The Board has made this report widely available as a source of guidance until final guidelines are developed. After receiving the committee's report, the Board published it as an advance notice of proposed rulemaking (59 FR 48542, September 21, 1994). Over 600 comments were received on the report and questions asked in the advance notice. The Board also sponsored research on access to swimming pools in 1995; and held informational meetings and site visits on access to miniature golf facilities in September 1996, and amusement rides in December 1999 and March and April 2000 to obtain additional information for this rulemaking.

A notice of proposed rulemaking on accessibility guidelines for recreation facilities was published in the **Federal Register** on July 9, 1999. 64 FR 37326 (July 9, 1999). The comment period was originally scheduled to close on November 8, 1999, but was extended until December 8, 1999 to allow more time for public comments to be submitted. Comments were submitted electronically, written, or as oral testimony received during two public hearings. Public hearings were held in Dallas, TX (August 26, 1999) and Boston, MA (November 17, 1999). Over 200 people attended the hearings and approximately 54 people provided testimony. Approximately 300 comments were received during the public comment period.

The proposed rule covered various recreation facilities, including amusement rides, boating facilities, fishing piers and platforms, golf courses, miniature golf, sports facilities, and swimming pools and spas. The proposed rule provided scoping requirements, which specify what has to be accessible, and technical requirements, which spell out how access is to be achieved. When finalized, these guidelines will supplement the Americans with Disabilities Act Accessibility Guidelines (ADAAG), which address a wide range of facilities but does not currently cover these types of recreation facilities in any particular detail.

The Access Board has created an ad hoc committee of Board members to review the comments received on the proposed rule. The ad hoc committee has discussed significant issues associated with the comments and has made recommendations to the full Board for the final rule. The Board has placed a summary of the ad hoc committee's recommendations in the rulemaking docket (Docket No. 98–5) for public review. The summary is also available on the Access Board's Internet site (http://www.access-board.gov/recreation/summary.htm).

The summary is being made available for informational purposes and for purposes of receiving additional comments from interested parties prior to final action. Following a review of any additional comments on the summary, the Board will vote on the final rule. In addition to welcoming written comments, the Board will be conducting two informational meetings to provide the public with an additional opportunity to discuss the summary. The informational meetings will be informal and interested parties are encouraged to join in discussions with Board members and the public on the summary. Preliminary agendas for the meetings are as follows:

Washington, DC, Hilton Garden Inn, 815 14th Street, NW

August 21, 2000

8:30 a.m.–12 noon—amusement rides

1:30 p.m.–3 p.m.—amusement rides (continued)

3 p.m.–5:30 p.m.—golf, sports facilities, fishing piers and platforms

August 22, 2000

8:30 a.m.–12:00 noon—boating facilities

1:30 p.m.–5:30 p.m.—miniature golf, swimming pools and spas

San Francisco, CA, Holiday Inn Golden Gateway, 1500 Van Ness Avenue

September 6, 2000

8:30 a.m.–12 noon—boating facilities

1:30 p.m.–3 p.m.—boating facilities (continued)

3 p.m.–5:30 p.m.—golf, sports facilities, fishing piers and platforms

September 7, 2000

8:30 a.m.–12 noon—amusement rides

1:30 p.m.–5:30 p.m.—miniature golf, swimming pools and spas

Interested members of the public are encouraged to contact the Access Board at (202) 272–5434 extension 136 or (202) 272–5449 (TTY) to preregister to attend the informational meetings.

Lawrence W. Roffee,

Executive Director.

[FR Doc. 00–18515 Filed 7–20–00; 8:45 am]

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Parts 1 and 39

RIN 2900–AJ77

Prohibition of Interment or Memorialization in National Cemeteries and Certain State Cemeteries Due to Commission of Capital Crimes

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: We propose to amend the Department of Veterans Affairs (VA) regulations governing eligibility for interment or memorialization in national cemeteries and in State cemeteries receiving State cemetery grants from VA. The proposed rule concerns statutory provisions designed to ensure that the remains of certain persons who committed Federal or State capital crimes are not interred in such cemeteries and that the memory of such persons is not memorialized in such cemeteries. We propose to restate a portion of these statutory provisions and to establish interpretations, delegations

of authority, and procedures which we believe to be appropriate for us to carry out the statutory provisions.

DATES: Comments must be received on or before September 19, 2000.

ADDRESSES: Mail or hand-deliver written comments to: Director, Office of Regulations Management (02D), Department of Veterans Affairs, 810 Vermont Ave., NW., Room 1154, Washington, DC 20420; or fax comments to (202) 273–9289; or e-mail comments to ''OGCRegulations@mail.va.gov''. Comments should indicate that they are submitted in response to ''RIN 2900-AJ77.'' All comments received will be available for public inspection in the Office of Regulations Management, Room 1158, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays).

FOR FURTHER INFORMATION CONTACT: Kenneth Greenberg, Staff Assistant, Office Deputy Under Secretary for Management (402) or Deanna Wilson, Program Analyst, Communications Division (402B1), National Cemetery Administration, Department of Veterans Affairs, 810 Vermont Ave., NW., Washington, DC 20420, (202) 273–5179 or (202) 273–5154 (these are not toll-free numbers).

SUPPLEMENTARY INFORMATION: The provisions of 38 U.S.C. 2408(d) and 2411 enacted on November 21, 1997, prohibit, under specified circumstances, interment or memorialization in VA national cemeteries of certain persons who are convicted of, or are found to have committed, Federal or State capital crimes and condition VA State cemetery grants on the prohibition of interment or memorialization of such persons in State cemeteries receiving such grants. This document proposes to establish regulations relating to these statutory provisions.

Proposed 38 CFR 1.600 contains definitions for proposed §§ 1.617 and 1.618.

Proposed 38 CFR 1.617 restates statutory prohibitions against interment or memorialization in a VA national cemetery of persons who have been convicted of Federal capital crimes for which they have been sentenced to death or life imprisonment or State capital crimes for which they have been sentenced to death or life imprisonment without parole, as well as persons who have been found to have committed Federal or State capital crimes and not to have been convicted as a result of unavailability for trial due to death or flight to avoid prosecution. This section would also establish procedures for decisions on requests for interment of the remains of or memorialization of persons who may have been convicted of Federal or State capital crimes.

Proposed 38 CFR 1.618 sets forth procedures for handling eligibility determinations concerning interment or memorialization in a VA national cemetery when VA becomes aware of information suggesting that an individual has committed a capital crime for which the individual would have been convicted, in either a Federal or State court, but has not been convicted due to unavailability for trial due to death or flight to avoid prosecution. These procedures are intended to implement the provisions of 38 U.S.C. 2411. Under paragraphs (b), (c), and (d) of that statute, the prohibitions against interment and memorialization apply in these cases only if there is a finding by VA that the person committed a Federal capital crime or a State capital crime but has not been convicted of such crime because such person was not available for trial due to death or flight to avoid prosecution. However, paragraph (a)(2) of that statute states that the prohibitions in these cases apply only if written notice of this finding is provided to VA by the Attorney General or an appropriate State official. We believe that this notice provision reflects a legislative error, since there would be no need for the Attorney General or a State official to notify VA of a finding made by VA. Accordingly, we have included a provision in § 1.617 to clarify that if an appropriate finding is made by VA the prohibitions will apply without any notice from the Attorney General or a State official.

We propose to amend 38 CFR 39.2 and 39.3 to reflect provisions of 38 U.S.C. 2408(d) making future grants for the establishment, expansion, or improvement of State veterans cemeteries contingent on the prohibition of interment in such cemeteries of the remains of certain persons who have committed Federal or State capital crimes.

Regulatory Flexibility Act

The Secretary hereby certifies that the adoption of the proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The proposed rule would not have more than a minuscule effect on any small entity. Therefore, pursuant to 5 U.S.C. 605(b), this proposed rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

The Catalog of Federal Domestic Assistance numbers for this proposed rule are 64.201, 64.202, and 64.203.

List of Subjects

38 CFR Part 1

Administrative practice and procedure, Cemeteries, Claims, Crimes, Criminal offenses.

38 CFR Part 39

Cemeteries, Grant programs-veterans, Veterans.

Approved: July 5, 2000.

Togo D. West, Jr.,

Secretary of Veterans Affairs.

For the reasons set forth in the preamble, 38 CFR parts 1 and 39 are proposed to be amended as follows:

PART 1—GENERAL PROVISIONS

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

Authority: 38 U.S.C. 501(a), unless otherwise noted.

2. Section 1.600 is added to read as follows:

§ 1.600 Definitions.

(a) [Reserved]

(b) *Definitions.* For purposes of §§ 1.617 and 1.618:

Appropriate State official means a State attorney general or other official with state-wide responsibility for law enforcement or penal functions.

Clear and convincing evidence means that degree of proof which produces in the mind of the fact-finder a firm belief regarding the question at issue.

Convicted means a finding of guilt by a judgment or verdict or based on a plea of guilty, by a Federal or State criminal court.

Federal capital crime means a crime under Federal law for which the death penalty or life imprisonment may be imposed.

Interment means the burial of casketed remains or the placement or scattering of cremated remains.

Life imprisonment means a sentence of a Federal or State criminal court directing confinement in a penal institution for life.

Memorialization means the erection of a memorial or marker to honor the memory of a deceased individual.

Personal representative means a family member or other individual who has identified himself or herself to the National Cemetery Administration cemetery director as the person responsible for making decisions concerning the interment of the remains of or memorialization of a deceased individual.

State capital crime means, under State law, the willful, deliberate, or premeditated unlawful killing of another human being for which the death penalty or life imprisonment without parole may be imposed.

(Authority: 38 U.S.C. 2408, 2411)

3. Section 1.617 is added to read as follows:

§ 1.617 Prohibition of interment or memorialization of persons who have committed Federal or State capital crimes.

(a) *Prohibition.* The interment in a national cemetery under the control of the National Cemetery Administration of the remains, or the memorialization in such a cemetery, of any of the following persons is prohibited:

(1) Any person identified to the Secretary of Veterans Affairs by the United States Attorney General, prior to approval of interment or memorialization, as an individual who has been convicted of a Federal capital crime and sentenced to death or life imprisonment as a result of such crime.

(2) Any person identified to the Secretary of Veterans Affairs by an appropriate State official, prior to approval of interment or memorialization, as an individual who has been convicted of a State capital crime and sentenced to death or life imprisonment without parole as a result of such crime.

(3) Any person found under procedures specified in § 1.618 to have committed a Federal or State capital crime but to have avoided conviction of such crime by reason of unavailability for trial due to death or flight to avoid prosecution.

(b) *Notice.* The prohibition referred to in paragraph (a)(3) of this section is not contingent on receipt by the Secretary of Veterans Affairs or any other VA official of notice from any Federal or State official.

(c) *Receipt of notification.* The Under Secretary for Memorial Affairs is delegated authority to receive from the United States Attorney General and appropriate State officials on behalf of the Secretary of Veterans Affairs the notification of conviction of capital crimes referred to in paragraphs (a)(1) and (2) of this section.

(d) *Decision where notification previously received.* Upon receipt of a request for interment or memorialization, where the Secretary of Veterans Affairs has received the notification referred to in paragraph (a)(1) or (a)(2) of this section with regard to the deceased, the cemetery director will make a decision on the request for interment or memorialization pursuant to 38 U.S.C. 2411.

(e) *Inquiry.* (1) Upon receipt of a request for interment or memorialization, where the Secretary of Veterans Affairs has not received the notification referred to in paragraph (a)(1) or (a)(2) of this section with regard to the deceased, but the cemetery director has reason to believe that the deceased may have been convicted of a Federal or State capital crime, the cemetery director will initiate an inquiry to either:

(i) The United States Attorney General, in the case of a Federal capital crime, requesting notification of whether the deceased has been convicted of a Federal capital crime for which the deceased was sentenced to death or life imprisonment; or

(ii) An appropriate State official, in the case of a State capital crime, requesting notification of whether the deceased has been convicted of a State capital crime for which the deceased was sentenced to death or life imprisonment without parole.

(2) The cemetery director will defer decision on whether to approve interment or memorialization until after a response is received from the Attorney General or appropriate State official.

(f) *Decision after inquiry.* Where an inquiry has been initiated under paragraph (e) of this section, the cemetery director will make a decision on the request for interment or memorialization pursuant to 38 U.S.C. 2411 upon receipt of the notification requested under that paragraph, unless the cemetery director initiates an inquiry pursuant to section 1.618(a).

(g) *Notice of decision.* Written notice of a decision under paragraph (d) or (f) of this section will be provided by the cemetery director to the personal representative of the deceased, along with written notice of appellate rights in accordance with § 19.25 of this title. This notice will include notice of the opportunity to file a notice of disagreement with the decision of the cemetery director. Action following receipt of a notice of disagreement with a denial of eligibility for interment or memorialization under this section will be in accordance with §§ 19.26 through 19.38 of this title.

Note to § 1.617: A decision under this section will not affect eligibility for any benefit under title 38, United States Code, other than interment or memorialization.

(Authority: 38 U.S.C. 512, 2411, 7105)

4. § Section 1.618 is added to read as follows:

§ 1.618 Findings concerning commission of a capital crime where a person has not been convicted due to death or flight to avoid prosecution.

(a) *Inquiry.* With respect to a request for interment or memorialization, if a cemetery director has reason to believe that a deceased individual who is otherwise eligible for interment or memorialization may have committed a Federal or State capital crime, but avoided conviction of such crime by reason of unavailability for trial due to death or flight to avoid prosecution, the cemetery director, with the assistance of the VA regional counsel, as necessary, will initiate an inquiry seeking information from Federal, State, or local law enforcement officials, or other sources of potentially relevant information. After completion of this inquiry and any further measures required under paragraphs (c), (d), (e), and (f) of this section, the cemetery director will make a decision on the request for interment or memorialization in accordance with paragraph (b), (e), or (g) of this section.

(b) *Decision approving request without a proceeding.* If, after conducting the inquiry described in paragraph (a) of this section, the cemetery director determines that there is no clear and convincing evidence that the deceased committed a Federal or State capital crime of which he or she was not convicted due to death or flight to avoid prosecution, and the deceased remains otherwise eligible, the cemetery director will make a decision approving the interment or memorialization.

(c) *Initiation of a proceeding.* (1) If, after conducting the inquiry described in paragraph (a) of this section, the cemetery director determines that there appears to be clear and convincing evidence that the deceased has committed a Federal or State capital crime of which he or she was not convicted by reason of unavailability for trial due to death or flight to avoid prosecution, the cemetery director will provide the personal representative of the deceased with a written summary of the evidence of record and a written notice of procedural options.

(2) The notice of procedural options will inform the personal representative that the personal representative may, within the earlier of ten days of mailing of the notice or ten days of hand delivery of the notice:

(i) Request a hearing on the matter;

(ii) Submit a written statement, with or without supporting documentation, for inclusion in the record; or

(iii) Waive a hearing and submission of a written statement and have the matter forwarded immediately to the

Under Secretary for Memorial Affairs for a finding.

(3) The notice of procedural options will also inform the personal representative that, if the personal representative does not exercise one or more of the stated options within the prescribed period, the matter will be forwarded to the Under Secretary for Memorial Affairs for a finding based on the existing record.

(d) *Hearing.* If a hearing is requested, the hearing will be conducted by the cemetery director or his or her designee. The purpose of the hearing is to permit the personal representative of the deceased to present evidence concerning whether the deceased committed a crime which would render the deceased ineligible for interment or memorialization in a national cemetery. Testimony at the hearing will be presented under oath, and the personal representative will have the right to representation by counsel and the right to call witnesses. The VA official conducting the hearing will have the authority to administer oaths. The hearing will be conducted in an informal manner and court rules of evidence will not apply. The hearing will be recorded on audiotape and, unless transcription is waived by the personal representative, a transcript of the hearing will be produced and included in the record.

(e) *Decision of approval or referral for a finding after a proceeding.* Following a hearing or the timely submission of a written statement, or in the event a hearing is waived or no hearing is requested and no written statement is submitted within the time specified:

(1) If the cemetery director determines that it has not been established by clear and convincing evidence that the deceased committed a Federal or State capital crime of which he or she was not convicted due to death or flight to avoid prosecution, and the deceased remains otherwise eligible, the cemetery director will make a decision approving interment or memorialization, or

(2) If the cemetery director believes that there is clear and convincing evidence that the deceased committed a Federal or State capital crime of which he or she was not convicted due to death or flight to avoid prosecution, the cemetery director will forward a request for a finding on that issue, together with the cemetery director's recommendation and a copy of the record, to the Under Secretary for Memorial Affairs.

(f) *Finding by the Under Secretary for Memorial Affairs.* Upon receipt of a request from the cemetery director under paragraph (e) of this section, the Under Secretary for Memorial Affairs will make a finding concerning whether the deceased committed a Federal or State capital crime of which he or she was not convicted by reason of unavailability for trial due to death or flight to avoid prosecution. The finding will be based on consideration of the cemetery director's recommendation and the record supplied by the cemetery director.

(1) A finding that the deceased committed a crime referred to in paragraph (f) of this section must be based on clear and convincing evidence.

(2) The cemetery director and the personal representative of the deceased will be provided with written notification of the finding of the Under Secretary for Memorial Affairs.

(g) *Decision after finding.* Upon receipt of notification of the finding of the Under Secretary for Memorial Affairs, the cemetery director will make a decision on the request for interment or memorialization pursuant to 38 U.S.C. 2411. In making that decision, the cemetery director will be bound by the finding of the Under Secretary for Memorial Affairs.

(h) *Notice of decision.* The cemetery director will provide written notice of a decision under paragraph (b), (e)(1), or (g) of this section and notice of appellate rights to the personal representative of the deceased, in accordance with § 19.25 of this title. This notice will include notice of the opportunity to file a notice of disagreement with the decision of the cemetery director and the finding of the Under Secretary for Memorial Affairs. Action following receipt of a notice of disagreement with a denial of eligibility for interment or memorialization under this section will be in accordance with §§ 19.26 through 19.38 of this title.

(Authority: 38 U.S.C. 512, 2411)

PART 39—STATE CEMETERY GRANTS

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

Authority: 38 U.S.C. 2408.

6. In § 39.2, a new paragraph (d) is added to read as follows:

§ 39.2 Scope of the State cemetery grants program.

* * * * *

(d) Any grant under this part made on or after November 21, 1997, is made on the condition that after the date of receipt of the grant the State receiving the grant, subject to requirements for receipt of notice in 38 U.S.C. 2408 and 2411, will prohibit in the cemetery for which the grant is furnished the interment of the remains of or the memorialization of any person:

(1) Who has been convicted of a Federal capital crime for which the person was sentenced to death or life imprisonment;

(2) Who has been convicted of a State capital crime for which the person was sentenced to death or life without parole; or

(3) Who has been found by an appropriate State official, under procedures to be established by the State, to have committed a Federal or State capital crime but to have not been convicted of such crime by reason of unavailability for trial due to death or flight to avoid prosecution.

(Authority: 38 U.S.C. 2408, 2411)

7. In § 39.3, paragraph (b)(1) is revised and an authority citation is added at the end of paragraph (b) to read as follows:

§ 39.3. Applications with respect to projects.

* * * * *

(b) * * *

(1) Any cemetery established, expanded, or improved through assistance of this program shall be used exclusively for the interment or memorialization of eligible persons, as set forth in §§ 39.1(h) and 39.2(a), whose interment or memorialization is not contrary to the conditions of the grant (see § 39.2(d) and 38 U.S.C. 2408 and 2411).

* * * * *

(Authority: 38 U.S.C. 2408, 2411)

* * * * *

[FR Doc. 00–18325 Filed 7–20–00; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 184–0245b; FRL–6734–6]

Revisions to the California State Implementation Plan, Ventura County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the Ventura County Air Pollution Control District's (VCAPCD) portion of the California State Implementation Plan (SIP). These revisions concern volatile organic compound (VOC) emissions from degreasers. We are proposing to approve local rules to regulate these emission

sources under the Clean Air Act as amended in 1990 (CAA or the Act).

DATES: Any comments must arrive by August 21, 2000.

ADDRESSES: Mail comments to Andy Steckel, Rulemaking Office Chief (AIR–4), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

You can inspect copies of the submitted SIP revisions and EPA's technical support document (TSD) at our Region IX office during normal business hours. You may also see copies of the submitted SIP revisions at the following locations:

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812.

Ventura County Air Pollution Control District, 669 County Square Dr., 2nd Fl., Ventura, CA 93003–5417.

FOR FURTHER INFORMATION CONTACT: Yvonne Fong, Rulemaking Office (Air–4), U.S. Environmental Protection Agency, Region IX, (415) 744–1199.

SUPPLEMENTARY INFORMATION: This proposal addresses the following local rules: VCAPCD Rules 74.6.1, 74.6.2, and 74.6.3. In the Rules and Regulations section of this **Federal Register**, we are approving these local rules in a direct final action without prior proposal because we believe these SIP revisions are not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in subsequent action based on this proposed rule. We do not plan to open a second comment period, so anyone interested in commenting should do so at this time. If we do not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

Dated: June 28, 2000.

Nora L. McGee,

Acting Regional Administrator, Region IX.

[FR Doc. 00–18432 Filed 7–20–00; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AG29

Endangered and Threatened Wildlife and Plants; Proposed Designation of Critical Habitat for the Mexican Spotted Owl

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; availability of supplementary information.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose the designation of critical habitat pursuant to the Endangered Species Act of 1973, as amended (Act), for the Mexican spotted owl (*Strix occidentalis lucida*) (owl). The owl inhabits canyon and montane forest habitats across a range that extends from southern Utah and Colorado, through Arizona, New Mexico, and west Texas, to the mountains of central Mexico. We propose to designate approximately 5.5 million hectares (ha) (13.5 million acres (ac)) of critical habitat in Arizona, Colorado, New Mexico, and Utah, mostly on federal lands.

If this proposed rule is finalized, section 7(a)(2) of the Act would require that Federal agencies ensure that actions they fund, authorize, or carry out are not likely to result in the ''destruction or adverse modification'' of critical habitat. Section 4 of the Act requires us to consider economic and other relevant impacts of specifying any particular area as critical habitat. We request data and comments from the public and all interested parties on all aspects of this proposal, including data on economic and other impacts of the designation. A draft analysis of the economic and other relevant impacts of this proposal that will be available for review and comments on during the public comment period for this proposal. We will announce the availability of this analysis in a future **Federal Register** notice and local newspapers. We also have prepared a draft environmental assessment for this proposal and are accepting public comments on the draft document.

DATES: We will consider all comments on the proposed rule, the draft economic analysis, and draft Environmental Assessment received from interested parties by September 19, 2000. We will hold six public hearings (see Public Hearings in the **SUPPLEMENTARY INFORMATION** section of this rule for dates).

ADDRESSES: 1. Send your comments on this proposed rule, draft economic analysis, and draft environmental assessment to the New Mexico Ecological Services Field Office, 2105 Osuna Road NE, Albuquerque, New Mexico 87113.

2. The complete file for this proposed rule will be available for public inspection, by appointment, during normal business hours at the New Mexico Ecological Services Field Office, 2105 Osuna Road NE, Albuquerque, New Mexico 87113. The draft environmental assessment is available by writing to the above address. We will specify the availability of the draft economic analysis in local newspapers and through a notice in the **Federal Register** once it has been completed.

3. For locations of the public hearings, see Public Hearings in the **SUPPLEMENTARY INFORMATION** section of this rule.

FOR FURTHER INFORMATION CONTACT: Joy Nicholopoulos, Field Supervisor, New Mexico Ecological Services Field Office, at the above address; telephone 505/346–2525, facsimile 505/346–2542.

SUPPLEMENTARY INFORMATION:

Background

The Mexican spotted owl (*Strix occidentalis lucida*) is one of three subspecies of spotted owl occurring in the United States; the other two are the northern spotted owl (*S. o. caurina*) and the California spotted owl (*S. o. occidentalis*). The Mexican spotted owl is distinguished from the California and northern subspecies chiefly by geographic distribution and plumage. The Mexican spotted owl is mottled in appearance with irregular white and brown spots on its abdomen, back, and head. The spots of the Mexican spotted owl are larger and more numerous than in the other two subspecies, giving it a lighter appearance.

The Mexican spotted owl has the largest geographic range of the three subspecies. The range extends north from Aguascalientes, Mexico, through the mountains of Arizona, New Mexico, and western Texas, to the canyons of southern Utah and southwestern Colorado, and the Front Range of central Colorado. Much remains unknown about the species' distribution in Mexico, where much of the owl's range has not been surveyed. The owl occupies a fragmented distribution throughout its United States range, corresponding to the availability of forested mountains and canyons, and in some cases, rocky canyonlands. Although there are no estimates of the owl's historical population size, its

historical range and present distribution are thought to be similar.

According to the Recovery Plan for the Mexican Spotted Owl (USDI 1995) (Recovery Plan), 91 percent of owls known to exist in the United States between 1990 and 1993 occurred on land administered by the U.S. Forest Service (FS); therefore, the primary administrator of lands supporting owls in the United States is the FS. Most owls have been found within Region 3 of the FS, which includes 11 National Forests in New Mexico and Arizona. FS Regions 2 and 4, including two National Forests in Colorado and three in Utah, support fewer owls. The range of the owl is divided into 11 Recovery Units (RU), 5 in Mexico and 6 in the United States, as identified in the Recovery Plan. The Recovery Plan also identifies recovery criteria and provides distribution, abundance, and density estimates by RU. Of the RUs in the United States, the Upper Gila Mountain RU, located in the central portion of the species' U.S. range in central Arizona and west-central New Mexico, has the greatest known concentration of owl sites (55.9 percent of U.S. population). Owls here use a wide variety of habitat types, but are most commonly found inhabiting mature mixed-conifer and ponderosa pine-Gambel oak forests. The Basin and Range-East RU, with 16.0 percent of the U.S. population, encompassing central and southern New Mexico, and includes numerous parallel mountain ranges separated by alluvial valleys and broad, flat basins. Most breeding spotted owls occur in mature mixed-conifer forest. The Basin and Range-West RU contains mountain ranges separated by non-forested habitat. These ''sky island'' mountains of southern Arizona and far-western New Mexico contain mid-elevation mixed-conifer forest and lower elevation Madrean pine-oak woodlands that supports 13.6 percent of the spotted owls. Colorado Plateau RU contains 8.2 percent of the U.S. population of Mexican spotted owls. This large unit includes northern Arizona, southern Utah, southwestern Colorado, and northwestern New Mexico, with owls generally confined to deeply incised canyon systems and wooded areas of isolated mountain ranges. Southern Rocky Mountains-New Mexico RU, with 4.5 percent of the population, consists of the mountain ranges of northern New Mexico. Owls in this unit typically inhabit mature mixed-conifer forest in steep canyons. The smallest percentage of spotted owls (1.8 percent) occurs in the Southern Rocky Mountains-Colorado RU. This unit includes the southern Rocky Mountains in Colorado, where spotted owls are largely confined to steep canyons, generally with significant rock faces and various amounts of mature coniferous forest. The critical habitat units identified in this proposal are all within these RUs.

A reliable estimate of the numbers of owls throughout its entire range is not currently available. Using information gathered by Region 3 of the FS, Fletcher (1990) calculated that 2,074 owls existed in Arizona and New Mexico in 1990. Based on more up-to-date information, we subsequently modified Fletcher's calculations and estimated a total of 2,160 owls throughout the United States (USDI 1991). However, these numbers are not considered reliable estimates of current population size for a variety of statistical reasons. While the number of owls throughout the range is currently not available, the Recovery Plan reports an estimate of owl sites based on 1990–1993 data. Surveys from 1990 through 1993 indicate one or more owls have been observed at a minimum of 758 sites in the United States and 19 sites in Mexico. In addition, these surveys indicate that the species persists in most locations reported prior to 1989, with the exception of riparian habitats in the lowlands of Arizona and New Mexico, and all previously occupied areas in the southern States of Mexico. Owl surveys since 1993 have provided new location data, increasing the knowledge of owl distribution and abundance. However, information summarized within the Recovery Plan was the last comprehensive effort to estimate the total number of owls.

Mexican spotted owls nest, roost, forage, and disperse in a diverse array of biotic communities. Nesting habitat is typically in areas with complex forest structure or rocky canyons, and contains uneven-aged, multi-storied mature or old-growth stands that have high canopy closure (Ganey and Balda 1989, USDI 1991). In the northern portion of the range (southern Utah and Colorado), most nests are in caves or on cliff ledges in steep-walled canyons. Elsewhere, the majority of nests appear to be in Douglas fir (*Pseudotsuga menziesii*) trees (Fletcher and Hollis 1994, Seamans and Gutierrez 1995). A wide variety of tree species is used for roosting; however, Douglas fir is the most commonly used species (Ganey 1988, Fletcher and Hollis 1994, Young *et al.* 1998). Owls generally use a wider variety of forest conditions for foraging than they use for nesting/roosting.

Seasonal movement patterns of Mexican spotted owls are variable. Some individuals are year-round residents within an area, some remain in the same general area but show shifts in habitat use patterns, and some migrate considerable distances (20–50 kilometers (km)) (12–31 miles (mi)) during the winter, generally migrating to more open habitat at lower elevations (Ganey and Balda 1989b, Willey 1993, Ganey *et al.* 1998). The home-range size of Mexican spotted owls appears to vary considerably among habitats and/or geographic areas (USDI 1995), ranging in size from 261–1,487 ha (647–3,688 ac) for individuals birds, and 381–1,551 ha (945–3,846 ac) for pairs (Ganey and Balda 1989b, Ganey *et al.* 1999). Little is known about habitat use by juveniles dispersing soon after fledging. Ganey *et al.* (1998) found dispersing juveniles in a variety of habitats ranging from high-elevation forests to pinon-juniper woodlands and riparian areas surrounded by desert grasslands.

Mexican spotted owls do not nest every year. The owl's reproductive pattern varies somewhat across its range. In Arizona, courtship usually begins in March with pairs roosting together during the day and calling to each other at dusk (Ganey 1988). Eggs are typically laid in late March or early April. Incubation begins shortly after the first egg is laid, and is performed entirely by the female (Ganey 1988). The incubation period is about 30 days (Ganey 1988). During incubation and the first half of the brooding period, the female leaves the nest only to defecate, regurgitate pellets, or receive prey from the male, who does all or most of the hunting (Forsman *et al.* 1984, Ganey 1988). Eggs usually hatch in early May, with nestling owls fledging 4 to 5 weeks later, and then dispersing in mid-September to early October (Ganey 1988).

Little is known about the reproductive output for the spotted owl. It varies both spatially and temporally (White *et al.* 1995), but the subspecies demonstrates an average annual rate of about one young per pair. Based on short-term population and radio tracking studies, and longer-term monitoring studies, the probability of an adult owl surviving from 1 year to the next is 80 to 90 percent. Average annual juvenile survival is considerably lower, at 6 to 29 percent, although it is believed these estimates may be artificially low due to the high likelihood of permanent dispersal from the study area, and the lag of several years before marked juveniles reappear as territory holders and are detected as survivors through recapture efforts (*White et al.* 1995). Little research has been conducted on the causes of mortality, but predation by great horned owls (*Bubo virginianus*), northern goshawks (*Accipter gentilis*),

red-tailed hawks (*Buteo jamaicensis*), and golden eagles (*Aquila chrysaetos*), as well as starvation, and collisions (*e.g.,* with cars, powerlines), may all be contributing factors.

Mexican spotted owls consume a variety of prey throughout their range, but commonly eat small- and medium-sized rodents such as woodrats (*Neotoma* spp.), peromyscid mice (*Peromyscus* spp.), and microtine voles (*Microtus* spp.). Owls also may consume bats, birds, reptiles, and arthropods (Ward and Block 1995). Each prey species uses a unique habitat, so that the differences in the owl's diet across its range likely reflect geographic variation in population densities and habitats of both the prey and the owl (Ward and Block 1995). Deer mice (*P. maniculatus*) are widespread in distribution in comparison to brush mice (*P. boylei*), which are restricted to drier, rockier substrates, with sparse tree cover. Mexican woodrats (*N. mexicana*) are typically found in areas with considerable shrub or understory tree cover and high log volumes or rocky outcrops. Mexican voles (*M. mexicanus*) are associated with high herbaceous cover, primarily grasses, whereas long-tailed voles (*M. longicaudus*) are found in dense herbaceous cover, primarily forbs, with many shrubs and limited tree cover.

Two primary reasons were cited for listing the owl as threatened in 1993: (1) Historical alteration of its habitat as the result of timber management practices, specifically the use of even-aged silviculture, and the threat of these practices continuing; and (2) the danger of catastrophic wildfire. The Recovery Plan for the owl outlines management actions that land management agencies and Indian tribes should undertake to remove recognized threats and recover the spotted owl. This critical habitat designation is based on recovery needs identified in the Recovery Plan.

Previous Federal Actions

The entire spotted owl species (*Strix occidentalis*) was classified in the January 6, 1989, Animal Notice of Review (54 FR 554) as a category 2 candidate species. A category 2 candidate species was one for which listing may have been appropriate, but for which additional biological information was needed to support a proposed rule.

On December 22, 1989, we received a petition submitted by Dr. Robin D. Silver requesting the listing of the Mexican spotted owl as an endangered or threatened species. On February 27, 1990, we found that the petition presented substantial information indicating that listing may be warranted and initiated a status review. In conducting our review, we published a notice in the **Federal Register** (55 FR 11413) on March 28, 1990, requesting public comments and biological data on the status of the Mexican spotted owl. On February 20, 1991, we made a finding, based on the contents of the status review, that listing the Mexican spotted owl under section 4(b)(3)(B)(I) of the Act was warranted. Notice of this finding was published in the **Federal Register** on April 11, 1991 (56 FR 14678). We published a proposed rule to list the Mexican spotted owl as threatened without critical habitat in the **Federal Register** on November 4, 1991 (56 FR 56344).

We published a final rule listing the Mexican spotted owl as a threatened species on March 16, 1993 (58 FR 14248). Section 4(a)(3) of the Act requires that, to the maximum extent prudent and determinable, we designate critical habitat at the time a species is determined to be endangered or threatened. The Act's implementing regulations (50 CFR 424.12(a)(2)) state that critical habitat is not determinable if information sufficient to perform required analyses of the impacts of the designation is lacking or if the biological needs of the species are not sufficiently well known to permit identification of an area as critical habitat. At the time of listing, we found that, although considerable knowledge of owl habitat needs had been gathered in recent years, habitat maps in sufficient detail to accurately delineate these areas were not available. After the listing, we began gathering the data necessary to develop a proposed rule to designate critical habitat.

On June 23, 1993, and again on August 16, 1993, we received petitions to remove the Mexican spotted owl from the List of Endangered and Threatened Wildlife. In subsequent petition findings published in the **Federal Register** (58 FR 49467, 59 FR 15361), we addressed the issues raised in the petitions and determined that the delisting petitions did not present substantial information indicating that delisting the Mexican spotted owl was warranted. The petitioners challenged this decision in Federal District Court in New Mexico in *Coalition of Arizona/New Mexico Counties for Stable Economic Growth* v. *United States Fish and Wildlife Service, et al.,* CIV 94–1058–MV. The district court held that the Coalition failed to show that the Service violated any procedural rules that amounted to more than harmless error and failed to demonstrate that the Service acted arbitrarily or capriciously in listing or refusing to delist the Mexican spotted owl. A judgment was issued by the district court denying the plaintiff's petition to delist the owl.

On February 14, 1994, a lawsuit was filed in Federal District Court in Arizona against the Department of the Interior for failure to designate critical habitat for the owl (*Dr. Robin Silver, et al.* v. *Bruce Babbitt, et al.*, CIV–94–0337–PHX–CAM). On October 6, 1994, the Court ordered us to ''* * * publish a proposed designation of critical habitat, including economic exclusion pursuant to 16 U.S.C. Sec. 1533(b)(2), no later than December 1, 1994, [and] publish its final designation of critical habitat, following the procedure required by statute and Federal regulations for notice and comment,'' by submitting the final rule to the **Federal Register** no later than May 27, 1995. Under an extension granted by the court, we issued the proposed rule to designate critical habitat on December 7, 1994 (59 FR 63162).

We prepared a draft economic analysis, and notice of its availability was published in the **Federal Register** on March 8, 1995 (60 FR 12728; 60 FR 12730). The publication also proposed several revisions to the original proposal, solicited additional information and comments, opened an additional 60-day comment period extending to May 8, 1995, and announced the schedule and location of public hearings. We published a final rule designating critical habitat for the Mexican spotted owl on June 6, 1995 (60 FR 29914).

After the listing of the Mexican spotted owl, a Recovery Team was appointed by our Southwestern Regional Director to develop a Recovery Plan in March 1993. The Team assembled all available data on Mexican spotted owl biology, the threats faced across the subspecies' range, current protection afforded the subspecies, and other pertinent information. Using that information, the Team developed the Recovery Plan, which was finalized in the fall of 1995. In 1996, the Southwest Region of the Forest Service incorporated elements of the Mexican Spotted Owl Recovery Plan within their Forest Plan Amendments.

In 1996, the Tenth Circuit Court of Appeals in *Catron County Board of Commissioners* v. *United States Fish and Wildlife Service,* 75 F.3d 1429, 1439 (10th Cir. 1996), ruled that the Service had to comply with the National Environmental Policy Act (NEPA) before designating critical habitat for two desert fish, the spikedace and loach minnow. In addition, a federal district court in New Mexico later set aside the

final rule designating critical habitat for the owl and forbid the Service from enforcing critical habitat for the owl (*Coalition of Arizona-New Mexico Counties for Stable Economic Growth* v. *U.S. Fish and Wildlife Service,* No. 95–1285–M Civil). As a result of these court rulings, we removed the critical habitat designation for the owl from the Code of Federal Regulations on March 25, 1998 (63 FR 14378).

On March 13, 2000, the United States District Court for the District of New Mexico, (*Southwest Center for Biological Diversity and Silver* v. *Babbitt and Clark,* CIV 99–519 LFG/LCS–ACE), ordered us to propose critical habitat within 4 months of the court order, and to complete and publish a final designation of critical habitat for the Mexican spotted owl by January 15, 2001.

Critical Habitat

Critical habitat is defined in section 3(5)(A) of the Act as—(i) The specific areas within the geographic area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) Essential to the conservation of the species and (II) that may require special management considerations or protection and; (ii) specific areas outside the geographic area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. The term ''conservation,'' as defined in section 3(3) of the Act, means ''to use and the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to this Act are no longer necessary'' (*i.e.,* the species is recovered and removed from the list of endangered and threatened species).

Section 4(b)(2) of the Act requires that we base critical habitat designation on the best scientific and commercial data available, taking into consideration the economic impact, and any other relevant impact, of specifying any particular area as critical habitat. We may exclude areas from critical habitat designation if we determine that the benefits of exclusion outweigh the benefits of including the areas as critical habitat, provided the exclusion will not result in the extinction of the species.

Designation of critical habitat helps focus conservation activities by identifying areas that are essential to the conservation of the species, regardless of whether they are currently occupied by the listed species, thus alerting the public and land managing agencies to the importance of an area to conservation. Critical habitat also identifies areas that may require special management or protection. Critical habitat receives protection from destruction or adverse modification through required consultation under section 7 of the Act with regard to actions carried out, funded, or authorized by a Federal agency. Aside from the added protection provided under section 7, the Act does not provide other forms of protection to lands designated as critical habitat.

Section 7(a)(2) of the Act requires Federal agencies to consult with us to ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a threatened or endangered species, or result in the destruction or adverse modification of critical habitat. In 50 CFR 402.02, ''jeopardize the continued existence'' (of a species) is defined as engaging in an activity likely to result in an appreciable reduction in the likelihood of survival and recovery of a listed species. ''Destruction or adverse modification'' (of critical habitat) is defined as a direct or indirect alteration that appreciably diminishes the value of the entire critical habitat designation for the survival and recovery of the listed species for which critical habitat was designated. Thus, the definitions of ''jeopardy'' to the species and ''adverse modification'' of critical habitat are nearly identical.

Designating critical habitat does not, in itself, lead to recovery of a listed species. Designation does not create a management plan, establish numerical population goals, prescribe specific management actions (inside or outside of critical habitat), or directly affect areas not designated as critical habitat. Specific management recommendations for areas designated as critical habitat are most appropriately addressed in recovery, conservation and management plans, and through section 7 consultations and section 10 permits.

Primary Constituent Elements

In accordance with section 3(5)(A)(I) of the Act and regulations at 50 CFR 424.12, in determining which areas to propose as critical habitat, we are required to base critical habitat designation on the best scientific and commercial data available and to consider those physical and biological features (primary constitute elements) that are essential to conservation of the species and that may require special management considerations or protection. Such requirements include, but are not limited to—space for individual and population growth, and for normal behavior; food, water, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, or rearing of offspring; and habitats that are protected from disturbance or are representative of the historic geographical and ecological distributions of a species.

The primary constituent elements essential to the conservation of the Mexican spotted owl include those physical and biological features that support nesting, roosting, and foraging. These elements were determined from studies of Mexican spotted owl behavior and habitat use throughout the range of the owl. Although the vegetative communities and structural attributes used by the owl vary across the range of the subspecies, they consist primarily of warm-temperate and cold-temperate forests, and, to a lesser extent, woodlands and riparian deciduous forests. The mixed-conifer community appears to be most frequently used community throughout most portions of the subspecies' range (Skaggs and Raitt 1988; Ganey and Balda 1989, 1994; USDI 1995). Although the structural characteristics of Mexican spotted owl habitat varies depending on uses of the habitat (e.g., nesting, roosting, foraging) and variations in the plant communities over the range of the subspecies, some general attributes are common to the subspecies' life-history requirements throughout its range.

We determined the primary constituent elements for Mexican spotted owl from studies of their habitat requirements and the information provided in the Recovery Plan (USDI 1995 and references therein). Since owl habitat can include both canyon and forested areas, we identified primary constituent elements in both areas. The primary constituent elements that occur in mixed conifer, pine-oak, and riparian forest types, as described in the Recovery Plan, have the following attributes:

—High basal area of large diameter trees;
—Moderate to high canopy closure;
—Wide range of tree sizes suggestive of uneven-age stands;
—Multi-layered canopy with large overstory trees of various species;
—High snag basal area;
—High volumes of fallen trees and other woody debris;
—High plant species richness, including hardwoods;
—Adequate levels of residual plant cover to maintain fruits, seeds, and regeneration to provide for the needs of Mexican spotted owl prey species.

For canyon habitat, the primary constituent elements include the following attributes:

—Cooler and often more humid conditions than the surrounding area;
—Clumps or stringers of trees and/or canyon wall containing crevices, ledges, or caves;
—High percent of ground litter and woody debris;
—Riparian or woody vegetation (although not at all sites).

The forest habitat attributes listed above usually develop with increasing forest age, but their occurrence may vary by location, past forest management practices or natural disturbance events, forest type, and productivity. These characteristics may also develop in younger stands, especially when the stands contain remnant large trees or patches of large trees from earlier stands. Certain forest management practices may also enhance tree growth and mature stand characteristics where the older, larger trees are allowed to persist.

Canyon habitats used for nesting and roosting are typically characterized by cooler conditions found in steep, narrow canyons, often containing crevices, ledges, and/or caves. These canyons frequently contain small clumps or stringers of ponderosa pine, Douglas fir, white fir, and/or pinon-juniper. Deciduous riparian and upland tree species may also be present. Adjacent uplands are usually vegetated by a variety of plant associations including pinon-juniper woodland, desert scrub vegetation, ponderosa pine-Gambel oak, ponderosa pine, or mixed conifer. Owl habitat may also exhibit a combination of attributes between the forested and canyon types.

Criteria for Identifying Critical Habitat Units

The primary objective in designating critical habitat is to identify existing and potential Mexican spotted owl habitat considered essential for the conservation of the subspecies, and to highlight specific areas where management considerations should be given highest priority. In proposing critical habitat for the owl, we reviewed the overall approach to the conservation of the species undertaken by local, State, tribal, and Federal agencies and private individuals and organizations since the species' listing in 1993. We also considered the features identified as necessary for recovery, as outlined in the species' Recovery Plan. We reviewed the previous proposed (59 FR 63162) and final critical habitat rules (60 FR 29914), new location data, habitat requirements and definitions described in the Recovery Plan, and habitat information provided by FS biologists as well as utilized our own expertise.

The previous critical habitat designation included extensive use and evaluation of owl habitat and territory maps, vegetation maps, aerial photography, and field verification to identify areas for designation as critical habitat. Several qualitative criteria (currently suitable habitat, large contiguous blocks of habitat, occupied habitat, rangewide distribution, the need for special management or protection, adequacy of existing regulatory mechanisms) were considered when identifying critical habitat areas. The previous designation was done prior to the completion of the Recovery Plan for the Mexican Spotted Owl. For this proposal, we examined the previously designated critical habitat units, but relied primarily on the recovery plan to provide guidance. We expanded or combined previous units to comply with the Recovery Plan. In doing so we included wilderness areas and other areas where additional owls have been located. In addition, we included areas where owls could occur based on the presence of the appropriate topography, elevation, and habitat types (protected and restricted habitat areas as defined in the Recovery Plan).

Proposed Critical Habitat Designation

The proposed critical habitat constitutes our best assessment of areas needed for the conservation of the owl and is based on the best scientific and commercial information available. The proposed areas are essential to the conservation of the species because they either currently support populations of the owl, or because they currently support the necessary habitat requirements for nesting, roosting, and foraging (see description of primary constituent elements). Thus, the proposed critical habitat is limited to areas within the identified RUs that meet the definition of protected and restricted habitat, as described in the Recovery Plan. Although a recovery plan is not a regulatory document, its management recommendations were considered in developing this proposed critical habitat rule. Excluded from the designation are those areas in restricted habitat that do not contain the primary constituent elements.

The Mexican Spotted Owl Recovery Plan provides for three levels of habitat management: Protected areas, restricted areas, and other forest and woodland types. Protected habitat includes all known owl sites, all areas within mixed conifer or pine-oak types with slopes greater than 40 percent where timber harvest has not occurred in the past 20 years, and all reserved (designated Wilderness areas) lands. The Recovery Plan recommends that protected areas, or Protected Activity Centers (PACs), be designated around known owl sites. A PAC would include an area of at least 243 ha (600 ac) that includes the best nesting and roosting habitat in the area. Based on available data, the recommended size for a PAC includes, on average, 75 percent of the foraging area of an owl.

Restricted habitat includes mixed conifer forest, pine-oak forest, and riparian areas outside of protected areas described above (*i.e.,* areas that do not currently contain owls). These areas are essential to the conservation of the species because the Recovery Plan identifies these areas as providing additional owl habitat for future occupancy. In restricted habitat, only areas that contain the primary constituent elements are designated as critical habitat. These areas, however, are important to owl conservation and should continue to be managed to attain the primary constituent elements.

Other forest and woodland types (ponderosa pine, spruce-fir, pinon-juniper, and aspen) are not expected to provide nesting or roosting habitat for the Mexican spotted owl (except when associated with rock canyons). Thus, these other forest and woodland types are not considered to be critical habitat unless specifically delineated within PACs. Although the Recovery Plan does not provide owl-specific guidelines to managing these areas, these and other habitat types may provide important foraging and dispersal habitat for the owl, particularly if adjacent to protected or restricted areas. Therefore, these areas should be managed for landscape diversity, mimicking natural disturbance patterns, incorporating natural variation in stands, and retaining special features such as snags and large trees (USDI 1995). We anticipate that species concerns in these areas can be adequately addressed under the Act through section 7 consultation, the section 9 prohibition against taking listed species, the section 10 habitat conservation planning process, and through other appropriate State and Federal statutes and regulations.

Critical habitat units are being proposed in portions of Bernalillo, Catron, Cibola, Colfax, Grant, Hidalgo, Lincoln, Los Alamos, McKinley, Mora, Otero, Rio Arriba, San Juan, San Miguel, Sandoval, Santa Fe, Sierra, Socorro, Taos, Torrance, Valencia Counties in

New Mexico; Apache, Cochise, Coconino, Gila, Graham, Greenlee, Maricopa, Mohave, Navajo, Pima, Pinal, Santa Cruz, Yavapai Counties in Arizona; Carbon, Emery, Garfield, Grand, Iron, Kane, San Juan, Washington, Wayne Counties in Utah; and Custer, Douglas, El Paso, Fremont, Huerfano, Jefferson, Pueblo, and Teller Counties in Colorado, on the maps. Precise legal descriptions of each critical habitat unit are on file at the New Mexico Ecological Services Field Office.

With the exception of some tribal lands (See discussion under American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act, below) and low-density areas, this proposed designation includes all habitat on Federal and tribal lands used by currently known populations of Mexican spotted owls. The inclusion of both occupied and currently unoccupied areas in this critical habitat proposal is in accordance with section 3(5)(A)(I) of the Act, which provides that areas outside the geographical area currently occupied by the species may meet the definition of critical habitat upon a determination that they are essential for the conservation of the species. We find that the inclusion of currently unoccupied areas identified in this rule as having one or more constituent elements is essential for conservation of the owl.

We did not designate some areas that are known to have widely scattered owl sites, low population densities, and/or marginal habitat quality, which are not considered to be essential to this species' survival or recovery. These areas include Dinosaur National Park in northwest Colorado; Mesa Verde National Park, Ute Mountain Ute Reservation, Southern Ute Reservation, other Forest Service and Bureau of Land Management land in southwest Colorado; and the Guadalupe and Davis Mountains in southwest Texas. Isolated mountains on the Arizona Strip, such as Mount Trumbull, were also not included due to their small size, isolation, and lack of information about owls in the area.

State and private lands are not included in this proposed designation. The overwhelming majority of Mexican spotted owl records are from Federal and Tribal lands, indicating that those lands are essential to the species' recovery. Some of the State (79,030 ha (195,288 ac)) and private (257,872 ha (637,216 ac)) parcels within the critical habitat boundaries likely support mid- and higher-elevation forests that are capable of providing nesting and roosting habitat. However, given that the majority of the owl's range occurs on Federal and tribal lands, we do not feel that State and private lands are essential to the recovery of the subspecies and should not be designated as critical habitat.

Given the above, we believe that Mexican spotted owl conservation can best be achieved by management of Federal and Tribal lands, and that State and private lands are not essential to the species' recovery. Where feasible, proposed critical habitat boundaries were drawn so as to exclude State and private lands. However, the short amount of time allowed by the court to complete this proposed designation did not allow us to conduct the fine-scale mapping necessary to physically exclude the smaller and widely scattered State and private parcels that remain within the proposed boundaries. Those areas under State or private ownership are therefore excluded from the proposed designation by definition.

The approximate gross area of proposed critical habitat by State and land ownership is shown in Table 1. Actual proposed critical habitat is limited to areas within the proposed boundaries that meet the definition of protected and restricted habitat in the Recovery Plan. Therefore, the area actually proposed as critical habitat is considerably less than the gross acreage indicated in Table 1.

TABLE 1.—CRITICAL HABITAT BY LAND OWNERSHIP AND STATE IN HECTARES (ACRES)

	Arizona	New Mexico	Colorado	Utah	Total
Forest Service	1,330,339 (3,287,339)	1,688,295 (4,171,869)	152,096 (375,837)	111,133 (274,616)	3,281,863 (8,109,661)
Bureau of Land Management	4,903 (12,115)	5,879 (14,528)	60,255 (148,894)	666,270 (1,646,388)	737,307 (1,821,925)
National Park Service	322,069 (795,850)	12,618 (31,179)	0	260,346 (643,328)	595,033 (1,470,357)
Department of Defense	9,728 (24,038)	1,682 (4,157)	17,966 (44,394)	0	29,376 (72,589)
Bureau of Reclamation	0	0	0	109,610 (270,853)	109,610 (270,853)
Unknown Federal[a]	0	0	0	156,207 (385,995)	156,207 (385,995)
Tribal	342,503 (846,344)	165,333 (408,548)	0	40,983 (101,272)	548,819 (1,356,164)
Total	2,009,542 (4,630,281)	1,873,807 (4,630,281)	230,317 (569,125)	1,344,549 (3,322,452)	5,458,215 (13,487,544)
Total critical habitat units	37[b]	31[b]	2	5	72

[a] Includes land identified in the current Utah land ownership file as National Recreation Area or National Recreation Area/Power Withdrawal; Federal land ownership is unclear (may be NPS, BOR, or other).

[b] Counts three critical habitat units that overlap two states.

Effect of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that actions they fund, authorize, or carry out do not destroy or adversely modify critical habitat to the extent that the action appreciably diminishes the value of the critical habitat for the survival and recovery of the species. Individuals, organizations, States, local governments, and other non-Federal entities are affected by the designation of critical habitat only if their actions occur on Federal lands, require a Federal permit, license, or other authorization, or involve Federal funding.

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is designated or proposed. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act require Federal agencies to confer with us on any action that is likely to jeopardize the continued existence of a proposed species or to result in destruction or adverse modification of proposed critical habitat. Conference reports provide conservation recommendations to assist the agency in eliminating conflicts that may be caused by the proposed action. The conservation recommendations in a conference report are advisory.

We may issue a formal conference report if requested by a Federal agency. Formal conference reports on proposed critical habitat contain a biological opinion that is prepared according to 50 CFR 402.14, as if critical habitat were designated. We may adopt the formal conference report as a biological opinion if the critical habitat is designated, if no significant new information or changes in the action alter the content of the opinion (see 50 CFR 402.10(d)).

If a species is subsequently listed or critical habitat is designated, then section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with us. Regulations at 50 CFR 402.16 also require Federal agencies to reinitiate consultation in instances where we have already reviewed an action for its effects on a listed species if critical habitat is subsequently designated. Consequently, some Federal agencies may request reinitiation of consultation or conferencing with us on actions for which formal consultation has been completed, if those actions may affect designated critical habitat or adversely modify or destroy proposed critical habitat.

When we issue a biological opinion concluding that a project is likely to result in jeopardy or the destruction or adverse modification of critical habitat, we also provide reasonable and prudent alternatives to the project, if any are identifiable. Reasonable and prudent alternatives are defined at 50 CFR 402.02 as alternative actions identified during consultation that can be implemented in a manner consistent with the intended purpose of the action, that are consistent with the scope of the Federal agency's legal authority and jurisdiction, that are economically and technologically feasible, and that the Director believes would avoid the likelihood of jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat. Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Section 4(b)(8) of the Act requires us to describe in any proposed or final regulation that designates critical habitat a description and evaluation of those activities involving a Federal action that may adversely modify such habitat or that may be affected by such designation. When determining whether any of these activities may adversely modify critical habitat, we base our analysis on the effects of the action on the entire critical habitat area and not just on the portion where the activity will occur. Adverse effects on constituent elements or segments of critical habitat generally do not result in an adverse modification determination unless that loss, when added to the environmental baseline, is likely to appreciably diminish the capability of the critical habitat to satisfy essential requirements of the species. In other words, activities that may destroy or adversely modify critical habitat include those that alter the primary constituent elements (defined above) to an extent that the value of critical habitat for both the survival and recovery of the Mexican spotted owl is appreciably reduced.

To properly portray the effects of critical habitat designation, we must first compare the section 7 requirements for actions that may affect critical habitat with the requirements for actions that may affect a listed species. Section 7 prohibits actions funded, authorized, or carried out by Federal agencies from jeopardizing the continued existence of a listed species or destroying or adversely modifying the listed species' critical habitat. Actions likely to ''jeopardize the continued existence'' of a species are those that would appreciably reduce the likelihood of the species' survival and recovery (50 CFR 402.02). Actions likely to ''destroy or adversely modify'' critical habitat are those that would appreciably reduce the value of critical habitat for the survival and recovery of the listed species (50 CFR 402.02).

Common to both definitions is an appreciable detrimental effect on both survival and recovery of a listed species. Given the similarity of these definitions, actions likely to destroy or adversely modify critical habitat would almost always result in jeopardy to the species concerned when the habitat is occupied by the species. The purpose of designating critical habitat is to contribute to a species' conservation, which by definition equates to survival and recovery. Section 7 prohibitions against the destruction or adverse modification of critical habitat apply to actions that would impair survival and recovery of the listed species, thus providing a regulatory means of ensuring that Federal actions within critical habitat are considered in relation to the goals and recommendations of any existing recovery plan for the species concerned. As a result of the direct link between critical habitat and recovery, the prohibition against destruction or adverse modification of the critical habitat should provide for the protection of the critical habitat's ability to contribute fully to a species' recovery.

A number of Federal agencies or departments fund, authorize, or carry out actions that may affect the Mexican spotted owl and proposed critical habitat. Among these agencies are the Forest Service, Bureau of Indian Affairs, Bureau of Land Management, Department of Defense, Department of Energy, National Park Service, and Federal Highway Administration. We have reviewed and continue to review numerous activities proposed within the range of the Mexican spotted owl that are currently the subject of formal or informal section 7 consultations. Actions on Federal lands that we reviewed in past consultations on effects to the owl include land management plans; land acquisition and

disposal; road construction, maintenance, and repair; timber harvest; livestock grazing and management; fire/ecosystem management projects (including prescribed natural and management ignited fire); powerline construction and repair; campground and other recreational developments; and access easements. We expect that the same types of activities will be reviewed in section 7 consultation if critical habitat is designated.

Actions that would be expected to both jeopardize the continued existence of the Mexican spotted owl and destroy or adversely modify its critical habitat would include those that significantly and detrimentally alter the species' habitat over an area large enough that the likelihood of the Mexican spotted owls' persistence and recovery, either range-wide or locally, is significantly reduced. Thus, the likelihood of an adverse modification or jeopardy determination would depend on the baseline condition of the recovery unit and the baseline condition of the entire designated critical habitat area. Some recovery units, such as the Southern Rocky Mountains-New Mexico and Southern Rocky Mountains-Colorado RUs, support fewer owls and owl habitat than other RUs and, therefore, may be much less able to withstand habitat-altering activities than RUs with large contiguous areas of habitat supporting higher densities of spotted owls.

Actions not likely to destroy or adversely modify critical habitat include activities that are implemented in compliance with the Recovery Plan, such as thinning trees less than 9 inches in diameter in PACs; fuels reduction to abate the risk of catastrophic wildfire; ''personal use'' commodity collection such as fuelwood, latillas and vigas, and Christmas tree cutting; livestock grazing in upland habitats; and most recreational activities including hiking, camping, fishing, hunting, cross-country skiing, off-road vehicle use, and various activities associated with nature appreciation. We do not expect any restrictions to those activities as a result of critical habitat designation. In addition, some activities may be considered to be of benefit to Mexican spotted owl habitat and, therefore, would not be expected to adversely modify critical habitat. Examples of activities that could benefit critical habitat may include some protective measures such as fire suppression, prescribed burning, brush control, snag creation, and certain silvicultural activities such as thinning.

If you have questions regarding whether specific activities will likely constitute destruction or adverse modification of critical habitat, contact the Field Supervisor, New Mexico Ecological Services Field Office (see **ADDRESSES** section). If you would like copies of the regulations on listed wildlife or have questions about prohibitions and permits, contact the U.S. Fish and Wildlife Service, Division of Endangered Species, P.O. Box 1306, Albuquerque, New Mexico 87103 (telephone 505–248–6920; facsimile 505–248–6788).

Economic Analysis

Section 4(b)(2) of the Act requires that we designate critical habitat on the basis of the best scientific and commercial information available and consider the economic and other relevant impacts of designating a particular area as critical habitat. We based this proposal on the best available scientific information, including the recommendations in the species' recovery plan. We will utilize the economic analysis and our analysis of other relevant impacts, and take into consideration all comments and information submitted during the public hearing and comment period, to make a final critical habitat designation. We may exclude areas from critical habitat upon a determination that the benefits of such exclusions outweigh the benefits of specifying such areas as critical habitat. However, we cannot exclude these areas from critical habitat when their exclusion will result in the extinction of the species. We are preparing a draft economic analysis that will be completed and available for public review and comment during the comment period for this proposal. Send your requests for copies of the economic analysis to the New Mexico Ecological Services Field Office (see **ADDRESSES** section).

American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act

In accordance with the Presidential Memorandum of April 29, 1994, we believe that, to the maximum extent possible, tribes should be the governmental entities to manage their lands and tribal trust resources. To this end, we support tribal measures that preclude the need for Federal conservation regulations. We provide technical assistance to Indian tribes who wish assistance in developing and expanding tribal programs for the management of healthy ecosystems so that Federal conservation regulations, such as designation of critical habitat, on tribal lands are unnecessary.

The Presidential Memorandum of April 29, 1994, also requires us to consult with the tribes on matters that affect them, and section 4(b)(2) of the Act requires us to gather information regarding the designation of critical habitat and the effects thereof from all relevant sources, including the tribes. Recognizing a government-to-government relationship with tribes and our Federal trust responsibility, we will consult with the Indian tribes that might be affected by the designation of critical habitat. We have already held two meetings with the Mescalero Apache Tribe.

Due to the time constraints imposed by the court order, we will make every effort to consult with the tribes during the comment period for this proposal to gain information on—(1) possible effects if critical habitat were designated on Indian reservation lands; and (2) possible effects on tribal resources resulting from designation of critical habitat on non-tribal lands. We will meet with each potentially affected tribe to ensure that consultation on critical habitat issues occurs in a timely manner.

Designation of Critical Habitat on Tribal Lands

Section 3(5) of the Act defines critical habitat, in part, as areas within the geographical area occupied by the species ''on which are found those physical and biological features (I) essential to the conservation of the species and (II) which may require special management considerations and protection.'' In our previous critical habitat proposal for the owl, we identified lands of the White Mountain Apache, Jicarilla Apache, Mescalero Apache, San Carlos Apache, Southern Ute, Ute Mountain Ute, and Navajo Nation Tribes as containing habitat that may be appropriate for designation of critical habitat. However, after reevaluating the available data, we no longer feel that designating all of these areas is appropriate.

Lands of the Mescalero Apache, San Carlos Apache, and Navajo Nation have areas that meet the definition of critical habitat with respect to the Mexican spotted owl, and portions of those lands are proposed as critical habitat. As provided under section 4(b)(2) of the Act, we are soliciting information on the possible economic and other impacts of critical habitat designation, and we will continue to work with the tribes in developing voluntary measures adequate to conserve Mexican spotted owls on tribal lands. We understand the Navajo Nation is nearing completion of a Forest Management Plan and the Mescalero Apache Tribes are working on Mexican Spotted Owl Habitat

Management Plans. Critical habitat proposed on the San Carlos Apache Reservation does not include areas covered by the Tribe's Malay Gap Management Plan. We reviewed this plan in 1996 and determined it to be adequate for the management of the owl. The San Carlos Apache Tribe is developing similar management plans for other management units on their lands. If any of these tribes submit management plans, we will consider whether these plans provide adequate special management or protection for the species, or we will weigh the benefits of including versus the benefits of excluding these areas under section 4(b)(2). We will use this information in determining which, if any, tribal land should be included in the final designation as critical habitat for the owl.

Since our previous critical habitat designation, we learned that the Southern Ute Reservation has not supported spotted owls historically, and our assessment revealed that the Reservation does not support habitat essential to the species' conservation. Thus, lands of the Southern Ute Reservation do not meet part (I) of the definition of critical habitat stated above; we are, therefore, not proposing to designate those lands as critical habitat.

Lands of the Ute Mountain Ute Tribe are not being proposed either. Due to the low population density and isolation from other occupied areas in Colorado, New Mexico, and Utah, the owls in southwestern Colorado are not believed to be essential for the survival or recovery of the species. Thus, these lands do not meet part (I) of the definition of critical habitat stated above; we are, therefore, not proposing to designate those lands as critical habitat.

The White Mountain Apache and Jicarilla Apache Tribes completed Mexican Spotted Owl Habitat Management Plans prior to the previous critical habitat designation. Since those plans are still valid and in use, we believe that the lands of the White Mountain Apache and Jicarilla Apache Tribes are not in need of special management considerations and protection, and therefore do not meet part (II) of the definition of critical habitat. Thus, we are not proposing critical habitat in those areas.

In addition, other tribal lands including the Picuris, Taos, and Santa Clara Pueblos in New Mexico and the Havasupai Reservation in Arizona are adjacent to critical habitat units proposed in this rule and may have potential owl habitat. However, the available information, although limited, on the habitat quality and current or past owl occupancy in these areas does not indicate that these areas meet the definition of critical habitat. Therefore, we are not proposing to designate these lands as critical habitat.

Effects on Tribal Trust Resources From Critical Habitat Designation on Non-Tribal Lands

We do not anticipate that proposal of critical habitat on non-tribal lands will result in any impact on tribal trust resources or the exercise of tribal rights. However, in complying with our tribal trust responsibilities, we must communicate with all tribes potentially affected by the designation. Therefore, we are soliciting information from the tribes and will arrange meetings with the tribes during the comment period on potential effects to them or their resources that may result from critical habitat designation.

Public Comments Solicited and Public Hearings

We intend to make any final action resulting from this proposal to be as accurate and as effective as possible. Therefore, we are soliciting comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule. We particularly seek comments concerning:

(1) The reasons why any habitat should or should not be determined to be critical habitat as provided by section 4 of the Act, including whether the benefits of excluding areas will outweigh the benefits of including areas as critical habitat. Specifically we ask if there is adequate special management and protection in place on any lands to allow us not to designate these lands as critical habitat. Further, we ask whether all areas identified in the Recovery Plan should be designated as critical habitat;

(2) Specific information on the amount and distribution of Mexican spotted owl habitat, and what habitat is essential to the conservation of the species and why;

(3) Land use practices and current or planned activities in the subject areas and their possible impacts on proposed critical habitat;

(4) Any foreseeable economic or other impacts resulting from the proposed designation of critical habitat, in particular, any impacts on small entities or families; and

(5) Economic and other values associated with designating critical habitat for the Mexican spotted owl, such as those derived from nonconsumptive uses (*e.g.*, hiking, camping, birding, enhanced watershed protection, increased soil retention, ''existence values,'' and reductions in administrative costs).

Executive Order 12866 requires each agency to write regulations and notices that are easy to understand. We invite your comments on how to make this proposed rule easier to understand including answers to questions such as the following: (1) Are the requirements in the document clearly stated? (2) Does the proposed rule contain technical language or jargon that interferes with the clarity? (3) Does the format of the proposed rule (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity? (4) Is the description of the proposed rule in the **SUPPLEMENTARY INFORMATION** section of the preamble helpful in understanding the document? (5) What else could we do to make the proposed rule easier to understand?

Our practice is to make comments that we receive on this rulemaking, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking record, which we will honor to the extent allowable by law. In some circumstances, we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish for us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, including individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Peer Review

In accordance with our policy published on July 1, 1994 (59 FR 34270), we will seek the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of such review is to ensure listing decisions are based on scientifically sound data, assumptions, and analyses. We will send copies of this proposed rule immediately following publication in the **Federal Register** to these peer reviewers. We will invite these peer reviewers to comment, during the public comment period, on the specific assumptions and conclusions regarding the proposed designation of critical habitat.

We will consider all comments and information received during the comment period on this proposed rule during preparation of a final rulemaking. Accordingly, the final decision may differ from this proposal.

Public Hearings

The Act provides for one or more public hearings on this proposal, if requested. Given the large geographic extent covered by this proposal, the high likelihood of multiple requests, and the need to publish a final determination by December 15, 2000, we have scheduled six public hearings. We will hold the hearings in Santa Fe, New Mexico, on August 14; Las Cruces, New Mexico, on August 15; Tucson, Arizona, on August 16, Flagstaff, Arizona, on August 17; Colorado Springs, Colorado, on August 21, 2000; and Cedar City, Utah, on August 23. We will hold the hearings at the following locations:

- Santa Fe, New Mexico: Morgan Hall, New Mexico State Land Office, 310 Old Santa Fe Trail, 6:30 to 9:30 p.m.
- Las Cruces, New Mexico: Dona Ana Room, Corbett Center Student Union, New Mexico State University, 6:30 to 9:30 p.m.
- Tucson, Arizona: Louis Rich Theater, Tucson Convention Center, 260 South Church Street, 6:30 to 9:30 p.m.
- Flagstaff, Arizona: Flagstaff High School, Main Auditorium, 400 West Elm Street, 6:30 to 9:30 p.m.
- Colorado Springs, Colorado: Pikes Peak Community College, Cafeteria, 5675 South Academy Boulevard, 6:30 to 9:30 p.m.
- Cedar City, Utah: Southern Utah University, Hunter Conference Center, The Great Hall, 351 West Center Street, 6:30 to 9:30 p.m.

Announcements for the public hearings will be made in local newspapers.

Written comments submitted during the comment period receive equal consideration with those comments presented at a public hearing.

Required Determinations

Regulatory Planning and Review

In accordance with the criteria in Executive Order 12866, this rule is a significant regulatory action and has been reviewed by the Office of Management and Budget. We are preparing a draft analysis of this proposed action, which will be available during the comment period for this proposed rule, to determine the economic consequences of designating the specific areas as critical habitat. The availability of the draft economic analysis will be announced in the **Federal Register** and in local newspapers so that it is available for public review and comments during the 60-day comment period for this proposed rule.

(a) This rule will not have an annual economic effect of $100 million or adversely affect an economic sector, productivity, jobs, the environment, or other units of government. A cost-benefit analysis is not required for purposes of Executive Order 12866. The Mexican spotted owl was listed as a threatened species in 1993. Since that time, we have conducted, and will continue to conduct, formal and informal section 7 consultations with other Federal agencies to ensure that their actions would not jeopardize the continued existence of the Mexican spotted owl.

Under the Act, critical habitat may not be adversely modified by a Federal agency action; critical habitat does not impose any restrictions on non-Federal persons unless they are conducting activities funded or otherwise sponsored or permitted by a Federal agency (see Table 2 below). Section 7 requires Federal agencies to ensure that they do not jeopardize the continued existence of the species. Based upon our experience with the species and its needs, we believe that any Federal action or authorized action that could potentially cause an adverse modification of the proposed critical habitat would currently be considered as ''jeopardy'' to the species under the Act. Accordingly, we do not expect the designation of currently occupied areas as critical habitat to have any incremental impacts on what actions may or may not be conducted by Federal agencies or non-Federal persons that receive Federal authorization or funding. Non-Federal persons who do not have a Federal ''sponsorship'' of their actions are not restricted by the designation of critical habitat (however, they continue to be bound by the provisions of the Act concerning ''take'' of the species).

TABLE 2.—IMPACTS OF DESIGNATING CRITICAL HABITAT FOR MEXICAN SPOTTED OWL

Categories of activities	Activities potentially affected by the designation of critical habitat in areas occupied by the species (in addition to those activities affected from listing the species)	Activities potentially affected by the designation of critical habitat in unoccupied areas
Federal Activities Potentially Affected [1].	None	Activities such as those affecting protected, restricted, and canyon habitats by the Forest Service, Bureau of Indian Affairs, Bureau of Land Management, Department of Defense, Department of Energy, National Park Service, and Federal Highway Administration; vegetative management projects (including timber harvest, timber salvage, and tree density control activities such as thinning, insect and disease suppression activities, snag removal, and certain fire/ecosystem projects such as prescribed natural and management ignited fire); livestock grazing in riparian habitat; land acquisition and disposal; oil and gas development; mining and mineral exploration; military maneuvers; road development, maintenance, and repair; utility construction and repair; construction of campgrounds and other recreational developments; and access easements.
Private or other non-Federal Activities Potentially Affected [2].	None	Activities that require a Federal action (permit, authorization, or funding) and that involve such activities as removing or destroying Mexican spotted owl habitat (as defined in the primary constituent elements discussion), whether by mechanical or other means (*e.g.*, timber harvest, right-of-way access, road construction, development, etc.), including indirect effects and that appreciably decrease habitat value or quality.

[1] Activities initiated by a Federal agency.

[2] Activities initiated by a private or other non-Federal entity that may need Federal authorization or funding.

Designation of unoccupied areas as critical habitat may have impacts on what actions may or may not be conducted by Federal agencies or non-Federal persons that receive Federal authorization or funding. In the case of the owl, however, we are already consulting with Federal agencies on activities that may affect the owl within the Recovery Units. Since the proposed critical habitat units all occur within the Recovery Units, we do not anticipate any additional impact due to designating unoccupied habitat within the Recovery Units. However, we will evaluate any potential impact through our economic analysis (see Economic Analysis section of this rule).

(b) This rule will not create inconsistencies with other agencies' actions. Federal agencies have been required to ensure that their actions do not jeopardize the continued existence of the Mexican spotted owl since its listing in 1993. The prohibition against adverse modification of critical habitat is not expected to impose any additional restrictions to those that currently exist in areas of proposed critical habitat. Because of the potential for impacts on other Federal agency's activities, we will continue to review this proposed action for any inconsistencies with other Federal agency's actions.

(c) The proposed rule, if made final, will not significantly impact entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients. Federal agencies are currently required to ensure that their activities do not jeopardize the continued existence of the species, and, as discussed above, we do not anticipate that the adverse modification prohibition (resulting from critical habitat designation) will have any incremental effects in areas of proposed critical habitat.

(d) This rule will not raise novel legal or policy issues. The proposed rule follows the requirements for determining critical habitat contained in the Endangered Species Act.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

In the draft economic analysis, we will determine if designation of critical habitat will have a significant effect on a substantial number of small entities. As discussed under Regulatory Planning and Review above, this rule is not expected to result in any restrictions in addition to those currently in existence for areas of proposed critical habitat.

Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 804(2))

We do not anticipate that our economic analysis will show that designation of critical habitat will cause (a) an annual effect on the economy of $100 million or more, (b) any increases in costs or prices for consumers; individual industries; Federal, State, or local government agencies; or geographic regions, or (c) any significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act:

a. This rule will not ''significantly or uniquely'' affect small governments. A Small Government Agency Plan is not required. Small governments will be affected only to the extent that any programs involving Federal funds, permits, or other authorized activities must ensure that their actions will not destroy or adversely modify critical habitat. However, as discussed above in the Regulatory Planning and Review section, these actions are currently subject to equivalent restrictions through the listing protections of the species, and no further restrictions are anticipated in areas of proposed critical habitat.

b. This rule will not produce a Federal mandate on State, local, or tribal governments or the private sector of more than $100 million or greater in any year, *i.e.,* it is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act. The designation of critical habitat imposes no obligations on State or local governments.

Takings

In accordance with Executive Order 12630, this rule does not have significant takings implications, and a takings implication assessment is not required. This proposed rule, if made final, will not ''take'' private property. However, we will evaluate whether the value of private property is altered by it being designated as critical habitat on a case-by-case basis. Critical habitat designation is applicable to Federal lands and to private lands only if a Federal nexus, through funding, permitting or licencing of activities, exists. We do not designate private lands as critical habitat unless the areas are essential to the conservation of a species.

Federalism

In accordance with Executive Order 13132, this proposed rule, if made final, will not affect the structure or role of States, and will not have direct, substantial, or significant effects on States. A Federalism assessment is not required. As previously stated, critical habitat is applicable only to Federal lands or to non-Federal lands only when a Federal nexus exists.

In keeping with Department of the Interior and Department of Commerce policy, we requested information from and coordinated development of this critical habitat proposal with appropriate State resource agencies in Arizona, New Mexico, Colorado, and Utah. In addition, Arizona and Utah have representatives on the recovery team for this species. We will continue to coordinate any future designation of critical habitat for Mexican spotted owl with the appropriate State agencies.

Civil Justice Reform

In accordance with Executive Order 12988, the Department of the Interior's Office of the Solicitor determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. The Office of the Solicitor will review the final determination for this proposal. We will make every effort to ensure that the final determination contains no drafting errors, provides clear standards, simplifies procedures, reduces burden, and is clearly written such that litigation risk is minimized.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain any information collection requirements for which Office of Management and Budget approval under the Paperwork Reduction Act is required.

National Environmental Policy Act (NEPA)

Our position is that, outside the Tenth Circuit, we do not need to prepare environmental analyses as defined by the NEPA in connection with designating critical habitat under the Endangered Species Act of 1973, as amended. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This assertion was upheld in the courts of the Ninth Circuit (*Douglas County* v. *Babbitt*, 48 F.3d 1495 (9th Cir. Ore. 1995), *cert. denied* 116 S. Ct. 698 (1996). However, when the range of the species includes States within the Tenth Circuit, such as that of the Mexican spotted owl, pursuant to the Tenth

Circuit ruling in *Catron County Board of Commissioners* v. *U.S. Fish and Wildlife Service*, 75 F.3d 1429 (10th Cir. 1996), we undertake a NEPA analysis for critical habitat designation. Send your requests for copies of the draft environmental assessment for this proposal to the New Mexico Ecological Services Field Office (see **ADDRESSES** section).

References Cited

A complete list of all references cited in this proposed rule is available upon request from the New Mexico Ecological Services Field Office (see **ADDRESSES** section).

Authors

The primary authors of this notice are the New Mexico Field Office staff (see **ADDRESSES** section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations as set forth below:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

2. Amend § 17.11(h), by revising the entry for ''Owl, Mexican spotted'' under ''BIRDS'' to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*	*	*		*
BIRDS							
*	*	*	*	*	*		*
Owl, Mexican spotted.	*Strix occidentalis lucida*.	U.S.A. (AZ, CO, NM, TX, UT), Mexico.	Entire	T	494	§ 17.95(b)	NA
*	*	*	*	*	*		*

3. Amend § 17.95(b) by adding critical habitat for the Mexican spotted owl (*Strix occidentalis lucida*) in the same alphabetical order as this species occurs in § 17.11(h).

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(b) Birds.

* * * * *

Mexican Spotted Owl (*Strix Occidentalis Lucida*)

Critical habitat is limited to areas within the proposed boundaries that meet the definition of protected (600 acres around known owl sites, mixed conifer or pine-oak forests with slopes greater than 40 percent where timber harvest has not occurred in the past 20 years, and all reserved (designated wilderness areas) lands) and restricted (mixed conifer forest, pine-oak forest, and riparian areas outside of protected areas) habitat as described in the Recovery Plan. Restricted habitat is designated only where primary constituent elements can be found. Private and state lands within mapped boundaries are not designated as critical habitat. Critical habitat proposed on the San Carlos Apache Reservation does not include areas covered by the Tribe's Malay Gap Management Plan. The lands of the White Mountain Apache, Jicarilla Apache, Ute Mountain Ute and Southern Ute Tribe are not being designated. Critical habitat units for the States of Arizona, Colorado, New Mexico, and Utah are depicted on the maps below. Larger maps for all four States and maps of critical habitat units in the State of New Mexico are available at the New Mexico Ecological Services Field Office, 2105 Osuna N.E., Albuquerque, New Mexico 87113, telephone (505) 346–2525. For the States of Arizona, Colorado, and Utah, maps of the critical habitat units specific to each State are available at the following U.S. Fish and Wildlife Service offices—Arizona Ecological Services Field Office, 2321 West Royal Palm Road, Suite 103, Phoenix, Arizona 85021, telephone (602) 640–2720; Colorado State Sub-Office, 764 Horizon Drive South, Annex A, Grand Junction, Colorado 81506, telephone (970) 243–2778; and Utah Ecological Services Field Office, Lincoln Plaza, 145 East 1300 South, Suite 404, Salt Lake City, Utah 84115, telephone (801) 524–5001.

1. Critical habitat units are depicted for portions of Bernalillo, Catron, Cibola, Colfax, Grant, Hidalgo, Lincoln, Los Alamos, McKinley, Mora, Otero, Rio Arriba, San Juan, San Miguel, Sandoval, Santa Fe, Sierra, Socorro, Taos, Torrance, and Valencia Counties in New Mexico; Apache, Cochise, Coconino, Gila, Graham, Greenlee, Maricopa, Mohave, Navajo, Pima, Pinal, Santa Cruz, and Yavapai Counties in Arizona; Carbon, Emery, Garfield, Grand, Iron, Kane, San Juan, Washington, and Wayne Counties in Utah; and Custer, Douglas, El Paso, Fremont, Huerfano, Jefferson, Pueblo, and Teller Counties in Colorado, on the maps. Precise legal descriptions of each critical habitat unit are on file at the New Mexico Ecological Services Field Office.

2. Within these areas, the primary constituent elements for Mexican spotted owl include, but are not limited to, those habitat components providing for nesting, roosting, or foraging activities. Primary constituent elements are provided in canyons and mixed conifer, pine-oak, and riparian habitat types that typically support nesting and/or roosting. These primary constituent elements include mixed conifer, pine-oak, and riparian forest types, as described in the Recovery Plan, that have the following attributes: high basal area of large-diameter trees; moderate to high canopy closure; wide range of tree sizes suggestive of uneven-age stands; multi-layered canopy with large overstory trees of various species; high snag basal area; high volumes of fallen trees and other woody debris; high plant species richness, including hardwoods; and adequate levels of residual plant cover to maintain fruits, seeds, and regeneration to provide for the needs of Mexican spotted owl prey species. For canyon habitats, the primary constituent elements include the following attributes: cooler and often higher humidity than the surrounding area; clumps or stringers of ponderosa pine, Douglas-fir, white fir, and/or pinon-juniper trees and/or canyon wall containing crevices, ledges, or caves; high percent of ground litter and woody debris; and riparian or woody vegetation (although not at all sites).

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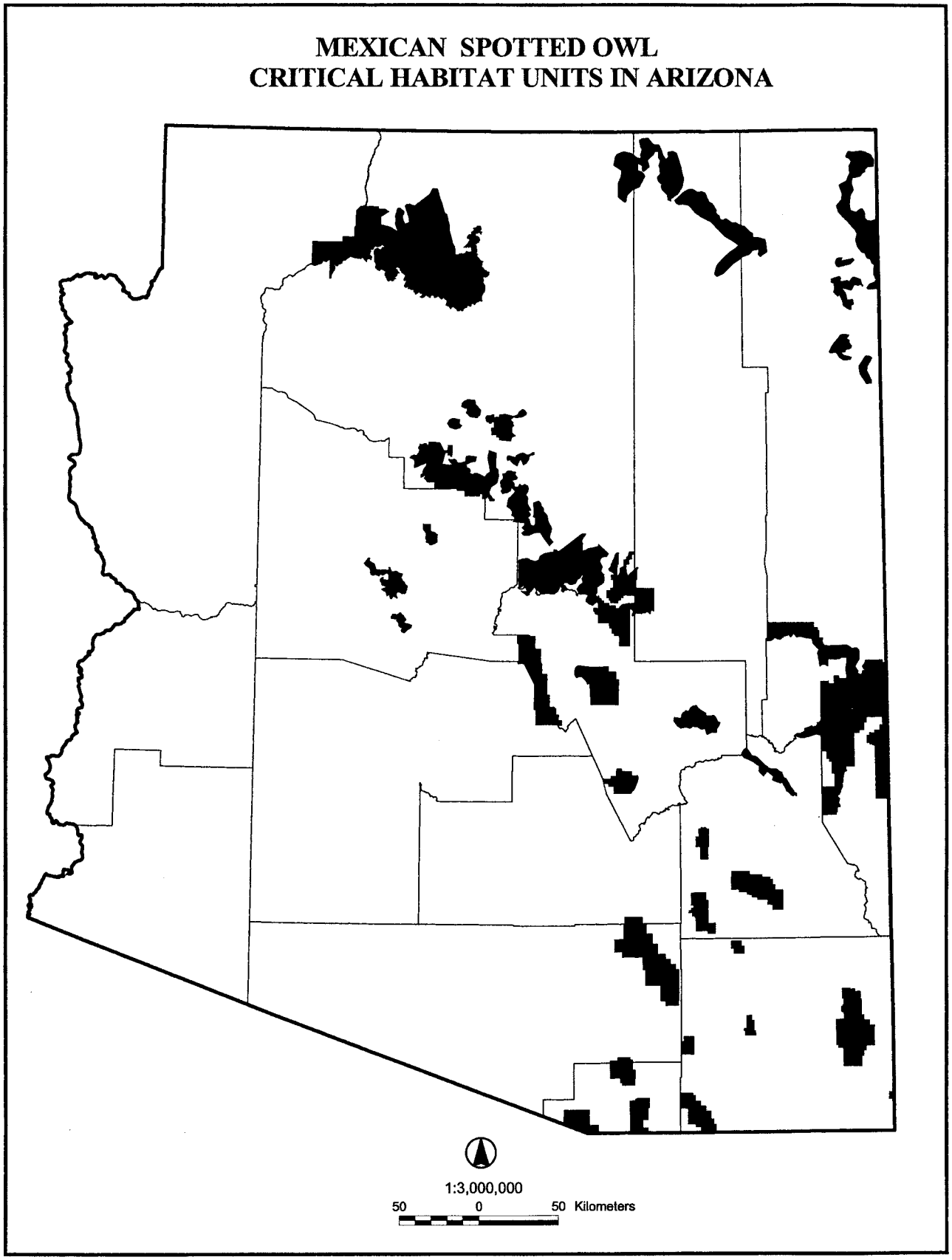
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CRITICAL HABITAT UNITS IN ARIZONA
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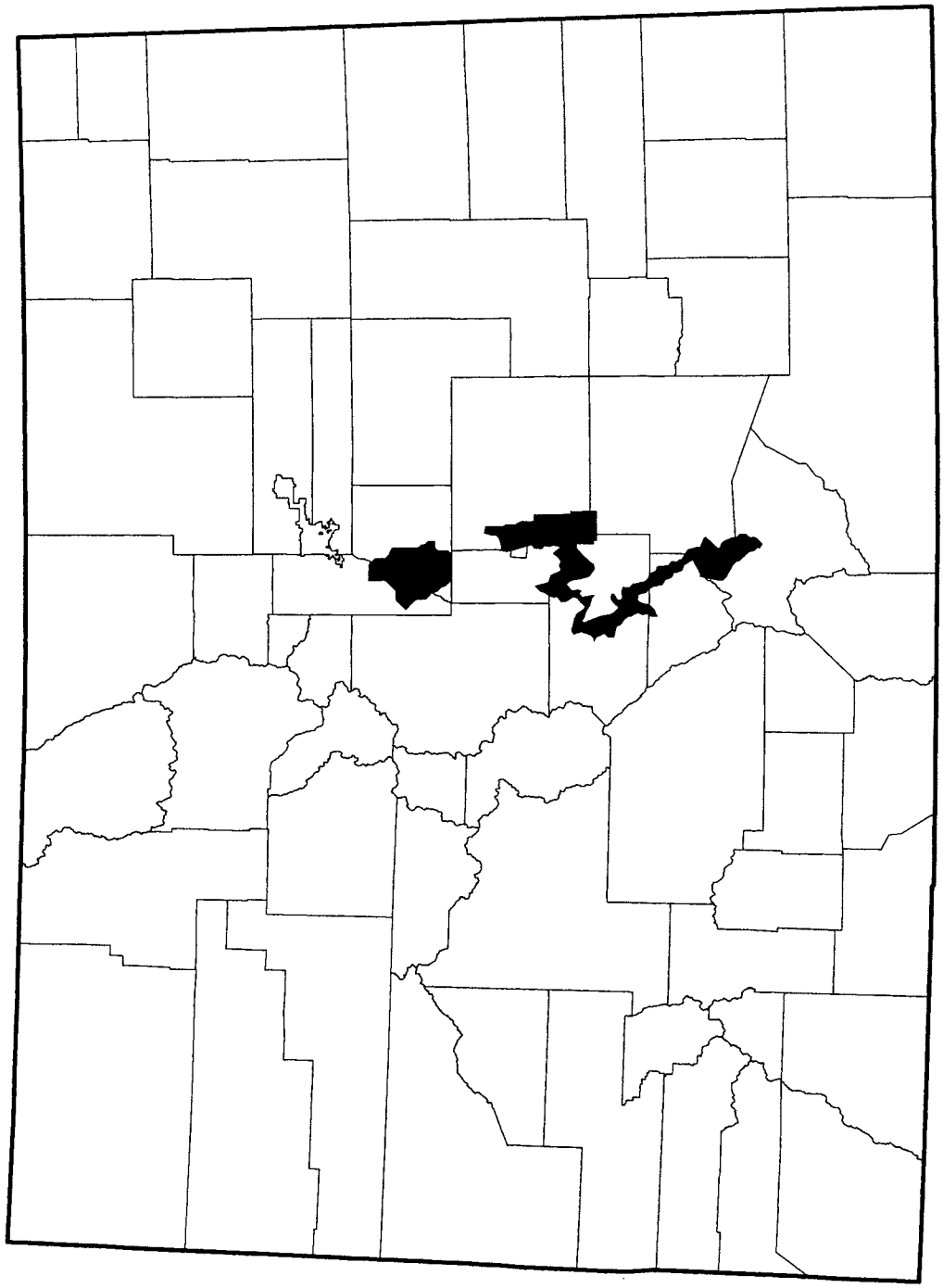
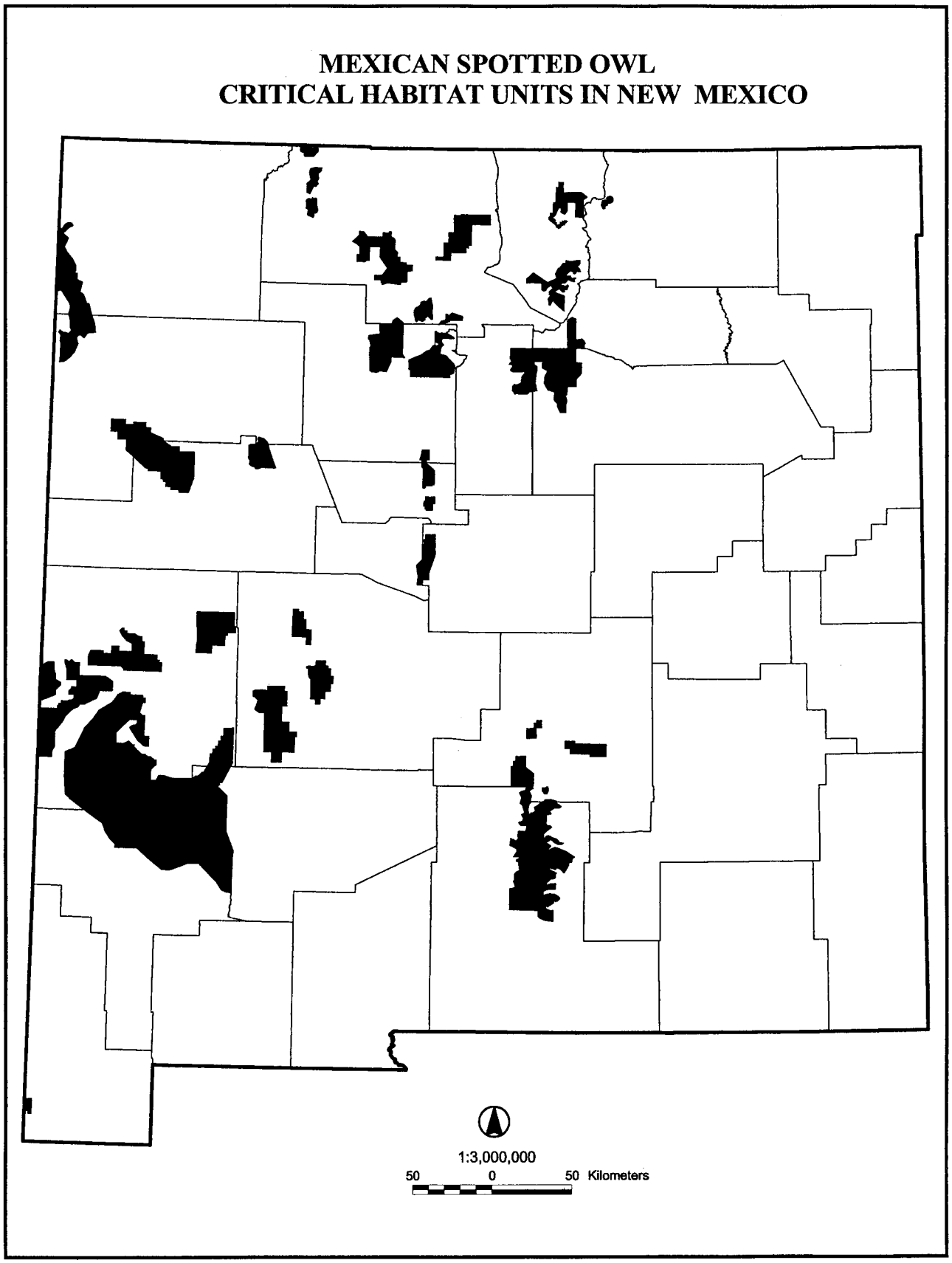
MEXICAN SPOTTED OWL
CRITICAL HABITAT UNITS IN COLORADO




MEXICAN SPOTTED OWL
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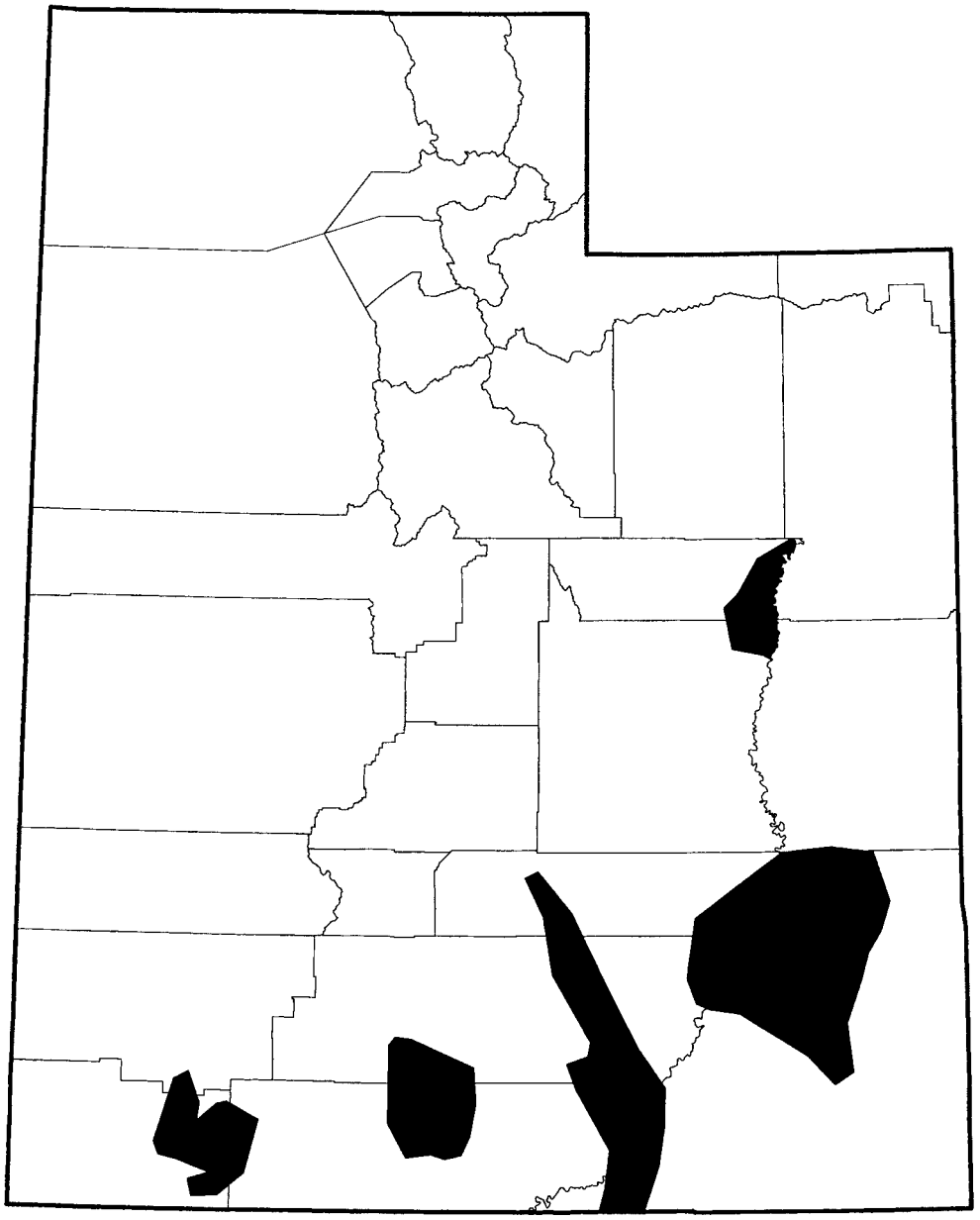
MEXICAN SPOTTED OWL
CRITICAL HABITAT UNITS IN UTAH



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Dated: July 14, 2000.

Donald J. Barry,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 00–18407 Filed 7–20–00; 8:45 am]

BILLING CODE 4310–55–C

Notices

Federal Register

Vol. 65, No. 141

Friday, July 21, 2000

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

Foreign Agricultural Service

Assessment of Fees for Dairy Import Licenses for the 2001 Tariff-Rate Import Quota Year

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice.

SUMMARY: This notice announces that the fee to be charged for the 2001 tariff-rate quota (TRQ) year for each license issued to a person or firm by the Department of Agriculture authorizing the importation of certain dairy articles which are subject to tariff-rate quotas set forth in the Harmonized Tariff Schedule of the United States (HTS) will be $120.00 per license.

EFFECTIVE DATE: January 1, 2001.

FOR FURTHER INFORMATION CONTACT: Richard P. Warsack, Dairy Import Quota Manager, Import Policies and Programs Division, STOP 1021, U.S. Department of Agriculture, 1400 Independence Avenue, S.W., Washington, D.C. 20250–1021 or telephone at (202) 720–9439 or e-mail at warsack@fas.usda.gov.

SUPPLEMENTARY INFORMATION: The Dairy Tariff-Rate Import Quota Licensing Regulation promulgated by the Department of Agriculture and codified at 7 CFR 6.20–6.37 provides for the issuance of licenses to import certain dairy articles which are subject to TRQs set forth in the HTS. Those dairy articles may only be entered into the United States at the in-quota TRQ tariff rates by or for the account of a person or firm to whom such licenses have been issued and only in accordance with the terms and conditions of the regulation.

Licenses are issued on a calendar year basis, and each license authorizes the license holder to import a specified quantity and type of dairy article from a specified country of origin. The use of licenses by the license holder to import dairy articles is monitored by the Dairy Import Quota Manager, Import Licensing Group, Import Policies and Programs Division, Foreign Agricultural Service, U.S. Department of Agriculture and the U.S. Customs Service.

The regulation at 7 CFR 6.33(a) provides that a fee will be charged for each license issued to a person or firm by the Licensing Authority in order to reimburse the Department of Agriculture for the costs of administering the licensing system under this regulation.

The regulation at 7 CFR 6.33(a) also provides that the Licensing Authority will announce the annual fee for each license and that such fee will be set out in a notice to be published in the **Federal Register**. Accordingly, this notice sets out the fee for the licenses to be issued for the 2001 calendar year.

Notice

The total cost to the Department of Agriculture of administering the licensing system during 2000 has been determined to be $312,830 and the estimated number of licenses expected to be issued is 2,625. Of the total cost, $150,080 represent staff and supervisory costs directly related to administering the licensing system during 2000; $50,350 represents the total computer costs to monitor and issue import licenses during 2000; and $112,400 represents other miscellaneous costs, including travel, postage, publications, forms, and an ADP system contractor.

Accordingly, notice is hereby given that the fee for each license issued to a person or firm for the 2001 calendar year, in accordance with 7 CFR 6.33, will be $120.00 per license.

Issued at Washington, D.C. the 17th day of July, 2000.

Richard P. Warsack,

Licensing Authority.

[FR Doc. 00–18517 Filed 7–20–00; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Forest Service

Deadwood Ecosystem Analysis '96, Boise National Forest, Boise and Valley Counties, ID

AGENCY: Forest Service, USDA.

ACTION: Withdrawal of notice of intent to prepare Environmental Impact Statement.

SUMMARY: The Deadwood Ecosystem Analysis '96 project NOI, which was published in the **Federal Register** on August 9, 1996 (Volume 61, Number 155; pp. 41563–41565) is hereby withdrawn.

DATES: This notice is effective July 21, 2000.

ADDRESSES: For more information, contact Randall Hayman, Boise National Forest, 1249 South Vinnell Way, Suite 200, Boise, ID 83709; 208–373–4517.

Dated: July 10, 2000.

David D. Rittenhouse,

Forest Supervisor.

[FR Doc. 00–18452 Filed 7–20–00; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Small Business Timber Sale Set-Aside Program Share Recomputation

AGENCY: Forest Service, USDA.

ACTION: Notice of final policy.

SUMMARY: This final policy revises the formula used for calculating timber sale set-aside market shares. The recomputation formula has been revised to use only purchased timber sale volume data. Purchased timber sale data from the past 5-year period is to be used to determine the shares for the next 5-year period. This change is needed to make the recomputation process as fair, accurate, and simple as possible.

DATES: This policy is effective August 7, 2000.

FOR FURTHER INFORMATION CONTACT: Rod Sallee, Small Business Timber Sale Set-aside Program Manager, Forest Management Staff, by telephone at (202) 205–1766 or by internet at *rsallee@fs.fed.us.*

SUPPLEMENTARY INFORMATION: Developed in cooperation with the Small Business Administration, the Forest Service Small Business Timber Sale Set-aside Program is designed to ensure that qualifying small business timber purchasers have the opportunity to purchase a fair proportion of National Forest System timber offered for sale. The current Small Business Timber Sale

Set-aside Program was adopted July 26, 1990 (55 FR 30485). Direction that guides Forest Service employees in administering the Small Business Timber Sale Set-aside Program is issued in the Forest Service Manual, Chapter 2430, and in Chapter 90 of the Forest Service Timber Sale Preparation Handbook (FSH 2409.18).

According to the guidelines of the set-aside program, the Forest Service recomputes the shares of timber sales to be set aside for qualifying small businesses every 5 years. The share percentage is based on the actual volume of sawtimber that has been purchased and/or harvested by small businesses. In addition to the 5-year requirement, shares must be recomputed whenever manufacturing capability changes, purchaser class size changes, or when certain purchasers discontinue operations. On May 28, 1999, the agency published in the **Federal Register** (64 FR 28969) a proposed policy to modify several provisions of the recomputation procedures.

Response to Comments Received

Twenty-six responses were received on the proposed policy. Comments were received from 22 purchasers, 3 organizations representing member companies and log processing facilities, and the Small Business Administration. A summary of the comments and the agency's response follows.

Comments Specific to the Proposed Policy

Remove the harvest volume from the recomputation formula. The proposal to remove the harvest volume would affect recomputations of shares for the upcoming and future 5-year recomputations of the small business share of timber sales as well as recalculation of shares after a structural change occurs. The volume purchased would be the measurement used in the formula for the recomputations.

Comment. Twenty-one of the respondents, including the U.S. Small Business Administration, supported dropping the harvest volume and using only the volume purchased. Most of these respondents indicated that dropping the harvest volume would serve both the forest products industry and the agencies by eliminating unnecessary record keeping and undue complexities in the calculation procedures.

One respondent also noted that the Forest Service would be able to achieve a much higher degree of accuracy in calculating normal and structural recomputations. That respondent claimed that most errors found in 5-year recomputations were made by Forest Service field officers in keeping and interpreting harvest records.

The respondents, favoring the change, also indicated that the purchase/harvest ratio was developed to respond to a situation that no longer exists, that is, to prevent purchasers from buying and holding volume to artificially drive a recomputation to a desired outcome. They noted that the Forest Service is now selling so little timber that purchasers are unable to accumulate large federal portfolios and seldom are able to hold their sale volume longer than 3 years. They concluded that it is nearly impossible for a purchaser to purchase and hold a sufficient quantity of volume long enough to affect the Small Business Timber Sale Set-aside Program share recomputations. Furthermore, they noted that the shift away from scaled sales and the inability of the recomputation process to deal with under runs further reduced the need for the purchase/harvest ratio. One respondent also supported dropping the harvest volume from the calculation because of the uncertainty of harvest scheduling, which is interrupted by consultation and litigation concerning threatened, endangered and sensitive species, making it impossible for any small business to match harvest levels to sale purchase in a given time period. Another respondent noted that the term of the timber sale contract is shorter now than in the past, which reduces the importance of accounting for harvest volume in the formula.

Three respondents, including one organization that represents large forest product companies in the West, expressed opposition to dropping the harvest data from the formula for calculating shares. One respondent commented that a period of unstable timber supply and markets is simply a poor time to make changes in a long established criteria used in calculating shares for the set-aside program. They noted that the proposed change seemed to allow small businesses to have an unfair ability to manipulate the program in their favor by carrying excess share volumes of unharvested timber into the next 5-year period. Similarly, another respondent felt that the proposed change would allow small businesses to purchase and hoard excessive amounts of unharvested volumes into the future 5-year periods.

One respondent commented that an aggressive, relatively large, small business sawmill owner would have an unfair advantage over the smallest size operator. This respondent also expressed a belief that this unfair advantage would lead to fewer operations and could hurt the economic viability of the smallest owners. This respondent stated that there would be no reason for a qualifying small sawmill to use federal timber in a timely manner without the purchase-to-harvest ratio minimum. In addition, using only the purchased timber sale data would tie up resource areas for longer time periods and lead to the displacement of the smallest ''Mom and Pop'' sawmills by the larger mills, even though the larger mills still qualified as small businesses.

Response. The arguments for dropping the harvest volumes from the recomputation formula are persuasive. Available data concerning timber volume under contract does not provide evidence of the hoarding of large amounts of timber under contract. The competition for federal timber, as well as increasing prices for quality timber, indicate an increased demand for timber sales from federal lands. Furthermore, since July 1991, timber sale contracts require periodic payments, which discourages the hoarding of any timber under contract and provides an incentive for prompt harvest. Including harvest data in the formula is no longer necessary, given the current size of the timber program, the length of the timber sale contracts, and new timber sale contract provisions. The agency agrees with the argument that dropping the harvest volume from the formula would serve both the forest products industry and the agencies by eliminating unnecessary recordkeeping and undue complexities in the calculation procedures.

Finally, the Small Business Administration, which administers the Small Business Set-aside Program cooperatively with the Forest Service, supports this formula change. Therefore, the formula included in the final policy reflects the removal of the harvest volume from the recomputation of shares and relies, instead, only on the amount of timber purchased. This change is reflected in the revised instructions given in Chapter 90 of the Forest Service Timber Sale Preparation Handbook (FSH 2409.18).

Change the time period for a structural change recomputation from 36 months to 18 months. The proposed policy asked for comment on reducing the implementation time of a structural change from 36 months to 18 months.

Comments. Three respondents supported the proposal to shorten the timeframe for a structural change recomputation; one was a large business and the other two were small businesses. One respondent stated that since the rate of change in business, in

general, and in the timber industry, in particular, seemed to be continually accelerating, the proposed change would allow for share changes to be better-timed following business changes.

One respondent, who supported the proposal, noted that because of the drastic changes in the industry in the last 2 years, many companies were getting out of the sawmill business. The respondent stated that if a structural change was not made quickly, an imbalance in the marketplace would occur. Likewise, another respondent felt that the 18-month period would allow the Forest Service to be more responsive to the needs of small businesses in an ever-changing market situation.

Twenty-three respondents, including the Small Business Administration, opposed this proposal to shorten the time period for a structural change recomputation. These respondents included two organizations representing small businesses and one organization representing large businesses. The other 19 respondents were individual small businesses.

The Small Business Administration noted that structural changes are rapidly occurring in market areas where the number and volume of sales have decreased dramatically over the past few years. They stated that only by retaining the 36-month analysis period would there be adequate time to allow the small business set-aside share percentage to reflect the actual purchase patterns that would develop after a major purchaser has discontinued operations or changed its business size status. They suggested that it might be more effective to revise the qualified purchased volume amount that is needed to meet the definition for structural change. A respondent stated that a structural change should not be implemented until the entire small business set-aside program is analyzed in accordance with current market conditions.

One of the respondents opposed the proposed reduction in time stating that 18 months is not long enough time to yield an appropriate number of sales or amount of timber volume on which to make an accurate recomputation. This respondent provided examples where the proposal would not work; such as, when a forest went for more than 18 months without selling a qualifying timber sale or when forests offered large salvage sales with logging requirements that effectively precluded smaller companies form bidding on the sales. The respondent also noted that since current regulations on structural change recomputation allow the set-aside share to vary between the original share level and 80 percent of the original, there are too many instances where one or two large salvage sales, which have expensive logging system requirements, are the only sales sold in a market area during a recomputation period. The respondent noted that this situation is unfair to smaller purchasers because they have no legitimate opportunity to purchase the volume needed to maintain the set-aside share.

Similarly, another respondent representing small businesses, provided a chart of 18 national forests in Oregon and Washington, depicting low sale volumes and an erratic timber sale program from 1995 to 1998. The respondent suggested that under an 18-month base period, one or two sales on those example forests often constituted 50 to 75 percent of the entire sale program during that period. The respondent noted that shortening the recomputation time period created opportunities to manipulate the program and, as such, would be a substantial risk to small businesses.

One respondent commented that the joint circumstances of only a few timber sales making it through the gauntlet of litigation and the more traditional type of timber sale program changing to include the vastly different types of ''sales,'' such as salvage, stewardship, and forest health, make the proposed change to an 18-month period a poor choice. Another respondent noted that if the 18-month proposal was adopted only six sales likely would be offered in their area in 18 months. The respondent stated that the proposed timeframe simply is not long enough to yield an appropriate number of sales or an amount of timber volume with which to make an accurate recomputation.

Another respondent, opposed to the reduced timeframe, noted that because the timber program is erratic, the reduction in time might produce some unintended results. This respondent suggested that the agency consider extending the base period from 36 months to a full 5-year period. Another a stated that the time reduction would be adverse to the interests of small businesses and suggested that the structural recomputation procedure be eliminated completely.

The remaining respondents, opposed to the reduction of the structural change time period to 18 months, identified the same reasons previously noted by the other respondents. Most indicated that the timber sale program is too erratic and that too few sales would be offered in the 18-month period for a fair recomputation of small business shares.

Response. The arguments against proceeding with the proposal to reduce the time period for recomputing the shares and the evidence presented by the as are sufficient to convince the agency that there are too many negative factors to proceed with implementation of this part of the proposed policy. The negative factors that were especially noteworthy include Small Business Administration's concern that there needs to be adequate time to provide the opportunity for the share percentage to reflect the actual purchase patterns that develop after a major purchaser has discontinued operations or changed size status and the fact that most of the respondents expressed opposition to the proposal to reduce the time period. Respondents noted that the reduced number of sales in most market areas would be an inadequate representation of the timber sale program. The agency agrees that this could be a negative factor in the structural change consideration. Also, the agency is especially concerned about the potential impact of changing the time period on small businesses and the potential for manipulation of the share computation under a 18-month base timeframe. A 18-month base time period may not give small businesses adequate opportunity to show interest in a sale. Therefore, the proposal to reduce the recomputation period from 36 months to 18 months will not be adopted.

Other structural change related proposals suggested by the respondents, such as, revising the qualified purchased volume amount needed to trigger a structural change, dropping the structural change procedure completely, or changing the period to 5 years, are not being pursued at this time. However, the agency continues to monitor the effects of structural changes and to work with the Small Business Administration to determine what future policy changes may be needed to provide fair adjustments for both small and large timber businesses.

Other Comments. A number of the respondents commented on what they thought was a part of the agency's proposal, that is, to change the small business set-aside policy to allow only the timber sales sold on a tree measurement basis to be counted in the set-aside program.

Response. While the proposal, as presented in the May 1999, **Federal Register** notice, could be interpreted to suggest that the agency was proposing to allow only timber sales sold on a tree measurement basis to be counted in the set-aside program, this was not the intention of the agency. As one of the respondents noted, a recent study,

required by Congress to assess whether scaled or tree measurement sales provided the best results concluded that a mix of these methods was the most appropriate procedure. The agency will continue to allow sales from both tree measurement and scaled sales to be included.

Summary

The formula to be used for the recomputation of the small business shares of the timber sale set-aside program has been modified to remove the harvest volume data from the recomputation of shares. The recomputation formula will now use only the amount of timber purchased. This change is reflected in the revised instructions given in Chapter 90 of the Forest Service Timber Sale Preparation Handbook (FSH 2409.18). No other substantive policy changes were made to this chapter of the handbook. Copies may be obtained from the Forest Service website at Directives under the Administration pull-down menu at the worldwide web at *fs.fed.us* or by contacting the person listed under the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Regulatory Impact

This final policy has been reviewed under USDA procedures and Executive Order 12866 on Regulatory and Review. It has been determined that this is not a significant policy. This final policy will not have an annual effect of $100 million or more on the economy nor adversely affect productivity, competition, jobs, the environment, public health or safety, nor State or local governments. This final policy will not interfere with an action taken or planned by another agency nor raise new legal or policy issues. Finally, this action will not alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients of such programs. Accordingly, this final policy is not subject to OMB review under Executive Order 12866.

Moreover, this final policy has been considered in light of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), and it has been determined that this action will not have a significant economic impact on a substantial number of small entities as defined by that Act. The agency received comments primarily from small businesses and complied with most of the suggestions made by those entities.

Environmental Impact

Section 31.1b of Forest Service Handbook 1909.15 (57 FR 43180; September 18, 1992) excludes from documentation in an environmental assessment or impact statement ''rules, regulations, or policies to establish Service-wide administrative procedures, program processes, or instructions.'' The agency's assessment is that this final policy falls within this category of actions and that no extraordinary circumstances exist which would require preparation of an environmental assessment or environmental impact statement.

Unfunded Mandates Reform

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), which the President signed into law on March 22, 1995, the Department has assessed the effects of this final policy on state, local, and tribal governments and the private sector. This final policy does not compel the expenditure of $100 million or more by any State, local, or tribal governments, or anyone in the private sector. Therefore, a statement under section 202 of the Act is not required.

Controlling Paperwork Burdens on the Public

This final policy does not contain any record keeping or reporting requirements or other information collection requirements as defined in 5 CFR 1320 and, therefore, imposes no paperwork burden on the public. Accordingly, the review provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and implementing regulations at 5 CFR 1320 do not apply.

Dated: June 22, 2000.

Mike Dombeck,

Chief.

[FR Doc. 00–18482 Filed 7–20–00; 8:45 am]

BILLING CODE 3410–11–M

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds to the Procurement List commodities and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: August 21, 2000.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Louis R. Bartalot (703) 603–7740.

SUPPLEMENTARY INFORMATION: On May 5, 12 and 26 and June 2 and 9, 2000, the Committee for Purchase From People Who Are Blind or Severely Disabled published notices (65 F.R. 26178, 30562, 34145, 35319 and 36663) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodities and services and impact of the additions on the current or most recent contractors, the Committee has determined that the commodities and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities and services to the Government.

2. The action will not have a severe economic impact on current contractors for the commodities and services.

3. The action will result in authorizing small entities to furnish the commodities and services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46—48c) in connection with the commodities and services proposed for addition to the Procurement List.

Accordingly, the following commodities and services are hereby added to the Procurement List:

Commodities

American Flag
M.R. 1011
Mailers, Audio Cassette
8105–01–386–2181
8105–01–386–2189
Nonfat Dry Milk
8910–00–NSH–0001

Services

Administrative Services, General Services Administration, 100 Penn Square East, Philadelphia, Pennsylvania

Administrative Services, Office of the Provost Marshal, Building 23020, Fort Hood, Texas
Administrative/General Support Services, Chaplain's Office, Great Lakes Naval Training Center, Great Lakes, Illinois
Dispatcher Services, Federal Building 222 West 7th Avenue, Anchorage, Alaska
Grounds Maintenance, U.S. Army Reserve Center, 50 East Street, Springfield, Massachusetts
Grounds Maintenance, U.S. Army Reserve Center, AMSA 68(G), 42 Albion Road, Lincoln, Rhode Island
Janitorial/Custodial, Marine Corps Reserve Training Center, 4201 Chester Avenue, Bakersfield, California
Janitorial/Custodial, Weapons Support Facility, Seal Beach, California
Janitorial/Custodial, GSA Distribution Depot, 500 Edwards Avenue, Harahan, Louisiana
Janitorial/Custodial, U.S. Army Space & Missile Defense Command, Arlington, Virginia
Operation of Central Issue Facility, Building 9640, Fort Lewis, Washington
Operation of Self Service Supply Store, U.S. Army Space & Missile Defense Command, Arlington, Virginia
Temporary Medical Record Filing for the following locations: VA Medical Center, Nashville, Tennessee; Alvin C. York VA Medical Center, Murfreesboro, Tennessee

This action does not affect current contracts awarded prior to the effective date of this addition or options that may be exercised under those contracts.

Louis R. Bartalot,

Deputy Director (Operations).

[FR Doc. 00–18540 Filed 7–20–00; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled

ACTION: Proposed Additions to Procurement List.

SUMMARY: The Committee has received proposals to add to the Procurement List commodities and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Comments must be received on or before August 21, 2000.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Louis R. Bartalot (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

If the Committee approves the proposed additions, all entities of the Federal Government (except as otherwise indicated) will be required to procure the commodities and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities and services to the Government.

2. The action will result in authorizing small entities to furnish the commodities and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities and services proposed for addition to the Procurement List. Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

The following commodities and services have been proposed for addition to Procurement List for production by the nonprofit agencies listed:

Commodities

Paper Shredder
75201241 (Strip Cut)
75201242 (Cross Cut)
75201419 (Strip Cut)
75201420 (Cross Cut)
NPA: L.C . Industries for the Blind, Inc.
Durham, North Carolina

Services

Grounds Maintenance
MCRD–SCE Parcels
Marine Corps Recruit Depot
San Diego, California
NPA: Association for Retarded Citizens—San Diego
San Diego, California

Janitorial/Custodial

NASA Headquarters
300 E Street, SW
Washington, DC
NPA: Fairfax Opportunities Unlimited, Inc.
Alexandria, Virginia

Janitorial/Custodial

New Executive Office Building
Jackson Place Townhouses
Winder Building and 1724 F Street
Washington, DC
NPA: Melwood Horticultural Training Center
Upper Marlboro, Maryland

Janitorial/Custodial

U.S. Fish & Wildlife Service
Great Swamp National Wildlife Refuge
Basking Ridge, New Jersey
NPA: Occupational Training Center of Morris County
Cedar Knolls, New Jersey

Laundry Service

Linen Exchange
Building 426
March Air Force Base, California
NPA: Job Options, Inc.
San Diego, California

Mailing Services

NASA Goddard Space Flight Center
Greenbelt, Maryland
NPA: Fairfax Opportunities Unlimited, Inc.
Alexandria, Virginia

Louis R. Bartalot,

Deputy Director (Operations).

[FR Doc. 00–18541 Filed 7–20–00; 8:45 am]

BILLING CODE 6353–01–p

DEPARTMENT OF COMMERCE

[I.D. 071800LE]

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (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: National Oceanic and Atmospheric Administration (NOAA).

Title: Licensing of Private Land Remote-Sensing Space Systems.

Form Number(s): None.

OMB Approval Number: 0648–0174.

Type of Request: Emergency.

Burden Hours: 314.

Number of Respondents: 13.

Average Hours Per Response: 40 hours for a license application, 10 hours for a license amendment, 2 hours for a notification of a foreign agreement, 1 hour for an executive summary, 2 hours for a notification of the demise of a

system or a decision to discontinue system operations, 2 hours for a notification of any operational deviation, 5 hours for a data collection restriction plan, 3 hours for a plan for restricting collection or dissemination of Israeli territory, 3 hours for submission of a data flow diagram, 1 hour for submission of satellite sub-system drawings, 3 hours for submission of final imaging system specifications, 2 hours for a notification of intent to purge data, 2 hours for spacecraft operational information, 2 hours for a notification of disposition of a satellite or orbital debris, 3 hours for a quarterly operational report, 8 hours for a pre-operational compliance audit, and 10 hours for an operational compliance audit.

Needs and Uses: NOAA is issuing regulations that revise the agency's minimal requirements for the licensing, monitoring, and compliance review of private Earth remote-sensing space systems under Title II of the Land Remote-Sensing Policy Act of 1992 (15 U.S.C. 5601 *et. seq.*). Application information is needed to ensure that the applicant will be in compliance with the Act and with national security and international obligations. Persons receiving a license will be required to make reports (see ''Average Hours Per Response'' above for a listing of the reports). *Affected Public*: Business and other for-profit organizations.

Frequency: On occasion, quarterly, annually.

Respondent's Obligation: Mandatory.

OMB Desk Officer: David Rostker, (202) 395-3897.

Copies of the above information collection proposal can be obtained by calling or writing Linda Engelmeier, DOC Forms Clearance Officer, (202) 482-3272, Department of Commerce, Room 6086, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at lengelme@doc.gov).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503.

Dated: July 17, 2000.

Madeleine Clayton,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 00–18563 Filed 7–20–00; 8:45 am]

BILLING CODE 3510–HR–F

DEPARTMENT OF COMMERCE

International Trade Administration

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce seeks U.S. companies to exhibit their catalogues in the U.S. Environmental Technologies Product Literature Center at Pollutec in Lyon, France, October 17–20, 2000. Recruitment closes on September 15, 2000. For information contact: Ms. Anne Novak, U.S. Department of Commerce, telephone: 202–482–8178, fax: 202–501–7909, e-mail: Anne__Novak@ita.doc.gov

Every year Pollutec, France's premier trade show for air, water, solid and hazardous waste technologies, draws a worldwide audience of over 60,000 professional visitors. About six in ten have become customers of exhibitors they met at Pollutec, and American companies which exhibited at Pollutec last year received approximately 1,100 business leads. See their website http://www.Pollutec.com for more information on Pollutec.

The U.S. Environmental Technologies Product Literature Center will be managed by experienced specialists from Department of Commerce offices in France and Washington. The participation fee for this catalog showcase is $380.00, and companies will need to forward sets of their company literature, which will be displayed at the U.S. Pavilion at Pollutec and promoted by Department of Commerce specialists.

FOR FURTHER INFORMATION CONTACT: Reginald Beckham, U.S. Department of Commerce. Tel: 202–482–5478, Fax: 202–482–1999.

Dated: July 17, 2000.

Thomas H. Nisbet,

Director, Promotion Planning and Support Division, Office of Export Promotion Coordination.

[FR Doc. 00–18550 Filed 7–20–00; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[Docket No. 000515143–0205–02]

RIN 0625–XX23

Special American Business Internship Training Program (SABIT)

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of extension of funding availability for grants under the Special American Business Internship Training Program (SABIT).

SUMMARY: This Notice supplements the **Federal Register** Notice of May 12, 2000 (65 FR 36117–36120) announcing the availability of funds for the SABIT American Business Internship Training Program (SABIT), for training business executives (also referred to as ''interns'') from the Newly Independent States of the Former Soviet Union. All information in the previous announcement remains current, except for the changes to the closing date.

DATES: This Notice extends the closing date of the referenced **Federal Register** Notice for 1 month to 5 p.m. August 31, 2000. All awards are expected to be made prior to September 30, 2000.

FOR FURTHER INFORMATION CONTACT: Liesel Duhon, Director, Special American Business Internship Training Program, International Trade Administration, U.S. Department of Commerce, phone—(202) 482–0073, facsimile—(202) 482–2443. These are not toll free numbers.

Dated: July 18, 2000.

Liesel Duhon,

Director, SABIT Program.

[FR Doc. 00–18562 Filed 7–20–00; 8:45 am]

BILLING CODE 3510–HE–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Judges Panel of the Malcolm Baldridge National Quality Award

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of closed meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, 5 U.S.C. app. 2, notice is hereby given that there will be a closed meeting of the Judges Panel of the Malcolm Baldrige National Quality Award on Wednesday, August 3, 2000. The Judges Panel is composed of nine members prominent in the field of quality management and appointed by the Secretary of Commerce. The purpose of this meeting is to discuss the criteria for moving applicants to consensus/site visits; review of Stage I process, including data and selection of applicants for consensus, and comparison of Stage I decisions in 2000 with trend data from past; report on Judges Survey modifications; and review of senior training. The

applications under review contain trade secrets and proprietary commercial information submitted to the Government in confidence.

DATES: The meeting will convene August 3, 2000, at 9:00 a.m. and adjourn at 4:30 p.m. on August 4, 2000. The entire meeting will be closed.

ADDRESSES: The meeting will be held at the National Institute of Standards and Technology, Chemistry Building, Room A228, Gaithersburg, Maryland 20899.

FOR FURTHER INFORMATION CONTACT: Dr. Harry Hertz, Director, National Quality Program, National Institute of Standards and Technology, Gaithersburg, Maryland 20899, telephone number (301) 975–2361.

SUPPLEMENTARY INFORMATION: The Assistant Secretary for Administration, with the concurrence of the General Counsel, formally determined on March 31, 2000, that the meeting of the Judges Panel will be closed pursuant to Section 10(d) of the Federal Advisory Committee Act, 5 U.S.c. app. 2, as amended by Section 5(c) of the Government in the Sunshine Act, Public Law 94–409. The meeting, which involves examination of records and discussion of Award applicant data, may be closed to the public in accordance with Section 552b(c)(4) of Title 5, United States Code, since the meeting is likely to disclose trade secrets and commercial or formation obtained from a person and privileged or confidential.

Dated: July 13, 2000.

Karen H. Brown,

Deputy Director.

[FR Doc. 00–18536 Filed 7–20–00; 8:45 am]

BILLING CODE 3510–13–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 062300E]

Marine Mammals; Scientific Research Permit (978–1567–00)

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

ACTION: Issuance of permit.

SUMMARY: Notice is hereby given that Paul E. Nachtigall, Ph.D., Director, Marine Mammal Research Program, Hawaii Institute of Marine Biology, University of Hawaii, P.O. Box 1106, Kailua, Hawaii 96734, has been issued a permit to conduct scientific research on three captive bottlenose dolphins (*Tursiops truncatus*) and one captive false killer whale (*Pseudorca crassidens*) for scientific research.

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the following offices:

Permits Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910 (301/713–2289);

Regional Administrator, Southwest Region,501 West Ocean Boulevard, Suite 4200, Long Beach, California 90802–4213, (562/980–4000); and

Protected Resources Program Manager, Pacific Islands Area Office, 1601 Kapiolani Boulevard, Suite 1110, Honolulu, Hawaii 96814–4700, (808/973–2937).

FOR FURTHER INFORMATION CONTACT: Jeannie Drevenak at 301/713–2289.

SUPPLEMENTARY INFORMATION: On April 25, 2000, notice was published in the **Federal Register** (65 FR 24186) that a request was received for a scientific research permit on three (3) captive bottlenose dolphins (*Tursiops truncatus*) and one (1) captive false killer whale (*Pseudorca crassidens*) for studies on the hearing and echolocation processes in odontocete cetaceans. The research will occur over a five year period. The requested permit has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: July 17, 2000.

Ann D. Terbush,

Chief, Permits and Documentation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 00–18565 Filed 7–20–00; 8:45 am]

BILLING CODE 3510–22–F

DEPARTMENT OF DEFENSE

Office of the Secretary

Submission for OMB Review; Comment Request

AGENCY: Notice.

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

Title, Associated Form, and OMB Number: Application for a Department of the Army Permit; ENG Form 4345; OMB Number 0710–0003.

Type of Request: Reinstatement.

Number of Respondents: 15,500.

Responses per Respondent: 1.

Annual Responses: 15,500.

Average Burden per Response: 10 hours.

Annual Burden Hours: 155,000.

Needs and Uses: The Corps of Engineers uses the information to evaluate proposed construction of filling in U.S. waters for impacts on the environment and nearby properties as required by federal law to determine if issuance of a permit is in the public interest. Respondents are private landowners, businesses, non-profit organizations, and government agencies.

Affected Public: Individuals; Business or Other For-Profit; Not-For-Profit Institutions; Farms; Federal Government; State, Local or Tribal Government.

Frequency: On Occasion.

Respondent's Obligation: Mandatory.

OMB Desk Officer: Mr. Jim Laity.

Written comments and recommendations on the proposed information collection should be sent to Mr. Laity at the Office of Management and Budget, Desk Officer for U.S. Army COE, Room 10202, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Mr. Robert Cushing.

Written requests for copies of the information collection proposal should be sent to Mr. Cushing, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302.

Dated: July 14, 2000.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 00–18448 Filed 7–20–00; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Partnership Council Meeting

AGENCY: Department of Defense.

ACTION: Notice of meeting cancellation.

SUMMARY: On June 21, 2000, 65 FR 38518, the Department of Defense published a notice to announce a meeting of the Defense Partnership Council to be held July 26, 2000.

This notice is to announce that the meeting is cancelled due to conflicts in members' schedules.

FOR FURTHER INFORMATION CONTACT: Mr. Ben James, Chief, Labor Relations Branch, Field Advisory Services

Division, Defense Civilian Personnel Management Service, 1400 Key Boulevard, Suite B–200, Arlington, VA 22209–5144, (703) 696–1450.

Dated: July 14, 2000.

Patricia L. Toppings,

Alternate OSD Federal Register Lisison Officer, Department of Defense.

[FR Doc. 00–18450 Filed 7–20–00; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Department of the Air Force

Notice of Intent to Prepare an Environmental Impact Statement (EIS) for the Barry M. Goldwater Range Integrated Natural Resources Management Plan

AGENCY: Department of the Air Force, DoD.

SUMMARY: Pursuant to Section 102(2)(c) of the National Environmental Policy Act of 1969 (NEPA), as implemented by the Council on Environmental Quality regulations (40 CFR 1500 to 1508), the Departments of the Air Force and Navy, in partnership with the Department of the Interior and the State of Arizona (Arizona Game and Fish Department), intend to prepare an EIS to evaluate the environmental effects of the implementation of the Integrated Natural Resources Management Plan being prepared for the Barry M. Goldwater Range.

DATES: Comments must be received no later than August 28, 2000 to ensure full consideration in the EIS.

ADDRESSES: See **SUPPLEMENTARY INFORMATION** section for meeting addresses.

FOR FURTHER INFORMATION CONTACT: Luke Air Force Base, 56 FW/RMO, 6605 North 140th Drive, Luke AFB, AZ 85309–1934 (Attn: Mr. Bob Barry, telephone 623–856–3823, extension 242); Marine Corps Air Station Yuma at Range Management Department, Box 99160, Yuma, AZ 85369–9160 (Attn: Mr. Ron Pearce, telephone 520–341–3401); Bureau of Land Management at Phoenix Field Office, 2015 West Deer Valley Road, Phoenix, AZ 85027 (Attn: Mr. Gene Dahlem, telephone 623–580–5525); or Arizona Game and Fish Department, 2221 W. Greenway Road WM–HB, Phoenix, AZ 85023–4312 (Attn: Mr. John Kennedy, telephone 602–789–3602).

SUPPLEMENTARY INFORMATION: The Barry M. Goldwater Range, located in southwestern Arizona, was rewithdrawn from the public domain for military training purposes under the Military Lands Withdrawal Act of 1999 (Public Law 106–65). In compliance with this Act, the Air Force and Marine Corps, in partnership with the Department of the Interior and the State of Arizona (Arizona Game and Fish Department), will manage the natural resources present on the Range in accordance with the Sikes Act (16 U.S.C. 670).

Accordingly, the Air Force and Marine Corps, in partnership with the Department of Interior and the State of Arizona (Arizona Game and Fish Department), are preparing and will implement an Integrated Natural Resources Management Plan for the Goldwater Range. Pursuant to the requirements of Public Law 106–65 and the Sikes Act, this Plan will provide for: (1) Management of natural and cultural resources present on the Range in support of the requirements of the military mission, (2) sustainable public use to the extent that use is compatible with military activities and natural and cultural resource compliance requirements, (3) compliance with laws protecting sensitive biological and cultural resources, including endangered species management, and (4) participation in local initiatives to advance regional biodiversity goals. The EIS, which is being prepared concurrently with the Integrated Natural Resources Management Plan, will evaluate the environmental effects of the management alternatives proposed in the Plan. Given the military purposes of the Range and the safety and security requirements associated with those purposes, the alternatives to be studied will focus on the protection, conservation, and management of resources and public use opportunities to the extent possible while not jeopardizing the military purposes of the Range.

Environmental issues to be addressed in the EIS include but are not limited to earth, biological, cultural, water, and visual resources; regional biological diversity management; wildlife management; threatened and endangered species; air quality; noise; land use compatibility; socioeconomics; recreation; environmental justice; and public health and safety.

The Air Force and Marine Corps, in partnership with the Department of the Interior and the State of Arizona (Arizona Game and Fish Department), are initiating a scoping process to determine the extent of issues to be addressed and identify the significant issues related to this action. Scoping meetings will be held in six southern Arizona communities, as indicated in the Meetings section below. Each meeting will begin with an open house at which the public may review maps and other displays. At each meeting location, the open house will be followed by a formal presentation beginning at 7:00 p.m. These meetings also will be advertised in area newspapers. A Tohono O'odham translator will be available at the meeting in Sells, AZ.

Air Force, Marine Corps, Department of the Interior, and State of Arizona representatives will be available at these meetings to receive comments from the public regarding issues of concern to the public. Federal, state and local agencies, any affected Native American tribes, and interested individuals are encouraged to take this opportunity to identify environmental concerns that should be addressed during the preparation of the EIS. Agencies and the public are also invited and encouraged to provide written comment on issues that are important to them in addition to, or in lieu of, oral comments at the public meeting. To be most helpful, comments should clearly describe specific issues or topics, which the commentor believes the EIS should address. Written statements and or questions regarding the Integrated Natural Resources Management Plan and associated EIS should be mailed to BMGR INRMP, P.O. Box 67132, Phoenix, AZ 85082–7132.

Meetings

Public scoping meetings will be held:

1. Monday, August 7, 2000, 5:30 to 8:30 p.m., Glendale Adult Center Palo Verde Building, 7121 North 57th Avenue, Glendale, AZ.

2. Tuesday, August 8, 2000, 5:30 to 8:30 p.m., Ajo Community Center, 290 East 5th Street, Ajo, AZ.

3. Wednesday, August 9, 2000, 5:30 to 8:30 p.m., El Rio Center, 1390 West Speedway Boulevard, Tucson, AZ.

4. Thursday, August 10, 2000, 5:30 to 8:30 p.m., Kofa High School, 3100 Avenue A, Yuma, AZ.

5. Friday, August 11, 2000, 5:30 to 8:30 p.m., Gila Bend Union High School, 308 North Martin, Gila Bend, AZ.

6. Tuesday, August 15, 2000, 5:30 to 8:30 p.m., Tribal Council Chambers, Sells, AZ.

Janet A. Long,

Air Force Federal Register Liaison Officer.

[FR Doc. 00–18561 Filed 7–20–00; 8:45 am]

BILLING CODE 5001–05–U

DEPARTMENT OF DEFENSE

Department of the Army

Notice of Proposed Change to MTMC Freight Transportation Procurement Procedures

AGENCY: Military Traffic Management Command, U.S. Army, DoD.

ACTION: Notice (Request for Comments).

SUMMARY: The Military Traffic Management Command (MTMC) proposes to revise the procedures it uses in procuring long term recurring freight transportation services from motor carriers and barge operators. MTMC often procures transportation services using contracting procedures that are not governed by the Federal Acquisition Regulation, *e.g.,* guaranteed traffic (GT) agreements. A revision of these procedures is being proposed due to change in the governing law.

DATES: Interested parties are requested to submit comments on this proposal by September 19, 2000. All comments received within 60 days of publication of this notice will considered prior to any decision on whether to adopt this proposal.

ADDRESSES: Comments should be addressed to Headquarters, Military Traffic Management Command, ATTN: MTAQ Room 12N67, Hofffman Building II, 200 Stovall Street, Alexandria, Virginia 22331–5000.

FOR FURTHER INFORMATION CONTACT: Christina N. Dossman, (703–) 428–2052.

SUPPLEMENTARY INFORMATION: Historically, freight transportation services procured by MTMC have not been governed by the Federal Acquisition Regulation (FAR) contained in Title 48 of the Code of Federal Regulations.

The FAR states at FAR 47.000 that it does not regulate transportation procured by bills of lading and similar documents. FAR 47–104.1 states that under 49 U.S.C. 10721 (now recoded at 49 U.S.C. sections 10721 [rail], 13721 [motor, water and freight forwarder] and 15504 [pipeline], carriers can offer reduced rates for Government Bill of Lading service and that agencies can negotiate reduced rates for volume moves or for shipments on a recurring basis. Under the exception recognized in FAR 47.200 the government could acquire transportation using 49 USC 10721 rates even though the FAR normally applies to transportation acquire by sealed bid or negotiated contracts (*i.e.,* not individual GBL traffic).

Under the above rules MTMC could and did used FAR exempt procedures for traffic based upon GBLs and also for traffic based upon Section 10721 rates.

49 U.S.C. 10721 was part of the Interstate Commerce Act which regulated rates offered by common carriers. This Act has been substantially amended in recent years, most notably by the Trucking Industry Reform Act of 1994, which abolished tariff filing requirements for motor carriers of freight, and by Public Law 104–88, the ICC Termination Act of 1995, which abolished the Interstate Commerce Commission. Thus, the provisions of the former Section 10721, to the extent it still exists in revised form as sections 10721, 13712 and 15504, have no practical application to the freight service DOD acquires from carriers. (*See Munitions Carriers Conference, Inc.* v. *United States*, 147 F.3D 1027 (1998).

In view of this change in the law, MTMC proposes to procure future transportation services involving recurring shipments or long term contracts under the FAR, including use of the FAR contract format and inclusion of all required FAR provisions and clauses. This will include future procurements based upon, or similar to, the guaranteed traffic (GT) agreements that MTMC now utilizes under FAR exempt procedures. This proposal does not apply to the current household goods program which is covered by different laws, but it should be noted that some household goods transportation contracts are already being conducted under the FAR.

MTMC will continue to use a voluntary tender procedure for shipments not covered under a long term contract. Those GBL-based movements continue to be recognized as exceptions to the legal requirement to use the FAR.

Regulatory Flexibility Act

This proposed change of procurement policy is not considered rule making within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601–612. Paperwork Reduction Act. The Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* does not apply because no information collection requirements or records keeping responsibilities are imposed on offerors, contractors, or members of the general public.

Brenda R. Jackson-Sewell,

Lieutenant Colonel, U.S. Air Force, Deputy Principal Assistant Responsible for Contracting.

[FR Doc. 00–18538 Filed 7–20–00; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Intent To Prepare a Draft Environmental Impact Statement [DEIS] for the Boeuf-Tensas Basin, Southeast Arkansas, Feasibility Report

AGENCY: U.S. Army Corps of Engineers, Vicksburg District, DOD.

ACTION: Notice of Intent.

SUMMARY: The feasibility study for the Boeuf-Tensas Basin, Southeast Arkansas will be conducted to fully evaluate a range of alternatives to provide a plan for flood control, environmental protection/restoration, and agricultural water supply in Chicot, Desha, Ashley, Drew, Lincoln, and Jefferson Counties, Arkansas.

FOR FURTHER INFORMATION CONTACT: Mr. Larry Marcy (telephone (601) 631–5965), CEMVK–PP–PQ, 4155 Clay Street, Vicksburg, Mississippi 39183–3435.

SUPPLEMENTARY INFORMATION: This study is authorized by a resolution of the Senate Committee on Environment and Public Works adopted 23 June 1988.

1. Proposed Action: Feasibility studies for the Boeuf-Tensas Basin, Southeast Arkansas study will be conducted to fully evaluate a range of alternatives to provide a multipurpose plan for flood control, agricultural water supply, and environmental protection and/or enhancement. Various alternatives will be analyzed, and assuming a feasible plan is identified, design studies will be completed to develop a baseline cost estimate and schedule for implementation.

2. Alternatives: One feasible implementable plan was identified during the Reconnaissance Study and documented in the Final Reconnaissance Report, February 1991. This plan would use water from seven different sources and/or methods, including rainfall, existing streamflows at the safe and legal rate of withdrawal, ground water at the safe yield, existing on-farm storage reservoirs, new on-farm storage reservoirs, import water from the Arkansas River, and water conservation. The primary delivery system to import water from the Arkansas River would consist of approximately 136 miles of channel excavation; one 75-cubic-foot-per-second pump station at Harding Drain in Pine Bluff, Arkansas; four gravity structures through the Arkansas River south bank levees at Linwood, Douglas Lake, Silver Lake, and Belcoe Lake; a dam across the south end of Morgan Point Cutoff; a 680-cubic-foot-

per-second pump station near Tillar, Arkansas; and 28 weirs in the main water supply channels. The secondary delivery system would consist of 75 lateral and 8 sublaterals to divert irrigation water from the main water supply channels to the beginning of an on-farm irrigation system; 4,830 relifts to supply water to the laterals and on-farm delivery systems; approximately 1,361,000 linear feet of permanent underground pipelines; and 670 on-farm reservoirs.

3. Additional alternatives that may be included are:

a. Water supply plans to meet three different design drought conditions.

b, Additional import points along the Arkansas River similar to the plan selected for detailed analysis in the Reconnaissance Study.

c. One import point on the Mississippi River to supply a portion of the unmet water needs of the Basin.

d. Utilization of on-farm storage and water conservation measures to meet all or a portion of the water needs in the Basin.

e. Upland reservoirs west of Bayou Bartholomew to supply a portion of the unmet water needs of the Basin.

f. Various levels of flood control and the impacts of the water supply alternatives on the existing level of flood protection.

g. Features to restore, protect, and/or enhance the environment. Opportunities exist to improve the productivity of streams and oxbow lake fisheries; restore, protect, and/or enhance the remaining tracts of bottom-land hardwoods and forested wetlands to benefit Neotropical migratory birds; and migratory waterfowl.

h. Other alternatives may be developed through the scoping process described below.

4. The National Environmental Policy Act (40 CFR Parts 1500–1508) requires all Federal agencies involved in water resources planning to conduct a process termed ''scoping.'' This scoping process determines the issues to be addressed and identifies the significant issues related to a proposed action. To accomplish this, two public scoping meetings will be held. One meeting is tentatively scheduled to be held at Pine Bluff, Arkansas, and one meeting at McGehee, Arkansas. These meetings are scheduled to be held in August 2000. Significant issues identified in the scoping meetings will be analyzed in depth in the DEIS. Significant issues currently identified include, but are not limited to, excessive sedimentation, excessive nutrients, trash dumping, log jams, reduced instream flow, habitat alteration, lack of diverse use, lack of public access, contaminants, and rock weirs. The Environmental Protection Agency, U.S. Fish and Wildlife Service, Natural Resources Conservation Service, Arkansas Department of Environmental Quality, Arkansas Game and Fish Commission, and the Arkansas Soil and Water Conservation Commission will be invited to become cooperating agencies. These agencies will be asked to review data, the feasibility report, and appendixes. A public meeting will be held once the DEIS is completed. All interested agencies, groups, tribes, and individuals will be sent copies of the DEIS and final EIS.

5. The DEIS is estimated to be completed in March 2005.

Robert Crear,

Colonel, Corps of Engineers, District Engineer.

[FR Doc. 00–18537 Filed 7–20–00; 8:45 am]

BILLING CODE 3710–PU–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER00–2885–000]

Cedar Brakes I, L.L.C.; Notice of Issuance of Order

July 17, 2000.

Cedar Brakes I, L.L.C. (Cedar Brakes) submitted for filing a rate schedule under which Cedar Brakes will engage in wholesale electric power and energy transactions at market-based rates. Cedar Brakes also requested waiver of various Commission regulations. In particular, Cedar Brakes requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Cedar Brakes.

On July 12, 2000, pursuant to delegated authority, the Director, Division of Corporate Applications, Office of Markets, Tariffs and Rates, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Cedar Brakes should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, Cedar Brakes is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Cedar Brakes' issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is August 14, 2000.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, N.E., Washington, D.C. 20426. The Order may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 00–18473 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EC00–109–000]

Cinergy Capital & Trading, Inc. CinCap VI, LLC Sunbury Holdings, LLC; Notice of Filing

July 17, 2000.

Take notice that on July 11, 2000, Cinergy Capital & Trading, Inc, Inc., CinCap VI, LLC and Sunbury Holdings, LLC (collectively, the Applicants), tendered for filing a supplement to Exhibit H to their joint application filed on June 27, 2000, in the above-captioned docket.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before July 25, 2000. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on

file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 00–18479 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. SA00–1–000]

J. Dennis Corbin, Arlene E. Corbin, and the Estate of Mary Alice Corbin; Notice of Petition for Adjustment

July 17, 2000.

Take notice that on June 12, 2000, J. Dennis Corbin (filing on behalf of himself, Arlene E. Corbin, and the Estate of Mary Alice Corbin (collectively: Corbin) filed a petition for adjustment under section 502(c) of the Natural Gas Policy Act of 1978,[1] requesting to be relieved of its obligation to pay the interest on the Kansas ad valorem tax reimbursement refunds Corbin owes to Northern Natural Gas Company. Absent such relief, Corbin would be required to make such refunds under the Commission's September 10, 1997 order in Docket No. RP97–369–000 *et al.*[2] The Commission's September 10 order on remand from the D.C. Circuit Court of Appeals [3] directed first sellers under the NGPA to make Kansas ad valorem tax refunds, with interest, for the period from 1983 to 1988. The Corbin petition is on file with the Commission and open to public inspection.

J. Dennis Corbin states that he and his wife (Arlene E. Corbin) never purchased any working interest in oil wells, or any other type of petroleum interest. Mr. Corbin further notes that, although he did inherit an interest in some Kansas oil properties from his father (F.J. Corbin), after his father and step-mother (Mary Alice Corbin) died in 1981, the wells involved were shut down approximately 10 to 11 years ago, and he believes that his father's estate was closed some time in 1983 or 1984. Accordingly, Mr. Corbin states that he does not understand how he and his wife could owe the refunds at issue, which pertain to certain Kansas wells operated by Burnett Corporation.

Mr. Corbin further acknowledges that he transferred one-half of his inherited interest in the Kansas oil properties to his wife. However, Mr. Corbin contends that, in view of the fact that his wife is presently responsible for caring for her 81-year-old blind mother, the burden imposed on his wife by the Commission's September 10 order is totally unjustified.

Any person desiring to be heard or to make any protest with reference to said petition should on or before 15 days after the date of publication in the **Federal Register** of this notice, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 384.214, 385.211, 385.1105, and 385.1106). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

David P. Boergers,

Secretary.

[FR Doc. 00–18477 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–M

[1] 15 U.S.C. 3142(c) (1982).

[2] See 80 FERC ¶ 61,264 (1997); order denying reh'g issued January 28, 1998, 82 FERC ¶ 61,058 (1998).

[3] *Public Service Company of Colorado* v. *FERC,* 91 F.3d 1478 (D.C. 1996), cert. denied, Nos. 96–954 and 96–1230 (65 U.S.L.W. 3751 and 3754, May 12, 1997) (Public Service).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP00–386–000]

Destin Pipeline Company, L.L.C.; Notice of Proposed Changes in FERC Gas Tariff

July 18, 2000.

Take notice that on July 12, 2000 Destin Pipeline Company, L.L.C. (Destin) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the following revised tariff sheets to become effective August 15, 2000:

Fourth Revised Sheet No. 5
Second Revised Sheet No. 96
Second Revised Sheet No. 98
First Revised Sheet No. 99
Original Sheet No. 121A

On February 9 and May 19, 2000, the Federal Energy Regulatory Commission (Commission) issued Order Nos. 637 and 637–A, respectively, which, among other things directed pipelines to file revised tariff sheets to remove the price cap for short-term capacity releases for a 2½ year period and to modify any ''Right of First Refusal'' provisions to comply with the Commission's new policy determinations. Destin states that it is filing revised tariff sheets to comply with these directives.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's rules and regulations. All such motions or protests must be filed in accordance with section 154.210 of the Commission's regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 00–18509 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EC00–95–000]

Dynegy Inc., Dynegy Holdings Inc., Illinova Corporation and Midwest Generation, LLC; Notice of Filing

July 17, 2000.

Take notice that on July 11, 2000, Dynegy Inc. (Dynegy) Illinova Corporation (Illinova), Dynegy Holdings Inc. (DHI), and Dynegy Midwest Generation, Inc. (DMGI) (together, Applicants) tendered for filing a Supplement to the application filed May 22, 2000 under section 203 of the Federal Power Act, which requested that the Commission approve a series of transactions (Proposed Transfer) designed to transfer the equity ownership of DMGI from Illinova to Dynegy Catlin Member, Inc., a wholly-owned subsidiary of DHI.

The Supplement consists of the documents that comprise Exhibit H

under Section 33.3 of the Commission's Regulations (18 CFR 33.3).

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before July 28, 2000. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222) for assistance).

David P. Boergers,

Secretary.

[FR Doc. 00–18469 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER00–2706–000]

Foote Creek IV, L.L.C.; Notice of Issuance of Order

July 17, 2000.

Foote Creek IV, L.L.C. (Foote Creek) submitted for filing rate schedule under which Foote Creek will engage in wholesale electric power and energy transactions at market-based rates. Foote Creek also requested waiver of various Commission regulations. In particular, Foote Creek requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Foote Creek.

On July 12, 2000, pursuant to delegated authority, the Director, Division of Corporate Applications, Office of Markets, Tariffs and Rates, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Foote Creek should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, Foote Creek is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Foote Creek's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is August 14, 2000.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, N.E., Washington, D.C. 20426. The Order may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 00–18471 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP00–385–000]

Garden Banks Gas Pipeline, LLC; Notice of Proposed Changes in FERC Gas Tariff

July 28, 2000.

Take notice that on July 12, 2000, Garden Banks Gas Pipeline, LLC (Garden Banks) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the following revised tariff sheets with a proposed effective date of August 15, 2000:

Third Revised Sheet No. 6
Second Revised Sheet No. 99
Fourth Revised Sheet No. 100
First Revised Sheet No. 103
Original Sheet No. 121C

On February 9 and May 19, 2000, the Federal Energy Regulatory Commission (Commission) issued Order Nos. 637 and 637–A, respectively, which, among other things, directed pipelines to file revised tariff sheets to remove the price cap for short-term capacity releases for a 2½ year period and to modify any ''Right of First Refusal'' provisions to comply with the Commission's new policy determinations. Garden Banks states that it is filing revised tariff sheets to comply with these directives.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's rules and regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 00–18508 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP00–288–001]

Kern River Gas Transmission Company; Notice of Compliance Filing

July 18, 2000.

Take notice that on July 13, 2000, Kern River Gas Transmission Company (Kern River) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1 Substitute Original Sheet No. 11, with an effective date of July 1, 2000.

Kern River states that the purpose of this filing is to comply with the Commission's letter order in this proceeding, which directed Kern River to file a revised Sheet No. 11 to include a page number reference for the transportation service request form.

Kern River states that it has served a copy of this filing upon each person designated on the official service list compiled by the Secretary in this proceeding.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission,

888 First Street, NE, Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rimbs.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 00–18506 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER00–2785–000]

Lakefield Junction, L.P.; Notice of Issuance of Order

July 17, 2000.

Lakefield Junction, L.P. (Lakefield Junction) submitted for filing a rate schedule under which Lakefield Junction will engage in wholesale electric power and energy transactions at market-based rates. Lakefield Junction also requested waiver of various Commission regulations. In particular, Lakefield Junction requested that the Commission grant blanket approval under 18 CFR part 34 of all future issuances of securities and assumptions of liability by Lakefield Junction.

On July 12, 2000, pursuant to delegated authority, the Director, Division of Corporate Applications, Office of Markets, Tariffs and Rates, granted requests for blanket approval under part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Lakefield Junction should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, Lakefield Junction is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Lakefield Junction's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is August 14, 2000.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, N.E., Washington, D.C. 20426. The Order may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 00–18472 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER00–3112–000]

Madison Gas and Electric Company; Notice of Filing

July 17, 2000.

Take notice that on July 10, 2000, Madison Gas and Electric Company (MGE) tendered for filing service agreements under MGE's Market-Based Power Sales Tariff with:

- GEN~SYS Energy
- Northern States Power Company

MGE requests the agreements be effective on the date they were filed with the FERC.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before July 31, 2000. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 00–18475 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER00–2887–000]

Newark Bay Cogeneration Partnership, L.P.; Notice of Issuance of Order

July 17, 2000.

Newark Bay Cogeneration Partnership, L.P. (Newark Bay) submitted for filing a rate schedule under which Newark Bay will engage in wholesale electric power and energy transactions at market-based rates. Newark Bay also requested waiver of various Commission regulations. In particular, Newark Bay requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Newark Bay.

On July 12, 2000, pursuant to delegated authority, the Director, Division of Corporation Applications, Office of Markets, Tariffs and Rates, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Newark Bay should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, Newark Bay is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Newark Bay's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is August 14, 2000.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, NE., Washington, DC 24026. The Order may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 00–18474 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER00–3119–000]

Niagara Mohawk Power Corporation; Notice of Filing

July 17, 2000.

Take notice that on July 7, 2000, NYSD Limited Partnership, Warrensburg Hydro Power Limited Partnership, Sissonville Limited Partnership and Adirondack Hydro Development Corporation (collectively, the Projects), tendered for filing on behalf of Niagara Mohawk Power Corporation (Niagara Mohawk), Interconnection Agreements between Niagara Mohawk and the Projects.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before July 28, 2000. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 00–18476 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER00–2676–000]

Panda Perkiomen Power, L.P.; Notice of Issuance of Order

July 17, 2000.

Panda Perkiomen Power, L.P. (Panda Perkiomen) submitted for filing a rate schedule under which Panda Perkiomen will engage in wholesale electric power and energy transactions at market-based rates. Panda Perkiomen also requested waiver of various Commission regulations. In particular, Panda Perkiomen requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Panda Perkiomen.

On July 12, 2000, pursuant to delegated authority, the Director, Division of Corporate Applications, Office of Markets, Tariffs and Rates, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Panda Perkiomen should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, Panda Perkiomen is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Panda Perkiomen's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is August 14, 2000.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, N.E., Washington, D.C. 20426. The Order may also be viewed on the Internet at *http://www.ferc.fed.us./online/rims.htm* (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 00–18470 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP91–229–030]

Panhandle Eastern Pipe Line Company; Notice of Refund Request

July 18, 2000.

Take notice that on July 13, 2000, Panhandle Eastern Pipe Line Company (Panhandle) tendered for filing its Refund Report pursuant to the Commission's letter order issued May 31, 2000.

Panhandle states that it refunded on June 16, 2000 to its customers their appropriate pro rata share of the amounts which Panhandle received from Trunkline Gas Company pursuant to Section 3 of Article VIII of Trunkline's Settlement in Docket No. RP87–15–033, *et al.*

Panhandle further states it is submitting herein Appendix A to the filing, which reflects the amounts refunded to each affected customer on June 16, 2000.

Panhandle states that a copy of this information is being sent to all parties to the Docket No. RP91–229–000 proceeding and respective State Regulatory Commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with section 385.211 of the Commission's rules and regulations. All such protests must be filed on or before July 25, 2000. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference

Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 00–18503 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EC00–108–000]

Public Service Company of Colorado; Notice of Filing

July 17, 2000.

Take notice that on July 12, 2000, Public Service Company of Colorado (PSCo) filed a supplement to its application under Section 203 of the Federal Power Act for authorization to dispose of transmission facilities. The specific facilities addressed in the application are two 4/115kV generation step-up transformers interconnecting the powerhouse of PSCo's Boulder Canyon Hydroelectric Project (Boulder Project) to PSCo's transmission system. In its application, PSCo states that it is transferring these facilities to the City of Boulder, Colorado, as part of its proposed sale of the Boulder Project to that City. The supplement provides a brief explanation as to why the transaction will not have an adverse effect on competition, rates, or regulation.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests must be filed on or before July 26, 2000. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call (202) 208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 00–18478 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP00–108–003]

Questar Pipeline Company; Notice of Tariff Filing

July 18, 2000.

Take notice that on July 13, 2000, Questar Pipeline Company tendered for filing to become part of its FERC Gas Tariff, the following tariff sheets, to be effective January 1, 2000:

First Revised Volume No. 1

Substitute Thirteenth Revised Sheet No. 5

Original Volume No. 3

Substitute Twenty-Fourth Revised Sheet No. 8

On May 22, 2000, Questar filed an uncontested Offer of Settlement to adjust its fuel gas reimbursement percentage (FGRP) in Docket No. RP00–108–000. On June 30, 2000, the Commission approved the uncontested Offer of Settlement, and directed Questar to file tariff sheets to decrease the FGRP from 2.4 percent to 2.1 percent, to be effective January 1, 2000.

Questar stated that a copy of this filing has been served upon all parties to the proceeding, its customers, the Public Service Commission of Utah and the Public Service Commission of Wyoming.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with section 385.211 of the Commission's rules and regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 00–18505 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory commission

[Docket No. RP96–129–012]

Trunkline Gas Company; Notice of Compliance Filing

July 18, 2000.

Take notice that on July 13, 2000, Trunkline Gas company (Trunkline) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the following tariff sheet to be effective August 12, 2000:

Fourth Revised Sheet No. 79

Trunkline states that the purpose of this filing is to comply with the Commission's Letter Order dated June 28, 2000 in Docket No. RP96–129–011, 91 FERC ¶ 61,300 (2000). This filing reflects Trunkline's proposal to liberalize the current directional limitations on its TABS–1 transfer service.

Trunkline states that copies of this filing are being served on all affected customers, applicable state regulatory agencies and parties to this proceeding.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with section 385.211 of the Commission's rules and regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 00–18504 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP00–307–001]

U–T Offshore System, L.L.C; Notice of Compliance Filing

July 18, 2000.

Take notice that on July 12, 2000, U–T Offshore System, L.L.C (UTOS), tendered for filing as part of its FERC Gas Tariff, Fourth Revised volume No. 1, Substitute First Revised Sheet No. 97, with an effective date of November 5, 1999.

UTOS states that it is filing this tariff sheet to comply with the Commission's June 27, 2000 Letter Order in the referenced proceeding.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with section 3385.211 of the Commission's rules and regulations. All such protests must be filed as provided in Section 154.210 of the Commission's regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 00–18507 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EG00–177–000, et al.]

Conectiv Mid-Merit, Inc., et al.; Electric Rate and Corporate Regulation Filings

July 13, 2000.

Take notice that the following filings have been made with the Commission:

1. Conectiv Mid-Merit, Inc.

[Docket No. EG00–177–000]

Take notice that on June 16, 2000, Conectiv Mid-Merit, Inc. (CMM) filed with the Federal Energy Regulatory Commission (Commission), an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

CMM is a subsidiary of Conectiv, which is a public utility holding company under the Public Utility Holding Company Act (PUHCA). Conectiv also owns Delmarva Power & Light Company (Delmarva) and Atlantic City Electric Company (ACE), each of which is operating public utilities under PUHCA and the Federal Power Act. Conectiv also owns Conectiv Energy Supply, Inc. (CESI), which is engaged in competitive wholesale and retail sales of electricity, among other activities.

CMM intends to own and operate eighteen (18) combustion turbine generation facilities each with a capacity of about 110 MV. The facilities do not currently exist but are to be constructed pursuant to a contract with a manufacturer. CMM represents that it will be exclusively in the business of owning and operating eligible facilities and selling electric energy at wholesale. CMM represents that no State Commission determinations are necessary with respect to these facilities to be constructed.

Comment date: August 3, 2000, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

2. Adirondack Hydro Development Corporation

[Docket No. EG00–221–000]

Take notice that on July 7, 2000, Adirondack Hydro Development Corporation (Adirondack) filed with the Federal Energy Regulatory Commission an application or determination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

Adirondack owns and operates a 0.525 MV hydroelectric facility located on the Otter Creek in the Town of Greig, in Lewis County, New York. Adirondak's business offices are located at 39 Hudson Falls Road in South Glens Falls, New York.

Comment date: August 3, 2000, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

3. Sissonville Limited Partnership

[Docket No. EG00–222–000]

Take notice that on July 7, 2000, Sissonville Limited Partnership (Sissonville) filed with the Federal Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

Sissonville is a limited partnership formed under the laws of the State of New York for the purpose of owning and operating a 2.3 MV hydroelectric facility located on the Raquette River in the Town of Potsdam, St. Lawrence County, New York. Sissonville's business offices are located at 39 Hudson Falls Road, in South Glens Falls, New York.

Comment date: August 3, 2000, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

4. NYSD Limited Partnership

[Docket No. EG00–223–000]

Take notice that on July 7, 2000, New York State Dam Limited Partnership (NYSD) filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

NYSD is a limited partnership formed under the laws of the State of New York for the purpose of owning and operating a 10.83 MW hydroelectric facility located on the Mohawk River near the Town of Waterford and City of Cohoes in Saratoga and Albany Counties. NYSD has an easement from the State of New York for purposes of construction and operation of the Facility. NYSD's business offices are located at 39 Hudson Falls Road, in South Glens Falls, New York.

Comment date: August 3, 2000, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

5. Warrensburg Hydro Power Limited Partnership

[Docket No. EG00–224–000]

Take notice that on July 7, 2000, Warrensburg Hydro Power Limited Partnership (Warrensburg) filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

Warrensburg is a limited partnership formed under the laws of the State of New York for the purpose of owning and operating a 2.835 MW hydroelectric facility located on the Schroon River in the Town of Warrensburg, in Warren County, New York. Warrensburg has a 40-year easement from the State of New York for purposes of the construction

and operation of the Facility. Warrensburg's business offices are located at 39 Hudson Falls Road in South Glens Falls, New York.

Comment date: August 3, 2000, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

6. Newington Energy, L.L.C.

[Docket No. EG00–225–000]

Take notice that on July 10, 2000, Newington Energy, L.L.C. (NEL), a Delaware limited liability company with its principal place of business at 111 Broadway, New York, NY 10006, filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

NEL proposes to own and operate a nominally rated approximately 525 MW natural gas-fired, combined cycle power plant in the town of Newington, New Hampshire. The proposed power plant is expected to commence commercial operation in May, 2002. All capacity and energy from the plant will be sold exclusively at wholesale.

Comment date: August 3, 2000, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

7. New Century Services, Inc.

[Docket No. ER00–3095–000]

Take notice that on July 11, 2000, New Century Services, Inc., on behalf of Public Service Company of Colorado (PSCo) tendered for filing revisions to Exhibits B to its Interconnection and Transmission Service Agreement with Tri-State Generation and Transmission Association Inc. as contained in Public Service's Rate Schedule FERC No.24.

PSCo requests an effective date of June 16, 2000 for this filing.

Copies of the filing were served upon Tri-State, Colorado Public Utilities Commission, and the Colorado Office of Consumer Counsel.

Comment date: August 1, 2000, in accordance with Standard Paragraph E at the end of this notice.

8. Baconton Power LLC

[Docket No. ER00–3096–000]

Take notice that on July 10, 2000, Baconton Power LLC (Baconton) tendered for filing a long-term service agreement with Coral Power L.L.C. pursuant to Baconton Power LLC's market-based tariff, FERC Electric Tariff, Original Vol. No. 1.

Baconton is requesting an effective date of June 13, 2000 for the Tolling Agreement.

Comment date: July 31, 2000, in accordance with Paragraph E at the end of this notice.

9. Virginia Electric and Power Company

[Docket No. ER00–3097–000]

Take notice that on July 10, 2000, Virginia Electric and Power Company (Virginia Power) tendered for filing Assignment and Assumption Agreements entered into by and among PPL Electric Utilities Corporation (Assignor), and PPL EnergyPlus, LLC (Assignee) dated April 17, 2000. Under these assignments, the Assignor assigns to the Assignee and the Assignee assumes all of the Assignor's rights and obligations pertaining to the following Service Agreements with Virginia Power:

Service Agreement for Short-Term Market Based Rate Power Sales dated May 15, 1995 and accepted by Letter Order dated July 19, 1995 in Docket No. ER95–1214–000;

Service Agreement for Non-Firm Point-to-Point Transmission Service Power Sales dated April 17, 1997 and accepted by Letter Order dated June 30, 1997 in Docket No. ER97–3058–000;

Service Agreement for Firm Point-to-Point Transmission Service dated October 7, 1997 and accepted by Letter Order January 2, 1998 in Docket No. ER98–671–000;

The Company requests an effective date of the assignments of July 1, 2000.

Copies of this filing were served upon PPL Energy/Plus, LLC the Virginia State Corporation Commission and the North Carolina Utilities Commission.

Comment date: July 31, 2000, in accordance with Standard Paragraph E at the end of this notice.

10. PJM Interconnection, L.L.C.

[Docket No. ER00–3098–000]

Take notice that on July 10, 2000, PJM Interconnection, L.L.C. (PJM), tendered for filing an executed service agreement for firm point-to-point transmission service, an executed service agreement for non-firm point-to-point transmission service, and an executed service agreement for network integration transmission service under the PJM Open Access Transmission Tariff with Energy East Solutions, Inc. (Energy East).

Copies of this filing were served upon Energy East and the state commissions with the PJM control area.

Comment date: July 31, 2000, in accordance with Standard Paragraph E at the end of this notice.

11. PECO Energy Company

[Docket No. ER00–3099–000]

Take notice that on July 10, 2000, PECO Energy Company (PECO) filed under Section 205 of the Federal Power Act, 16 U.S.C. 792 et seq., an Agreement dated July 7, 2000 with Oglethorpe Power Corporation (OPC) under PECO's FERC Electric Tariff Original Volume No. 1 (Tariff).

PECO requests an effective date of July 7, 2000, for the Agreement.

PECO states that copies of this filing have been supplied to Oglethrope Power Corporation and to the Pennsylvania Public Utility Commission.

Comment date: July 31, 2000, in accordance with Standard Paragraph E at the end of this notice.

12. Hardee Power Partners Limited

[Docket No. ER00–3100–000]

Take notice that on July 10, 2000, Hardee Power Partners Limited (HPP) tendered for filing a service agreement with the City of Tallahassee, Florida (Tallahassee) under HPP's market-based sales tariff. HPP requests that the service agreement be made effective on June 11, 2000.

Copies of the filing have been served on Tallahassee and the Florida Public Service Commission.

Comment date: July 31, 2000, in accordance with Standard Paragraph E at the end of this notice.

13. The Empire District Electric Company

[Docket No. ER00–3101–000]

Take notice that on July 7, 2000, The Empire District Electric Company (Empire) tendered for filing a notice that it was adopting the Transmission Loading Relief procedures accepted by the Federal Energy Regulatory Commission in *North American Electric Reliability Council,* 91 FERC ¶ 61,122 (2000), and that its open access transmission tariff (OATT) should be considered so modified.

Copies of this filing have been served on all affected state commissions and on all customers taking service under Empire's OATT.

Comment date: July 28, 2000, in accordance with Standard Paragraph E at the end of this notice.

14. The New Power Company

[Docket No. ER00–3102–000]

Take notice that on July 10, 2000, The New Power Company submitted a Notice of Succession pursuant to 18 CFR 35.16 and 131.51 of the Commission's regulations. The New Power Company is succeeding to the Rate Schedule FERC No. 1, Market-

Based Rate Schedule, and Supplement No. 1 to Rate Schedule FERC No. 1, Code of Conduct filed in Docket No. ER00–2535–000, effective June 22, 2000.

Comment date: July 31, 2000, in accordance with Standard Paragraph E at the end of this notice.

15. Horsehead Industries, Inc.

[Docket No. ER00–3103–000]

Take notice that on July 10, 2000, Horsehead Industries, Inc. (Horsehead) tendered for filing a Form of Service Agreement to its FERC Electric Tariff, Original Volume No. 1, and an unexecuted Service Agreement for service to NewEnergy, Inc. (NewEnergy) thereunder.

A copy of the filing was served upon NewEnergy.

Comment date: July 31, 2000, in accordance with Standard Paragraph E at the end of this notice.

16. Arizona Public Service Company

[Docket No. ER00–3104–000]

Take notice that on July 10, 2000, Arizona Public Service Company (APS) filed with the Federal Energy Regulatory Commission (Commission) a Notice of Cancellation of Service Schedule D in the Agreement between APS and Citizens Utilities Company (Citizens) in accordance with the Commission's Rules under 18 CFR 35.15.

A copy of this filing was served on the Arizona Corporation Commission.

Comment date: July 31, 2000, in accordance with Standard Paragraph E at the end of this notice.

17. NYSD Limited Partnership; Warrensburg Hydro Power Limited Partnership; Sissonville Limited Partnership; Adirondack Hydro Development Corporation

[Docket No. ER00–3109–000]

Take notice that on July 7, 2000, NYSD Limited Partnership, Warrensburg Hydro Power Limited Partnership, Sissonville Limited Partnership, and Adirondack Hydro Development Corporation (collectively, the Applicants) filed an application for acceptance of their long-term power purchase agreements with Niagara Mohawk Power Company (NIMO) to make wholesale sales of electric power at market-based rates, waiver of certain of the Commission's regulations and blanket approval to engage in certain transactions.

The Applicants state that copies of this filing are being mailed to NIMO and to the New York Public Service Commission.

Comment date: July 28, 2000, in accordance with Standard Paragraph E at the end of this notice.

18. Alliant Energy Corporate Services, Inc.

[Docket No. ER00–3111–000]

Take notice that on July 10, 2000, Alliant Energy Corporate Services, Inc. tendered for filing executed Service Agreements for short-term firm point-to-point transmission service and non-firm point-to-point transmission service, establishing the City of Ames as a point-to-point Transmission Customer under the terms of the Alliant Energy Corporate Services, Inc. transmission tariff.

Alliant Energy Corporate Services, Inc. requests an effective date of June 26, 2000, and accordingly, seeks waiver of the Commission's notice requirements.

A copy of this filing has been served upon the Illinois Commerce Commission, the Minnesota Public Utilities Commission, the Iowa Department of Commerce, and the Public Service Commission of Wisconsin.

Comment date: July 31, 2000, in accordance with Standard Paragraph E at the end of this notice.

19. ISO New England Inc.

[Docket No. OA97–237–011]

Take notice that on June 20, 2000, ISO New England Inc. filed its ''Quarterly Report for Regulators,'' as required by New England Power Pool Market Rules and Procedures 17, for the first two quarters. A privileged version, and a redacted public version were filed, together with a request for privileged treatment under 18 CFR 388.112.

Comment date: July 27, 2000, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of these filings are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 00–18468 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EC00–112–000, et al.]

Entergy Gulf States, Inc., et al.; Electric Rate and Corporate Regulation Filings

July 17, 2000.

Take notice that the following filings have been made with the Commission:

1. Entergy Gulf States, Inc.

[Docket No. EC00–112–000]

Take notice that on July 6, 2000, Entergy Gulf States, Inc. tendered for filing five copies and an original of an Application for Transfer of Jurisdictional Assets Under Section 203 of the Federal Power Act, requesting that the Commission approve the sale of Bunch Gully Substation to Chevron Chemical Company LLC.

Comment date: August 7, 2000, in accordance with Standard Paragraph E at the end of this notice.

2. Southern Indiana Gas & Electric Company; Vectren Utility Holdings, Inc.; Vectren Corporation

[Docket No. EC00–113–000]

Take notice that on July 10, 2000, Southern Indiana Gas & Electric Company (SIGECO), Vectren Corporation (Vectren) and Vectren Utility Holdings, Inc. (VUHI), filed with the Federal Energy Regulatory Commission an application for approval of corporate reorganization under Section 203 of the Federal Power Act. The proposed Reorganization involves a change in the ownership structure of SIGECO, that will be accomplished by Vectren contributing the stock of SIGECO to its newly formed, wholly-owned subsidiary, VUHI.

Comment date: August 9, 2000, in accordance with Standard Paragraph E at the end of this notice.

3. Calpine Power Services Company; Calpine Energy Services, L.P.

[Docket No. EC00–114–000]

Take notice that on July 11, 2000, Calpine Power Services Company (CPSC) and Calpine Energy Services, L.P. (CES) tendered for filing an application under Section 203 of the Federal Power Act for approval of an

intra-corporate reorganization under which CPSC will transfer its market-based rate tariff and associated jurisdictional facilities to its affiliate, CES.

Comment date: August 11, 2000, in accordance with Standard Paragraph E at the end of this notice.

4. Ameren Energy Marketing Company and Central Illinois Public Service Company

[Docket No. ER00–3025–000]

Take notice that on July 12, 2000, Ameren Energy Marketing Company (AEM) and Central Illinois Public Service Company d/b/a AmerenCIPS (AmerenCIPS), tendered for filing an executed Voluntary Curtailment Agreement in the above referenced docket.

Comment date: August 2, 2000, in accordance with Standard Paragraph E at the end of this notice.

5. Wisvest-Connecticut, LLC

[Docket No. ER00–3107–000]

Take notice that on July 11, 2000, Wisvest-Connecticut, LLC (Wisvest-Connecticut), tendered for filing with the Commission an umbrella agreement for short-term service with Sempra Energy Trading Corp., pursuant to the Commission's order dated February 10, 1999. Wisvest-Connecticut, LLC., 86 FERC ¶ 61,133 (1999).

Comment date: August 1, 2000, in accordance with Standard Paragraph E at the end of this notice.

6. Southern California Edison Company

[Docket No. ER00–3108–000]

Take notice that on July 11, 2000, Southern California Edison Company (SCE), tendered for filing a Service Agreement for Wholesale Distribution Service and an Interconnection Facilities Agreement (Agreements) between Riverside County Waste Management Department and SCE.

These Agreements specify the terms and conditions pursuant to which SCE will interconnect RCWMD's generating facility to its electrical system and provide Distribution Service for up to 2.5 MW of power produced by RCWMD's Badlands Landfill generating facility.

Comment date: August 1, 2000, in accordance with Standard Paragraph E at the end of this notice.

7. Arizona Public Service Company

[Docket No. ER00–3110–000]

Take notice that on July 12, 2000, Arizona Public Service Company (APS), tendered for filing Service Agreements to provide Long-Term Firm Point-to-Point Transmission Service to Salt River Project Agricultural and Power Improvement District under APS' Open Access Transmission Tariff.

A copy of this filing has been served Salt River Project Agricultural and Power Improvement District, and the Arizona Corporation Commission.

Comment date: August 2, 2000, in accordance with Standard Paragraph E at the end of this notice.

8. Louisville Gas and Electric Company/Kentucky Utilities Company

[Docket No. ER00–3113–000]

Take notice that on July 11, 2000, Louisville Gas and Electric Company (LG&E)/Kentucky Utilities Company (KU) (hereinafter Companies), tendered for filing an unexecuted bilateral Service Sales Agreement between the Companies and Amerada Hess Corporation under the Companies Rate Schedule MBSS.

Comment date: August 1, 2000, in accordance with Standard Paragraph E at the end of this notice.

9. Louisville Gas and Electric Company/Kentucky Utilities Company

[Docket No. ER00–3114–000]

Take notice that on July 11, 2000, Louisville Gas and Electric Company (LG&E)/Kentucky Utilities (KU) (hereinafter Companies), tendered for filing an executed Netting Agreement between the Companies and Allegheny Energy Supply Company, LLC.

Comment date: August 1, 2000, in accordance with Standard Paragraph E at the end of this notice.

10. Louisville Gas and Electric Company/Kentucky Utilities Company

[Docket No. ER00–3115–000]

Take notice that on July 11, 2000, Louisville Gas and Electric Company (LG&E)/Kentucky Utilities (KU) (hereinafter Companies), tendered for filing an executed unilateral Service Sales Agreement between Companies and Allegheny Energy Supply Company, LLC under the Companies' Rate Schedule MBSS.

Comment date: August 1, 2000, in accordance with Standard Paragraph E at the end of this notice.

11. Illinois Power Company

[Docket No. ER00–3116–000]

Take notice that on July 11, 2000, Illinois Power Company (Illinois Power), 500 South 27th Street, Decatur, Illinois 62526, tendered for filing firm and non-firm transmission agreements under which Cargill-Alliant, LLC will take transmission service pursuant to its open access transmission tariff. The agreements are based on the Form of Service Agreement in Illinois Power's tariff.

Illinois Power has requested an effective date of June 15, 2000.

Comment date: August 1, 2000, in accordance with Standard Paragraph E at the end of this notice.

12. Illinois Power Company

[Docket No. ER00–3117–000]

Take notice that on July 11, 2000, Illinois Power Company (Illinois Power), 500 South 27th Street, Decatur, Illinois 62526, tendered for filing non-firm transmission agreements under which Unicom Energy, Inc., will take transmission service pursuant to its open access transmission tariff. The agreements are based on the Form of Service Agreement in Illinois Power's tariff.

Illinois Power has requested an effective date of July 1, 2000.

Comment date: August 1, 2000, in accordance with Standard Paragraph E at the end of this notice.

13. PacifiCorp

[Docket No. ER00–3118–000]

Take notice that on July 11, 2000, PacifiCorp, tendered for filing in accordance with 18 CFR 35 of the Commission's Rules and Regulations, a fully executed Unit Contingent Power Sale Agreement (Agreement) between Flathead Electric Cooperative, Inc. (Flathead) and PacifiCorp.

Copies of this filing were supplied to the Washington Utilities and Transportation Commission and the Public Utility Commission of Oregon.

Comment date: August 1, 2000, in accordance with Standard Paragraph E at the end of this notice.

14. Citizens Power Sales LLC, et al.

[Docket No. ER00–3120–000]

Take notice that on July 12, 2000, Citizens Power Sales LLC, Hartford Power Sales, L.L.C., CL Power Sales One, L.L.C., CL Power Sales Two, L.L.C., CL Power Sales Five, L.L.C., CL Power Sales Six, L.L.C., CL Power Sales Seven, L.L.C., CL Power Sales Eight, L.L.C., CL Power Sales Nine, L.L.C., CL Power Sales Ten, L.L.C., CP Power Sales Twelve, L.L.C., CP Power Sales Thirteen, L.L.C., CP Power Sales Fourteen, L.L.C., CP Power Sales Fifteen, L.L.C., CP Power Sales Seventeen, L.L.C., CP Power Sales Eighteen, L.L.C., CP Power Sales Nineteen, L.L.C., and CP Power Sales Power Sales Twenty, L.L.C., tendered for filing an amendments to their Rate Schedule FERC No. 1 to prohibit sales to and purchases from an affiliate with

a franchised electric service territory, include a related code of conduct, reflect a name change, and incorporate the requirements of Order No. 614, 90 FERC ¶ 61,352 (2000).

Comment date: August 2, 2000, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC. 20426, in accordance with rules 211 and 214 of the Commission's rules of practice and procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of these filings are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 00–18501 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Motions To Intervene, Protests, and Comments

July 18, 2000.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 11841–000.

c. *Date filed:* May 8, 2000.

d. *Applicant:* Ketchikan Public Utilities.

e. *Name of Project:* Whitman Lake Project.

f. *Location:* On Whitman Lake and Whitman Creek, in Ketchikan Gateway Borough, Alaska, partially within the Tongass National Forest.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Karl R. Amylon, Ketchikan Public Utilities, 2930 Tongass Avenue, Ketchikan, Alaska 99901, 907–225–3111.

i. *FERC Contact:* Robert Bell, 202–219–2806.

j. *Deadline for filing motions to intervene, protests and comments:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, D.C. 20426.

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Project:* The proposed project would consist of: (1) The existing 45-foot-high and 220-foot-long concrete arch Whitman Lake Dam ½-mile upstream from the entrance of Whitman Creek into Herring Bay; (2) Whitman Lake with a surface area of 148 acres, a proposed usable storage capacity of 6,500 acre-feet, and normal maximum water surface elevation of 380 feet above mean sea level; (3) an intake structure; (4) a 2,200-foot-long, 3-foot-diameter steel and steel-lined tunnel penstock; (6) a powerhouse containing two generating units having a total installed capacity of 4,600 kW; (7) a 34.5-kV, 1,500-foot-long transmission line; and other appurtenant facilities.

The project would have an annual generation of 19.6 GWh that would be sold to the applicant's customers.

l. A copy of the application is available for inspection and reproduction at the Commission's Pubic Reference Room, located at 888 First Street, NE, Room 2A, Washington, D.C. 20426, or by calling (202) 208–1371. The application may be viewed on http://www.ferc.fed.us/online/rims.htm (call (202) 208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item h above.

Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

Notice of intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant,and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title

''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

David P. Boergers,

Secretary.

[FR Doc. 00–18502 Filed 7–20–00; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6609–4]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared pursuant to the Environmental Review Process (ERP), under Section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of FEDERAL ACTIVITIES AT (202) 564–7167.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 14, 2000 (65 FR 20157).

Draft EISs

ERP No. D–AFS–A65168–00 Rating EC2, Forest Service Roadless Area Conservation, Implementation, Proposal to Protect Roadless Areas.

Summary: EPA expressed environmental concerns with the proposed alternative, citing potential adverse impacts to water quality and aquatic habitat. EPA also commented that the draft EIS does not adequately justify excluding the Tongass National Forest from the proposed rulemaking.

ERP No. D–AFS–J61103–MT Rating EC2, Discovery Ski Area Expansion, Implementation, Special-Use-Permit and COE Section 404 Permit, Beaverhead-Deerlodge National Forest, Pintler Ranger District, Rumsey Mountain, Granite County, MT.

Summary: EPA expressed environmental concerns regarding the lack of information to support expansion of the ski area; inadequate analysis and disclosure of indirect effects of induced development; and effects of additional snowmaking and increased wastewater pollutant loadings to area ground water. EPA requested additional information in the final document to assess and mitigate potential environmental impacts of the management actions.

ERP No. D–AFS–K65227–CA Rating EC2, 64-Acre Tract Intermodal Transit Center, Construction and Operation, Lake Tahoe Basin Management Unit, Tahoe City, Placer County, CA.

Summary: EPA expressed environmental concerns regarding water quality impacts and cumulative impacts associated with the proposal. EPA also had concerns because there is no provision for solid waste recycling nor integration of pollution prevention mechanisms in the project.

ERP No. D–NPS–K61149–CA Rating EC2, Yosemite Valley Plan, A Comprehensive Look of at Four Areas of Concern: Resource Preservation and Restoration, Visitor Enjoyment, Transportation, and Employee Housing, from Happy Isles to El Portal Road/Big Oak Flat Road, Merced River, several counties, CA.

Summary: EPA expressed concerns regarding the vehicle emission impacts from the proposed shuttle bus systems. EPA requested more information on the standards and criteria that will be used to select the fuel(s) technology used in the shuttle bus fleets.

ERP No. D–USN–K39059–HI Rating EC2, North Pacific Acoustic Laboratory Project, Reuse of Low Frequency Sound Source and Cable for Use in Acoustic Thermometry of Ocean Climate (ATOC) Research, Kauai, HI.

Summary: EPA expressed environmental concerns regarding potential direct, indirect and cumulative impacts to marine fish specie, turtles, seabirds and marine mammals. EPA recommended an implementing program lasting 24 to 36 months rather than the proposed 60 months, because of uncertainties regarding potential impacts to marine species. EPA also recommended Federal agency coordination to determine if marine mammal monitoring should be expanded to monitor populations of turtles and marine fish.

ERP No. DS–AFS–L65289–00 Rating EC2, Interior Columbia Basin Ecosystem Management Projects, Updated and New Information on three Management Alternatives, Implementation, WA, OR, ID and MT.

Summary: EPA continues to have concern that there is no discussion on how the FS and BLM will address competing objectives and the implications of implementing the preferred alternative with insufficient funding. In addition, there is no oversight process to ensure proper implementation and monitoring of the project. EPA requested that a multi-agency oversight organization be chartered.

Final EISs

ERP No. F–AFS–L65275–00 Targhee National Forest Plan Oil and Gas Leasing Analysis, Implementation, Bonneville, Butte, Clark, Fremont and Madison Counties, ID and Teton County, WY.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. F–BLM–J02038–WY Pinedale Anticline Oil and Gas Exploration and Development Natural Gas Wells Project, Implementation, Sublette County, WY.

Summary: ERP No. F–BLM–K67049–CA Soledad Canyon Sand and Gravel Mining Project, Proposal to Mine, Produce and Sell, ''Split Estate'' Private Owned and Federally Owned Lands, Transit Mixed Concrete, Los Angeles County, CA.

Summary: EPA concurred with BLM's conformity determination and is satisfied that air quality standards will be protected. EPA expressed continuing concerns that a jurisdictional analysis has not yet been conducted for waters of the U.S., and potential impacts and appropriate mitigation measures remain uncertain.

ERP No. F–IBR–K64018–CA Lower Mokelumne River Restoration Program, Implementation, Resource Management Plan, San Joaquin County, CA.

Summary: EPA has no objection to the action as proposed since EPA's comments on the Draft were adequately addressed. EPA did recommend that the Record of Decision clearly state the

specific actions to be taken in response to comments.

ERP No. F–NPS–K65325–CA Merced Wild and Scenic River Comprehensive Management Plan, Implementation, Yosemite National Park and the EL Portal Administrative Site, Tuolumne, Merced, Mono, Mariposa and Madera Counties, CA.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. FS–NOA–A91065–00 Atlantic Tunas, Swordfish and Sharks, Highly Migratory Species Fishery Management Plan.

Summary: EPA concurs with the proposed time/area closures to reduce longline bycatch but recommends resolving the potential adverse effects on protected turtles prior to any issuance of the ROD and Final Rule. Further research under the auspices of NOAA/NMFS should be pursued regarding the effectiveness of the considered longline gear modifications such as use of circle hooks.

Dated: July 18, 2000.

Joseph C. Montgomery,

Director, NEPA Compliance Division,, Office of Federal Activities.

[FR Doc. 00–18551 Filed 7–20–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6609–3]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information, (202) 564–7167 or www.epa.gov/oeca/ofa

Weekly receipt of Environmental Impact Statements

Filed July 10, 2000 Through July 14, 2000

Pursuant to 40 CFR 1506.9.

- EIS No. 000243, Draft EIS, FHW, CO, South I–25 and US 85 Corridors Improvements, CO–470 to Castle Rock, Funding, Douglas County, CO, Due: September 05, 2000, Contact: Scott Sands P.E. (303) 969–6730.
- EIS No. 000244, Draft EIS, AFS, CA, Airport Forest Health Project, Forest Health Improvements through Reduction of Fuel Loads and Fire Hazards and Wildlife Habitat Improvements Implementation, Pacific Ranger District, El Dorado National Forest, El Dorado and Placer Counties, CA, Due: September 05, 2000, Contact: Krista Deal (530) 644–2349.
- EIS No. 000245, Draft EIS, FRA, FL, GA, MD, PA, CA, LA, NV, Programmatic—Maglev Deployment Program, Development and Construction of an Operating Public Transportation System using Magnetic Levitation, Grants Issuance, CA, FL, GA, LA, MD, NV and PA, Due: September 05, 2000, Contact: David Valenstein (202) 493–6383.
- EIS No. 000246, Draft EIS, AFS, OR, Anthony Lakes Mountain Resort Master Development Plan, Upgrading and Additional Development, Approval, Baker Ranger District, Wallowa-Whitman National Forest, Grant, Union and Baker Counties, OR, Due: September 05, 2000, Contact: Charles L. Ernst (541) 523–1901.
- EIS No. 000247, Final EIS, AFS, UT, Monroe Mountain Ecosystem Restoration Project, Implementation, Fishlake National Forest, Richfield Ranger District, Sevier and Piute Counties, UT, Due: August 21, 2000, Contact: Don Okerlund (435) 896–9233.
- EIS No. 000248, Final EIS, FAA, TX, George Bush Intercontinental Airport Houston, Construction and Operation, Runway 8L–26R and Associated Near Term Master Plan Projects, Funding and Airport Layout Plan Approval, City of Houston, Harris County, TX, Due: August 21, 2000, Contact: Ben R. Guttery (817) 222–5614.
- EIS No. 000249, Final EIS, SFW, WA, Simpson Washington Timberlands Forest Management and Timber Harvesting Project, Proposed Issuing of a Multiple Species Incidental Take Permit, Mason, Thurston and Gray Harbor Counties, WA, Due: August 21, 2000, Contact: Craig Hansen (360) 753–9440.
- EIS No. 000250, Final Supplement, IBR, NM, CO, Animas-La Plata Project (APL Project), Municipal and Industrial Water Supply, Reservoir Construction in Ridges Basin, Implementation and Water Acquisition, Additional Information concerning Project Alternatives Developed in 1996 through 1997, CO and NM, Due: August 21, 2000, Contact: Lilas Lindell (801) 524–3689.
- EIS No. 000251, Final EIS, IBR, CA, Programmatic—Calfed Bay-Delta Program, Long-Term Comprehensive Plan to Restore Ecosystem Health and Improve Water Management, Implementation, San Francisco Bay—Sacramento/San Joaquin River Bay-Delta, CA, Due: August 21, 2000, Contact: Rodney Johnson (916) 653–7286.
- EIS No. 000252, Final EIS, FHW, MI, I–96 East Howell Interchange Project, Transportation Improvements, Funding, Major Investment Study, Cities of Howell and Brighton, Livington County, MI, Due: August 21, 2000, Contact: James Kirschensteine (517) 377–1880-Ext 41).

Dated: July 18, 2000.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 00–18552 Filed 7–20–00; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[PF–953; FRL–6593–5]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–953, must be received on or before August 21, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–953 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9354; e-mail address: waller.mary@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under ''FOR FURTHER INFORMATION CONTACT.''

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number PF–953. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–953 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: *''opp-docket@epa.gov*,'' or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–953. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under ''FOR FURTHER INFORMATION CONTACT.''

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 10, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition

was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Novartis Crop Protection, Inc.

PP 9F5044

EPA has received a pesticide petition PP 9F5044 from Novartis Crop Protection, Inc., 410 Swing Road, Greensboro, NC 27419 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of mefenoxam or CGA329351, (R)-2-(2,6-dimethylphenyl)-methoxyacetylamino-propionic acid methyl ester in or on the raw agricultural commodity rape seed (canola) at 0.05 parts per million (ppm). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. Novartis believes the studies supporting this mefenoxam petition well characterize metabolism in plants and animals. The metabolism profile supports the use of an analytical enforcement method that accounts for combined residues of mefenoxam and its metabolites which contain the 2,6-dimethylaniline (DMA) moiety.

2. *Analytical method*. Novartis has submitted a practical analytical method involving extraction, filtration, acid reflux, steam distillation, and solid phase cleanup with analysis by confirmatory gas chromatography using nitrogen/phosphorous (N/P) detection. A total residue method is used for determination of the combined residues of mefenoxam and its metabolites which contain the 2,6-dimethylaniline DMA moiety. The limit of quantitation (LOQ) for the method is 0.05 ppm.

3. *Magnitude of residues*—i. *Crops*. This petition is supported by six field residue trials that were analyzed in concordance with the OPPTS guidelines based on expected reduced residues and environmental benefits of seed applications. The six trials accounting for approximately 84% of commercial U.S. canola production (agricultural statistics, 1991), were conducted in Georgia (2%), Minnesota (16%), North Dakota (53%), South Dakota (2%), Idaho (6%), and Washington (5%). No residues <0.05 ppm of mefenoxam were detected as 2,6–DMA in canola seed at either the 1x or 3x treatment rate.

ii. *Animals*. As there were no detectable residues found with a 1x or 3x treatment regime, there is no expected impact on the dietary intake of livestock in association with this petition. Existing tolerances in 40 CFR part 180 are adequate to support the approval of this requested tolerance in the opinion of Novartis Crop Protection.

B. Toxicological Profile

1. *Acute toxicity*. The toxicological endpoints for mefenoxam are discussed in B.4. of the **Federal Register** notice of July 25, 1997, (62 FR 40084) (FRL–5726–4). The acute toxicity profile can be summarized as follows:

Rat acute oral study with a LD_{50} value of 490 milligrams/kilograms (mg/kg). Rat acute dermal study with a LD_{50} >2,000 mg/kg. Rat inhalation study with a LC_{50} >2.29 milligram/liter (mg/L) air. Primary eye irritation study in rabbit showing mefenoxam as severely irritating. Primary dermal irritation study in rabbit showing mefenoxam as slightly irritating. Skin sensitization studies in guinea pigs (Maximization and Buehler Test) showing mefenoxam is not a sensitizer.

2. *Genotoxicty*. The toxicological endpoints for mefenoxam are discussed in Unit B.4. of the **Federal Register** notice of July 25, 1997 (62 FR 40084). The genotoxicity profile can be summarized as follows:

In vitro gene mutation test: Ames test-negative. *In vitro* chromosomal aberration test: Chinese hamster ovary (CHO)-negative. *In vitro* gene mutation tests: Ames tests (3 independent studies)-negative; gene mutation in mouse lymphoma cells-negative; reverse mutation in *Saccharomyces cerevisiae*-negative. *In vitro* chromosomal aberration tests: Chinese hamster bone marrow cytogenetic test-negative. DNA repair study in rat hepatocytes-negative.

3. *Reproductive and developmental toxicity*. The toxicological endpoints for mefenoxam are discussed in B.4. of the **Federal Register** notice of July 25, 1997 (62 FR 40084). The reproductive and developmental toxicity profile can be summarized as follows:

Teratology study in rats with a maternal no observed adverse effect level (NOAEL) of 10 mg/kg based on reduced body weight (bwt) gain. The fetuses remained entirely unaffected at the highest dose tested (HDT), 250 mg/kg. Teratology study in rabbits with a maternal NOAEL of 150 mg/kg based on bwt loss. The developmental NOAEL was greater than or equal to the HDT, 300 mg/kg. Three–generation reproduction study in rats with a NOAEL of 1,250 ppm, which was the HDT. The treatment had no effect on reproduction or fertility. Dominant lethal study in mouse-negative.

4. *Subchronic toxicity*. The toxicological endpoints for mefenoxam are discussed in Unit IV.B. of the **Federal Register** notice of July 25, 1997 (62 FR 40084). The subchronic toxicity profile can be summarized as follows:

A 28–day cumulative toxicity study in rats with a NOAEL of 50 mg/kg based on liver changes. A 90–day subchronic dietary toxicity study in rats with a NOAEL of 250 ppm based on liver changes. A 90–day subchronic dietary toxicity study in dogs with a NOAEL of 250 ppm based on changes in blood biochemistry and hematology indicative of functional liver changes. A 21–day dermal toxicity study in rats with a NOAEL equal to or higher than the limit dose of 1,000 mg/kg. No local or systemic signs of toxicity were found. A 6–month dietary toxicity study in dogs with a NOAEL of 250 ppm based on changes in blood biochemistry indicative of hepatocellular damage.

5. *Chronic toxicity* The toxicological endpoints for mefenoxam are discussed in B.4. of the **Federal Register** notice of July 25, 1997 (62 FR 40084). The chronic toxicity profile can be summarized as follows:

A 24–month combined chronic toxicity/carcinogenicity study conducted in rats with a NOAEL of 250 ppm based on liver changes. No evidence of oncogenicity was seen. A 24–month oncogenicity study conducted in mice with a NOAEL of 250 ppm based on liver changes. No evidence of oncogenicity was seen.

6. *Animal metabolism*. The rat and goat rapidly metabolize and excrete via the same metabolic pathways as plants. Urinary metabolites are polar, primarily gucuronide and other conjugates. The parent compound is not retained in animal tissues nor secreted in milk.

7. *Metabolite toxicology*. Metabolites are considered to be of equal or less toxicity than the parent material.

8. *Endocrine disruption*. Mefenoxam does not belong to a class of chemicals known or suspected of having adverse effects on the endocrine system. Furthermore, supporting developmental toxicity studies in rats and rabbits, and a reproduction study in rats gave no indication of any effects on endocrine function related to development and reproduction. Subchronic and chronic

treatment did not induce any morphological changes in endocrine organs and tissues.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. For the purposes of assessing the potential dietary exposure under the proposed tolerance, Novartis Crop Protection has estimated aggregate exposure from all crops for which tolerances are established or proposed (i.e., rape seed).

a. *Chronic exposure*. Under the conservative exposure assumption of residue levels being at tolerance level, less than 15% of the reference dose (RfD) will be utilized by the U.S. general population. EPA generally has no concern for exposures below 100% of the RfD. Therefore, based on the completeness and reliability of the toxicity data supporting this petition, Novartis Crop Protection believes that there is a reasonable certainty that no harm will result from aggregate exposure to residues arising from this requested use, including anticipated dietary exposure and all other types of non-occupational exposures. From toxicity studies supporting the registration of mefenoxam, the active ingredient is classified as a Group ''E'' compound (evidence of noncarcinogenicty for humans). There was no evidence of carcinogenicity in a 24–month feeding trial in mice nor in a 24–month feeding study in rats at the dosage levels tested. The doses tested were adequate for identifying a cancer risk.

b. *Acute exposure*. The risk from acute dietary exposure to mefenoxam is considered to be very low. The NOAEL in a 28–day study was 50 mg/kg, which is 6–fold higher than the chronic NOAEL. Since chronic exposure assessment did not result in any unacceptable exposure for even the most impacted population subgroup, it is anticipated that also the acute exposure will be in an acceptable range. Calculations show that with the most exposed group (non-nursing infants) only 26% of the acute RfD will be utilized; the requested tolerance for rape seed (i.e., canola does not add any measurable contribution to this exposure according to our analysis).

ii. *Drinking water*. Novartis Crop Protection anticipates the potential exposure from residues of drinking water to be insignificant due to the proposed seed treatment use pattern associated with this petition.

2. *Non-dietary exposure*. Given the seed treatment use pattern proposed in this petition, there are no anticipated non-dietary exposures resulting from this requested tolerance. Mefenoxam is registered for use as a product for use on turf and ornamentals for control of soil-borne diseases. However, the product is not used residentially by homeowners and the potential exposure to the general public from turf and ornamentals is thought to be negligible.

D. Cumulative Effects

Novartis Crop Protection believes that consideration of a common mechanism of toxicity is not appropriate at this time since there is no information to indicate that toxic effects produced by mefenoxam would be cumulative with those of any other chemicals.

E. Safety Determination

1. *U.S. population*—i. *Acute risk*. The risk from acute dietary exposure to mefenoxam is considered to be very low. The NOAEL in a 28–day study was 50 mg/kg, which is 6–fold higher than the chronic NOAEL. Since chronic exposure assessment did not result in any unacceptable exposure for even the most impacted population subgroup, it is anticipated that also the acute exposure will be in an acceptable range. Again, the requested tolerance on rape seed (i.e., canola) was found not to contribute any measurable additional impact on acute exposure to mefenoxam so that for the general population less than 15% of the acute RfD is utilized.

ii. *Chronic risk*. Under the conservative exposure assumptions of residue levels being at tolerance level, less than 10% of the RfD will be utilized by the U.S. general population. Use on canola does not measurably contribute to this exposure, particularly given that no detectable residues were found even when 3x the use rate was utilized. Therefore, based on the completeness and reliability of the toxicity data supporting this petition, Novartis Crop Protection believes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of mefenoxam taking into account dietary and non-occupational exposures.

2. *Infants and children*. There is no indication that mefenoxam interferes with the prenatal or neonatal development, even when experimental animals were exposed to very high doses leading to maternal toxicity. Infants and children are not expected to show any particular sensitivity to mefenoxam.

i. *Acute risk*. The risk from acute dietary exposure to mefenoxam is considered to be very low. The NOAEL in a 28–day study was 50 mg/kg, which is 6–fold higher than the chronic NOAEL. According to our analysis there is no measurable impact of the requested tolerance on the exposure to mefenoxam. The utilization of the acute RfD from the most exposed group is 26% (non-nursing infants).

ii. *Chronic risk*. Calculated on the basis of the theoretical maximum residue contribution (TMRC) for mefenoxam, utilization of RfD from dietary exposure of children is estimated as: 4.3% for nursing infants, 14% for non-nursing infants, 21% for 1 to 6 years old, and 12% for children 7 to 12 years old.

F. International Tolerances

There are no Codex maximum residue levels established for CGA329351.

[FR Doc. 00–18519 Filed 7–20–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6839–3]

Proposed CERCLA Administrative Cost Recovery Settlement for the Hertel Landfill Superfund Site, Clintondale, Town of Plattekill, Ulster County, New York

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: In accordance with section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (''CERCLA''), 42 U.S.C. 9622(i), notice is hereby given by the U.S. Environmental Protection Agency (''EPA''), Region II, of a proposed administrative settlement pursuant to section 122(h) of CERCLA, 42 U.S.C. 9622(h), for recovery of past response costs concerning the Hertel Landfill Superfund Site (''Site'') located in Clintondale, Town of Plattekill, Ulster County, New York, with Mark Goodson Enterprises, Ltd. (d/b/a Kingston Daily Freeman or The Daily Freeman) and Brown & Sharpe Manufacturing Company (hereinafter collectively referred to as ''Settling Parties''). The settlement requires the Settling Parties to each pay $43,798.00 to the EPA Hazardous Substance Superfund in reimbursement of EPA's past response costs incurred with respect to the Site. The Settling Parties shall each also pay $43,798.00 to the Hertel Steering Committee Escrow Account to be applied toward funding the Site remedial work that has been or is being performed by the parties that comprise the Hertel Steering Committee. The settlement includes a covenant not

to sue the Settling Parties pursuant to section 106 and 107(a) of CERCLA, 42 U.S.C. 9606 and 9607(a), for all past response costs incurred at or in connection with the Site by the United States, and all response costs incurred and to be incurred by the United States and the Hertel Steering Committee at or in connection with the Site through the completion of the Site landfill cap (and operation and maintenance thereof). For thirty (30) days following the date of publication of this notice, EPA will receive written comments relating to the settlement. EPA will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations that indicate that the proposed settlement is inappropriate, improper, or inadequate. EPA's response to any comments received will be available for public inspection at the EPA Region II offices located at 290 Broadway, New York, New York 10007–1866.

DATES: Comments must be submitted on or before August 21, 2000.

ADDRESSES: The proposed settlement is available for public inspection at the EPA Region II offices located at 290 Broadway, New York, New York 10007–1866. Comments should reference the Hertel Landfill Superfund Site and the index number of the settlement, CERCLA–02–99–2004. A copy of the proposed settlement may be obtained from the individual listed below.

FOR FURTHER INFORMATION CONTACT: Carl P. Garvey, Assistant Regional Counsel, New York/Caribbean Superfund Branch, Office of Regional Counsel, U.S. Environmental Protection Agency Region II, 17th Floor, 290 Broadway, New York, New York 10007–1866. Telephone: 212–637–3181.

Dated: June 30, 2000.

William J. Muszynski,

Acting Regional Administrator, Region 2.

[FR Doc. 00–18535 Filed 7–20–00; 8:45 am]

BILLING CODE 6560–50–P

COUNCIL ON ENVIRONMENTAL QUALITY

Annual Report on Endangered Species Act Exemption

AGENCY: Council on Environmental Quality, Executive Office of the President.

ACTION: Availability of report.

SUMMARY: This notice announces the availability of the Annual Report submitted by Basin Electric Power Cooperative, as Project Manager for the Missouri Basin Power Project in the matter of an exemption granted from the requirements of the Endangered Species Act to Grayrocks Dam. The lead federal agency in the project is the Rural Electrification Administration.

DATES: The report was submitted to the Council in November, 1999.

ADDRESSES: The Annual Report is available from Basin Electric Power Cooperative, 1717 East Interstate Avenue, Bismarck, ND 58501–0564; Telephone: (701) 223–0441.

FOR FURTHER INFORMATION CONTACT: Dinah Bear, General Counsel, Council on Environmental Quality, 722 Jackson Place, NW., Washington, DC 20503; Telephone (202) 395–7421.

SUPPLEMENTARY INFORMATION: Under the Endangered Species Act, any agency granted an exemption under 16 U.S.C. § 1536(h) must submit to the Council on Environmental Quality an annual report describing its compliance methods with the mitigation and enhancement measures prescribed by 16 U.S.C. § 1536. See 16 U.S.C. § 1536(1)(2). This sub-section further requires that the Council publish availability of the report in the **Federal Register**.

On February 7, 1979, the Endangered Species Committee granted an exemption from the requirements of the Endangered Species Act to Grayrocks Dam. In granting the Exemption Order, the committee, as required by the act, established requirements for reasonable mitigation and enhancement measures. These requirements are set out in an ''Agreement of Settlement and Compromise'' and is part of the Annual Report announced here.

Dated: July 10, 2000.

George T. Frampton,

Acting Chair.

[FR Doc. 00–18384 Filed 7–20–00; 8:45 am]

BILLING CODE 3125–01–M

FEDERAL COMMUNICATIONS COMMISSION

[DA 00–1582 (Auction No. 32)]

AM Auction Remedial Filing Window; Notice and Filing Requirements Regarding July 31—August 4, 2000 Remedial Filing Window for AM Auction

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document announces an AM auction remedial filing window for corrective submissions by entities that timely filed only one of the two documents required by Commission AM auction procedures. Those entities will be permitted to supplement their prior submissions, between July 31, 2000, and August 4, 2000 (''AM Auction Remedial Window''), by filing either the previously omitted FCC Form 175 or the FCC Form 301 Section I and Tech Box of Section III–A.

DATES: The AM Auction Remedial Filing Window is between July 31, 2000, and August 4, 2000.

FOR FURTHER INFORMATION CONTACT: Kenneth Burnley, Auctions and Industry Analysis Division, Wireless Telecommunications Bureau, at (202) 418–0660; Jean Ann McGovern, Audio Services Division, Mass Media Bureau, at (202) 418–2700.

SUPPLEMENTARY INFORMATION: This is a summary of a public notice released July 14, 2000 (''*AM Auction Remedial Filing Window Public Notice*''). The complete text, including all attachments, of the *AM Auction Remedial Filing Window Public Notice* is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257), 445 12th Street, SW, Washington, DC. It may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (ITS, Inc.) 1231 20th Street, NW, Washington, DC 20035, (202) 857–3800. It is also available on the Commission's website at *http://www.fcc.gov/wtb/auctions*.

List of Attachments available at the FCC:

Attachment A—Pending FCC Form 301 Application—No Record of a Timely Filed FCC Form 175; FCC Form 175 Filed—No Record of Timely Filed Required FCC Form 301 Sections; and Required FCC Form 301 Sections Filed Between January 21, and February 1, 2000—No Record of a Timely Filed Associated FCC Form 175

Attachment B—Electronic Filing and Review of the FCC Form 175

Attachment C—Accessing the FCC Network To File FCC Form 175

I. General Information

A. Introduction

1. On July 14, 2000, the Mass Media Bureau (''MMB'') and the Wireless Telecommunications Bureau (''WTB'') (collectively, the ''Bureaus'') released the *AM Auction Remedial Filing Window Public Notice*, which announces an AM auction remedial filing window for corrective submissions by entities that timely filed only one of the two documents required

under AM auction procedures. Those entities will be permitted to supplement their prior submissions, between July 31, 2000, and August 4, 2000 (''AM Auction Remedial Window''), by filing either the previously omitted FCC Form 175 or the FCC Form 301 Section I and Tech Box of Section III–A.

2. *Background.* On November 19, 1999, a public notice (''*January Filing Window Public Notice*'') was released announcing an AM auction filing window for applications for new AM stations and major modifications to authorized AM facilities. The *January Filing Window Public Notice* required that entities interested in participating in the AM auction electronically file a FCC Form 175 (short-form application) during the January Filing Window and, concurrently, file a FCC Form 301 Section I and the Tech Box from Section III–A, if they had not done so previously. The Bureaus cautioned that the failure of any entity to file all required information on a timely basis would preclude that entity's participation in the AM auction proceeding. Nonetheless, the Commission received ten filings, listed in Attachment A of the *AM Auction Remedial Filing Window Public Notice*, that did not comply with the filing requirements set forth in the *January Filing Window Public Notice*.

3. *AM Auction Remedial Window.* Generally, participation in prior auctions conducted by the Bureaus required the filing of only FCC Form 175. The AM auction (''Auction No. 32'') filing window is the first to employ filing procedures which require the concurrent filing of FCC Form 175 and the engineering data contained in FCC Form 301. The Bureaus recognize that potential applicants may have experienced some confusion in the Bureaus' initial use of the two-part procedure. The purpose of the AM Auction Remedial Window is to allow those entities that only filed FCC Form 175 or the required engineering data on FCC Form 301 a short period of time to correct their filings to comply with our rules. We caution that this is a unique opportunity offered by the Bureaus. We do not anticipate offering such an opportunity in future auction proceedings.

4. Only entities identified in Attachment A of the *AM Auction Remedial Filing Window Public Notice* may make corrective submissions during the AM Auction Remedial Window. In order to be eligible to participate in Auction No. 32, those entities must correct their submissions as described below:

- If an entity has a pending FCC Form 301 application (Frozen AM Application) and did not timely file a FCC Form 175 during the January Filing Window, that entity must electronically file a FCC Form 175 by 6:00 p.m. Eastern Standard Time, August 4, 2000. Information regarding the completion and electronic filing of the FCC Form 175 is contained in the *AM Auction Remedial Filing Window Public Notice*.
- If an entity timely filed a FCC Form 175 during the January Filing Window and did not file the required engineering data sections of FCC Form 301, that entity must file FCC Form 301 (May 1999 version) Section I and the Tech Box of Section III–A. These sections of FCC Form 301 must be filed in triplicate with the Secretary of the Commission, 445 12th Street, SW, Washington, DC 20554. The required engineering data sections of the FCC Form 301 are due in hard copy by 7:00 p.m. Eastern Standard Time, August 4, 2000. No filing fee is required. A courtesy copy of any FCC Form 301 submission filed during the AM Auction Remedial Window should also be sent to James R. Crutchfield, Audio Services Division, Room 2–B450, at the above street address. Such entities should specify, in the cover letter accompanying the required FCC Form 301 sections or at the top of the first page of the FCC Form 301 submission, the account number of the associated pending FCC Form 175 as indicated in Attachment A to this public notice. It is not necessary for such entities to include a printed copy of their previous, electronically filed FCC Form 175 will the FCC Form 301 submission.
- If an entity filed the required FCC Form 301 engineering data or a complete FCC Form 301 during the January Filing Window and did not file an associated FCC Form 175, that entity must electronically file a FCC Form 175 by 6:00 p.m. Eastern Standard Time, August 4, 2000. Information regarding the completion and electronic filing of the FCC Form 175 is contained in the *AM Auction Remedial Filing Window Public Notice*.

5. Failure of any entity identified in Attachment A of the *AM Auction Remedial Filing Window Public Notice* to have all required forms and information timely and properly filed by August 4, 2000 will result in the dismissal of any prior submissions relating to the January Filing Window for AM applications.

6. *Electronic Filing Procedures for FCC Form 175.* Only the entities identified in Attachment A of the *AM Auction Remedial Filing Window Public Notice* that are required to complete a FCC Form 175 will be able to make corrective filings in the AM Auction Remedial Window. Each of these entities will receive via Federal Express an assigned temporary tax identification number (TIN) and password. This assigned temporary TIN and password will be required to access the FCC Form 175 submission software.

7. After the application has been submitted, the applicant will be required to write a letter to the Commission requesting a change to their TIN. The letter should contain the company name, FCC account number, assigned temporary TIN and the company's actual TIN. This letter should contain language authorize the Commission to replace the assigned temporary TIN with the company's actual TIN. This letter requesting a TIN change should be addressed to Any Zoslov, Chief, Auctions and Industry Analysis Division, Wireless Telecommunications Bureau, Federal Communications Commission, 445 12th Street, SW, Washington, DC 20554. A separate copy of the letter should be mailed to Kenneth Burnely, Auctions and Industry Analysis Division, 4–B524, Wireless Telecommunications Bureau, Federal Communications Commission, 445 12th Street, SW, Washington, DC 20554.

Federal Communications Commission.

Margaret W. Wiener,

Deputy Chief, Auctions and Industry Analysis Division.

[FR Doc. 00–18491 Filed 7–20–00; 8:45 am]

BILLING CODE 6712–01–U

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than August 7, 2000.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166–2034:

1. *First Robinson Financial Corporation Employee Stock Ownership Plan,* Robinson, Illinois; to retain voting shares of First Robinson Financial Corporation, Robinson, Illinois, and thereby indirectly retain voting shares of First Robinson Savings Bank, National Association, Robinson, Illinois.

Board of Governors of the Federal Reserve System, July 18, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00–18543 Filed 7–20–00; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 17, 2000.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Anita Bancorporation,* Atlantic, Iowa; to acquire 100 percent of the voting shares of EWN Investments, Inc., Ute, Iowa, and thereby indirectly acquire voting shares of Ute State Bank, Ute, Iowa.

Board of Governors of the Federal Reserve System, July 18, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00–18542 Filed 7–20–00; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

TIME AND DATE: 10 a.m., Wednesday, July 26, 2000.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 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 matters carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at http://www.federalreserve.gov for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: July 19, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00–18604 Filed 7–19–00; 10:35 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

PHS Policy for Instruction in the Responsible Conduct of Research; Availability of New Draft

AGENCY: Office of the Secretary, HHS.

ACTION: Notice of availability.

SUMMARY: The Office of Research Integrity (ORI) in collaboration with the Agency Research Integrity Liaison Officers for each of the PHS Operating Divisions, is announcing the availability for public comment of a new draft PHS Policy for Instruction in the Responsible Conduct of Research for extramural institutions receiving PHS funds for research or research training.

On October 22, 1999, HHS Secretary Donna E. Shalala announced a number of important changes in policy to improve the Department's research integrity efforts including a statement that ''through ORI, the Department will require research institutions to provide training in the responsible conduct of research to all staff engaged in research or research training with PHS funds.'' This decision was based on the Department's commitment to ensure that all PHS supported researchers receive basic instruction in the key elements of responsible research and are familiar with basic regulatory requirements. The decision was also supported by prior recommendations of the Commission on Research Integrity which stated, in part, that HHS

> ''require that each institution applying for or receiving a grant, contract, or cooperative agreement under the Public Health Service Act for research or research training add to its existing misconduct-in-science assurance a third declaration, one certifying that the institution has an educational program on the responsible conduct of research. Through this mechanism, the current NIH research integrity education requirement, now limited to recipients of institutional training grants at NIH-funded institutions, would be augmented by an assurance applied to all individuals supported by PHS research funds.'' Commission Report, ''Integrity and Misconduct in Research,'' p. 18 (HHS 1995).

Institutions and individuals interested in commenting on the proposed policy may obtain it on the ORI website at <http://ori.dhhs.gov> by clicking on ''What's New'' or by contacting ORI. To be considered, all comments must be received by ORI at the address below or by E-mail to jegan@osophs.dhhs.gov no later than August 21, 2000.

FOR FURTHER INFORMATION CONTACT: Chris B. Pascal, J.D., Acting Director, Office of Research Integrity, Rockwall II, Suite 700, 5515 Security Lane, Rockville, MD 20852, 301–443–3400.

Chris B. Pascal,

Acting Director, Office of Research Integrity.

[FR Doc. 00–18495 Filed 7–20–00; 8:45 am]

BILLING CODE 4160–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

[Program Announcement No. AoA–00–05]

Fiscal Year 2000 Program Announcement; Notice Requesting Applications

AGENCY: Administration on Aging, HHS

ACTION: Announcement of a request for applications to carry out Racial and Ethnic Approaches to Community Health 2010 (REACH 2010). An important goal of REACH 2010 is to eliminate health disparities among elderly racial and/or ethnic minority groups. Areas of concentration are: diabetes, cardiovascular diseases, and adult immunizations.

SUMMARY: Under this program announcement, the Administration on Aging (AoA) will hold a competition for grant awards of four (4) cooperative agreements to plan for implementation of community level interventions which can eliminate health disparities among elderly members of racial and ethnic minority groups. The purpose of REACH 2010 is to assist communities to organize and prepare an infrastructure for the development and conduct of community-based disease prevention and health promotion models.

The deadline date for the submission of applications is August 21, 2000. Eligibility for grant awards is limited to public and/or nonprofit agencies, organizations, and institutions with experience in health education and promotion for elderly populations. More specifically, the standard of eligibility requires that the applicant, together with the other organizations composing a community coalition, have extensive knowledge about the health concerns of the designated older minority population they plan to serve and proven records of accomplishment serving and working with the community group(s) identified.

Application kits are available by writing to the U.S. Department of Health and Human Services, Administration on Aging, Office of Program Development, 330 Independence Avenue, S.W., Room 4268, Washington, DC 20201, or by calling (202) 619–3428.

Dated: July 14, 2000.

Jeanette C. Takamura,

Assistant Secretary for Aging

[FR Doc. 00–18494 Filed 7–20–00; 8:45 am]

BILLING CODE 4154–01–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee for Energy-Related Epidemiologic Research: Conference Call Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following conference call meeting.

Name: Advisory Committee for Energy-Related Epidemiologic Research (ACERER).

Time and Date: 1 p.m.–3 p.m., August 4, 2000.

Place: The conference call will originate at the National Center for Environmental Health (NCEH), CDC, in Atlanta, Georgia. Please see **SUPPLEMENTARY INFORMATION** for details on accessing the conference call.

Status: Open to the public, limited only by the availability of telephone ports.

Purpose: This committee is charged with providing advice and recommendations to the Secretary, HHS; and to the Director, CDC, and Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), on establishment of a research agenda and the conduct of a research program pertaining to energy-related epidemiologic studies.

Matters to be Discussed: The conference call agenda is to reach consensus on the review and report submitted to the ACERER by its Subcommittee for Management Review of the Chernobyl Studies.

Agenda items are subject to change as priorities dictate.

SUPPLEMENTARY INFORMATION: This conference call is scheduled to begin at 1 p.m., Eastern Time. To participate in the conference call, please dial 1–877–475–9228 and enter conference code 195001. You will then be automatically connected to the call.

FOR FURTHER INFORMATION CONTACT: Michael J. Sage, Executive Secretary, ACERER, and Associate Director for Planning, Evaluation, and Legislation, NCEH, CDC, 4770 Buford Highway, NE, (F–29), Atlanta, Georgia 30341–3724, telephone 770/488–7020, fax 770/488–7024.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and ATSDR.

Dated: July 17, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 00–18600 Filed 7–20–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1379]

Agency Information Collection Activities; Proposed Collection; Comment Request; Procedures for the Safe Processing and Importing of Fish and Fishery Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on extending the existing reporting and recordkeeping requirements for processors and importers of fish and fishery products under the provisions of FDA's fish and fishery products regulations.

DATES: Submit written comments on the collection of information by September 19, 2000.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal

agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Procedures for the Safe Processing and Importing of Fish and Fishery Products (OMB Control Number 0910–0354)—Extension

FDA regulations in part 123 (21 CFR part 123) mandate the application of Hazard Analysis and Critical Control Point (HACCP) principles to the processing of seafood. HACCP is a preventive system of hazard control designed to help ensure the safety of foods. The regulations were issued under FDA's statutory authority to regulate food safety, including section 402(a)(1) and (a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) and (a)(4)), and became effective on December 18, 1997.

Certain provisions in part 123 require that processors and importers of seafood collect and record information. The HACCP records compiled and maintained by a seafood processor primarily consist of the periodic observations recorded at selected monitoring points during processing and packaging operations, as called for in a processor's HACCP plan (e.g., the values for processing times, temperatures, acidity, etc. as observed at critical control points). The primary purpose of HACCP records is to permit a processor to verify that products have been produced within carefully established processing parameters (critical limits) that ensure that hazards have been avoided. HACCP records are normally reviewed by appropriately trained employees at the end of a production lot or at the end of a day or week of production to verify that control limits have been maintained, or that appropriate corrective actions were taken if the critical limits were not maintained. Such verification activities are essential to ensure that the HACCP system is working as planned. A review of these records during the conduct of periodic plant inspections also permits FDA to determine whether the products have been consistently processed in conformance with appropriate HACCP food safety controls.

Section 123.12 requires that importers of seafood products take affirmative steps and maintain records that verify that the fish and fishery products they offer for import into the United States were processed in accordance with the HACCP and sanitation provisions set forth in part 123. These records are also to be made available for review by FDA as provided in § 123.12(c).

The time and costs of these recordkeeping activities will vary considerably among processors and importers of fish and fishery products, depending on the type and number of products involved, and the nature of the equipment or instruments required to monitor critical control points. The burdens have been estimated using typical small seafood processing firms as a model because these firms represent a significant proportion of the industry.

The burden estimate in Table 1 includes only those collections of information under the seafood HACCP regulations that are not already required under other statutes and regulations. For example, the current food manufacturing practices provisions in 21 CFR part 110 already require that all food processors ensure good sanitary practices and conditions, monitor the quality of incoming materials, monitor and control food temperatures to prevent bacterial growth, and perform certain corrective actions and verification procedures. Furthermore, the estimate does not include collections of information that are a usual and customary part of businesses' normal activities. For example, the tagging and labeling of molluscan shellfish (21 CFR 1240.60) is a customary and usual practice among seafood processors. Consequently the estimates in Table 1 account only for new information collection and recording requirements attributable to part 123. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of recordkeepers	Annual frequency per recordkeeping[2]	Total annual records	Hours per recordkeeper[3]	Total hours	Total operating and maintenance costs
123.6(a), (b), and (c)	243	1	243	16	3,888	$58,320
123.6(c)(5)	4,850	4	19,400	0.30	5,820	$87,300
123.8(a)(1) and (c)	4,850	1	4,850	4	19,400	$291,000
123.12(a)(2)(ii)	1,000	80	80,000	0.20	16,000	$240,000
123.6(c)(7)	4,850	280	1,358,000	0.30	407,400	$6,111,000
123.7(d)	1,940	4	7,760	0.10	1,940	$29,100
123.8(d)	4,850	47	227,950	0.10	22,795	$341,925
123.11(c)	4,850	280	1,358,000	0.10	135,800	$2,037,000
123.12(c)	1,000	80	80,000	0.10	8,000	$120,000
123.12(a)(2)	50	1	50	4	200	$3,000
123.10	243	1	24	24	5,832	$87,480
Annual burden hours					627,075	$9,406,125

[1]There are no capital costs associated with this collection of information.
[2]Based on an estimated 280 working days per year.
[3]Estimated average time per 8-hour work day unless one time response.
The above estimates include the information collection requirements in the following sections:
§ 123.16 Smoked Fish—process controls (see § 123.6(b))
§ 123.28(a) Source Controls—molluscan shellfish (see § 123.6(b))

§ 123.28(c), (d) Records—molluscan shellfish (see § 123.6(c)(7))

Dated: July 14, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–18459 Filed 7–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Dermatologic and Ophthalmic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 18 and 19, 2000, 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Kimberly L. Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 18 and 19, 2000, the committee will discuss two new drug applications (NDA's): NDA 18–662, Accutane® (isotretinoin) capsules, Hoffmann-LaRoche, Inc., for severe recalcitrant nodular acne; and NDA 21–177, (new formulation) isotretinoin capsules, Hoffmann-LaRoche, Inc., for severe recalcitrant nodular acne.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 7, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 7, 2000, 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 requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 11, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–18457 Filed 7–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1394]

Medical Devices; CLIA Waiver Criteria; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop to review the criteria used to determine whether specific laboratory tests are waived from certain requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The purpose of the public workshop is to obtain additional comments on the criteria and process the agency should use to determine when a particular test is waived.

Date and Time: The public workshop will be held on August 14 and 15, 2000, from 9 a.m. to 5 p.m. each day.

Location: The public workshop will be held at the Washingtonian Center Marriott Hotel, 9751 Washingtonian Blvd., Gaithersburg, MD 20878, 301–590–0044.

Contact: Clara A. Sliva, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–827–0496, FAX 301–827–1401, e-mail: CAS@cdrh.fda.gov.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), written material, and requests to make oral presentations to the contact person by August 4, 2000. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20850, by September 14, 2000.

If you need special accommodations due to a disability, please contact Clara A. Sliva at least 7 days in advance of the meeting.

SUPPLEMENTARY INFORMATION:

A. Background

CLIA specifies that laboratory requirements be based on the complexity of the tests performed and establishes criteria for categorizing a test as waived. Responsibility for determining whether a particular test is waived was transferred from the Centers for Disease Control and Prevention (CDC) to FDA on January 31, 2000. In the **Federal Register** of September 13, 1995 (60 FR 47534), CDC published proposed clarifications to the statutory criteria for waiver. CDC based the proposal on guidelines CDC developed to assist the manufacturers in submitting waiver requests. The proposed regulations recommend a methodology for demonstrating that a test system proposed for waived status be so ''simple'' and ''accurate'' as to render the likelihood of erroneous results negligible. The Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law No. 105–115) modified 42 U.S.C. 263a (d)(3) of the Public Health Service Act by adding the phrase ''by the user'' to clarify that waived tests include those which employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible. FDAMA also clarified that waived tests include those that are cleared by FDA for home use.

Following transfer of responsibility for waiver determinations from CDC to FDA, manufacturers now submit premarket applications for products and requests for complexity categorization of these products to one agency. FDA is currently following the same policies applied by CDC to the waiver criteria prior to the transfer; FDA is performing the ''same work'' the ''same way.'' Under the current process, FDA generally will waive: (1) Any test system that meets the specifications described in the guidelines published in the proposed rule of September 13, 1995, and (2) any test system that provides scientifically valid data verifying that the statutory criteria for waiver have been met.

FDA believes it needs additional information from stakeholders to effectively implement its new responsibilities with respect to waiver decisions. In particular, the agency needs to decide whether to continue to apply the current criteria, finalize the proposed rule published by CDC in 1995, or repropose other procedures and criteria for this process. FDA is inviting laboratory groups, medical professional societies, patient groups, manufacturers, manufacturing associations, and other interested parties to attend this open public workshop regarding the criteria for waiver. To the extent possible, oral and written testimony should address the following general and specific questions:

B. General Questions for Public Input

Criteria for waived tests under the Public Health Service Act were amended by FDAMA to read: Waived tests ''are laboratory examinations and procedures that have been approved by Food and Drug Administration for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that (A) employ methodologies that are so simple and accurate to render the likelihood of erroneous results by the user negligible, or (B) the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly * * *.''

1. What criteria should be used to demonstrate that a waived test is a simple laboratory examination and procedure with ''an insignificant risk of an erroneous result?'' For example:

a. Should a waived test, when performed by untrained users, provide an accurate result with no significant clinical or statistical error when compared to a measure of truth? This requires availability of well-characterized reference methods and/or materials as part of the waived test assessment. The current threshold for waiver as established by CDC is no significant inaccuracy and no significant imprecision.

b. Should a waived test, when performed by untrained users, provide a test result that shows no user error when compared to the same test performed in a CLIA certified lab by a trained user? This requires comparison of the test in a lay-user setting with performance of the test in a CLIA certified lab by a trained user. The threshold for waiver would be no difference in performance in the two settings.

c. Should FDA apply a different model to determine the waived status of a test?

2. What criteria should FDA use to determine if a methodology is ''so simple and accurate to render the likelihood of erroneous results by the user negligible?''

a. Should a waived test be so accurate when performed by untrained users that inaccurate results will not occur?

b. Should a waived test have variable accuracy if used adjunctively? Is it acceptable to waive tests that have inaccurate results but do not have any major negative clinical impact? How should FDA make this assessment?

3. What criteria should FDA use in determining that a test will ''pose no unreasonable risk of harm to the patient if performed incorrectly?''

4. Should the waiver process be different for screening tests that require a second test for confirmation? Because there are no CLIA standards for performance of waived testing, except instructions to follow the manufacturer's package insert, what is the assurance that confirmatory testing will be performed? Should the need for confirmatory testing raise, lower, or have no impact on the threshold for a waiver decision?

C. Specific Questions for Public Input

5. Should accuracy be determined using comparison of the waiver test to a well-characterized reference method and/or materials, to a designated comparative method and/or materials, to a working laboratory method and/or materials, to a clinical algorithm for diagnosis, and/or to other endpoints?

6. How many samples, what types of samples (real or artificial), by how many users and how many sites are appropriate to evaluate accuracy? (Current guidelines being followed by FDA are for performance to be demonstrated by laboratory users at a minimum of one site.)

7. What should be the background of these users?

8. What performance criteria (statistical or clinical) should FDA apply to the accuracy threshold for a waived test (e.g., t- test or McNemar test at key decision points, description of performance with confidence intervals at key decision points, use of set performance standards using a receiver operator curve–80 percent, 90 percent, 95 percent, or other–at key decision points, and/or others)?

9. How should FDA define precision for purposes of waiver determination? What types of samples, how many and what types of operators/sites are appropriate? Current CDC recommendation is for 20 samples at three levels representing appropriate decision points to be tested at three sites by lay users using materials in either artificial and/or real matrices depending on availability and biohazard issues.

10. What performance thresholds should FDA use to determine whether the precision studies are appropriate for waiver status (e.g., ANOVA (analysis of variance) analysis, use of a predefined performance goal, such as Tonks' formula, or percent agreement out of total repeat runs)?

11. What interference studies are appropriate to establish performance of waived tests (e.g., effects of hemolysis, lipemia, etc.)?

12. What environmental studies or flex (stress) studies are appropriate to establish performance of waived tests (e.g., temperature or humidity stresses, short fills)?

13. What additional studies (if any) should be submitted for evaluation of qualitative tests for waiver?

14. What additional studies (if any) should be submitted for evaluation of quantitative tests for waiver?

This will be an informal meeting conducted in accordance with 21 CFR 10.65.

Dated: July 14, 2000.

Lillian J. Gill,

Acting Deputy Director for Science, Center for Devices and Radiological Health.

[FR Doc. 00–18456 Filed 7–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301)443-7978.

National Cross-Site Assessment of the Addiction Technology Transfer Centers Network—(New)

The Substance Abuse and Mental Health Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) intends to conduct an assessment of its Addiction Technology Transfer Centers (ATTCs). The goal

underlying the training and education opportunities provided through the ATTCs is to enhance the competencies of professionals in a variety of disciplines to address the clinical needs of individuals with substance abuse problems using research-based curricula and training materials through both traditional and non-traditional technologies.

The ATTCs disseminate current health services research from the National Institute on Drug Abuse, National Institute on Alcohol Abuse and Alcoholism, National Institute of Mental Health, Agency for Health Care Policy and Research, National Institute of Justice, and other sources and applied knowledge development activities from SAMHSA using innovative technologies by developing and updating state-of-the-art research-based curricula and developing faculty and trainers. Participants in ATTC training events are self-identified and participate in either academic courses or continuing education/professional development training events. Academic courses are offered at all levels. Continuing education/professional development training is designed to meet identified needs of counselors and other professionals who work with individuals with substance abuse problems.

Both a process and an outcome assessment will be conducted. The process component will describe the training and education needs of pre-service and currently practicing professionals, the types of training events that students/trainees receive through the ATTCs, and student/trainee satisfaction with services. The outcome component will focus on changes in clinical practice made by trainees as a result of knowledge received.

Analysis of this information will assist CSAT in documenting the numbers and types of participants in ATTC education/training offerings, describing the extent to which participants improve in their clinical competency, and which method is most effective in disseminating knowledge to the various audiences. This type of information is crucial to support CSAT in complying with GPRA reporting requirements and will inform future development of knowledge dissemination activities.

The study design for students and trainees will include a description of each course/training event, and a pre-post design that collects identical information at initiation of ATTC courses/trainings, at the completion of the course/training, and again after 3 months. This time frame is necessary to allow students/trainees the opportunity to implement changes in clinical practice. In addition, the study will collect satisfaction measures after each course/training event.

The chart below summarizes the annualized burden for this project.

Respondent type	Number of respondents	Average responses/ respondent	Average time/ response (hours)	Annual burden (hours)
Students/trainees	12,000	4	.52	6,240
Faculty/trainers	195	1	.25	49
ATTC summary reports	13	4	2.00	104
Total	12,208			6,393

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: July 16, 2000.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 00–18484 Filed 7–20–00; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4562–N–06]

Notice of Proposed Information Collection for Public Comment: Doctoral Dissertation Research Grant Program

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. Public comments on the subject proposal are being solicited.

DATES: *Comments Due Date:* September 19, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name or OMB control number and be sent to: Reports Liaison Officer, Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th Street, SW, Room 8226, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Jane Karadbil, Office of University Partnerships, Department of Housing and Urban Development, 451 7th Street, Washington, DC 20410; telephone (202) 708–1537 (this is not a toll-free number). Copies of the proposed forms and other available documents to be submitted to OMB may be obtained from Ms. Karadbil.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Action of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected entities concerning the proposed information collection to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of information to be collected; and (4) Minimize the burden of collection of information on those who are to respond; including through the use of appropriate technology, *e.g.,* permitting electronic submission of responses.

This Notice also lists the following information:

Title of the Proposal: Doctoral Dissertation Research Grant Program (DDRG).

Description of the need for the information and proposed use: The information is being collected to enable HUD to select grantees in this competitive grant program. The information is also being used to monitor the performance of grantees to

ensure that they meet statutory and program goals and requirements.

Members of the affected public: Ph.D. candidates preparing dissertations on HUD-related topics: 80 applicant and 15 grantees.

Estimation of the total number of hours needed to prepare the information collection including the number of respondents, frequency of response, and hours of response: Information pursuant to submitting applications will be submitted once. Information pursuant to grantee monitoring requirements will be annually and at the completion of the grant.

The following chart details the respondent burden on an annual basis:

The following chart details the respondent burden on an annual basis:

	Number of respondents	Total annual responses	Hours per response	Total hours
Application	80	80	32	2,560
Annual Reports	15	15	4	60
Final Reports	15	15	2	30
Recordkeeping	15	15	4	60
				2,710

Status of proposed information collection: This is a new paperwork request.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: July 14, 2000.

Lawrence L. Thompson,

General Deputy Assistant Secretary for Policy Development and Research.

[FR Doc. 00–18447 Filed 7–20–00; 8:45 am]

BILLING CODE 4210–62–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–45461–N–45]

Notice of Submission of Proposed Information Collection to OMB; Emergency Comment Request Communities for Safer Guns Coalition Survey; Notice of Proposed Information Collection for Public Comment

AGENCY: Office of The Deputy Assistant Secretary for Intergovernmental Relations.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for emergency review and approval, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* July 28, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within seven (7) days from the date of this Notice. Comments should refer to the proposal by name/or OMB approval number) and should be sent to: Joseph F. Lackey, Jr., HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail Wayne__Eddins@HUD.gov; telephone (202) 708–2374. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: This Notice informs the public that the Department of Housing and Urban Development (HUD) has submitted to OMB, for emergency processing, an information collection package with respect to the gun violence reduction efforts of the Communities for Safer Guns Coalition and their implementation of their preference for safer guns. This Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Communities for Safer Guns Coalition Survey.

OMB Control Number: Pending.

Agency Form Numbers: None.

Members of Affected Public: State, Local or Tribal Government.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of responses, and hours of response: An estimation of the total number of hours needed to prepare the information collection is 125, number of respondents is 500, frequency response is annually, and the hours of response is 0.25.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: July 14, 2000.

Wayne Eddins,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 00–18446 Filed 7–20–00; 8:45 am]

BILLING CODE 4210–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4557–N–29]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Clifford Taffet, room 7266, Department of Housing and Urban Development, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Brian Rooney, Division of Property Management, Program Support Center, HHS, room 5B–41, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Clifford Taffet at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.,* acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: *COE:* Ms. Shirley Middleswarth, Army Corps of Engineers, Management & Disposal Division, Pulaski Bldg., Room 4224, 20 Massachusetts Avenue, NW, Washington, DC 20314–1000; (202) 761–0515; *GSA:* Mr. Brian K. Polly, Assistant Commissioner, General Services Administration, Office of Property Disposal, 18th and F Streets, NW, Washington, DC 20405; (202) 501–0052; *Navy:* Mr. Charles C. Cocks, Director, Department of the Navy, Real Estate Policy Division, Naval Facilities Engineering Command, Washington Navy Yard, 1322 Patterson Ave., SE, Suite 1000, Washington, DC 20374–5065; (202) 685–9200; (These are not toll-free numbers).

Dated: July 13, 2000.

John D. Garrity,

Director, Office of Special Needs Assistance Programs.

Title V, Federal Surplus Property Program Federal Register Report for 7/21/00

Suitable/Available Properties

Buildings (by State)

Illinois

Army Reserve Center
PVT Perry F. Modrow
5020 State Street
E. St. Louis Co: St. Clair IL 62205–1398
Landholding Agency: GSA
Property Number: 54200030001
Status: Excess
Comment: 16,300 sq. ft. training center & 2656 sq. ft. garage, presence of lead paint
GSA Number: 1–D–IL–726

Kansas

Federal Bldg.
330 Shawnee
Leavenworth Co: KS 66048–
Landholding Agency: GSA
Property Number: 54200030002
Status: Excess
Comment: 22,300 sq. ft., good condition, most recent use—post office/fed. bldg.
GSA Number: 7–G–KS–0517

Minnesota

Project Office
Mississippi Hdqts Lakes
Proj.
Remer Co: Cass MN 56672–
Landholding Agency: COE
Property Number: 31200020007
Status: Unutilized
Comment: 780 sq. ft., needs rehab

Storage 1
Mississippi Hdqts Lakes
Proj.
Remer Co: Cass MN 56672–
Landholding Agency: COE
Property Number: 31200020008
Status: Unutilized
Comment: 2240 sq. ft., needs rehab

Storage 2
Mississippi Hdqts Lakes
Proj.
Remer Co: Cass MN 56672–
Landholding Agency: COE
Property Number: 31200020009
Status: Unutilized
Comment: 180 sq. ft., needs rehab

New Hampshire

Bldg. 10
Portsmouth Naval Shipyard
Portsmouth Co: NH 03804–5000
Landholding Agency: Navy
Property Number: 77200030018
Status: Excess
Comment: 12,000 sq. ft., presence of asbestos lead paint, most recent use—shop facility, off-site use only

Bldg. 239
Portsmouth Naval Shipyard
Portsmouth Co: NH 03804–5000
Landholding Agency: Navy
Property Number: 77200030019
Status: Excess
Comment: 897 sq. ft., presence of asbestos/lead paint, off-site use only

Land (by State)

Minnesota

Land, 2.2 acres
Mississippi Hdqts Lakes
Proj.
Remer Co: Cass MN 56672–
Landholding Agency: COE
Property Number: 31200020010
Status: Unutilized
Comment: 2.2 acres, easements

Unsuitable Properties

Buildings (by State)

California

Bldg. 23025
Marine Corps Air Station
Miramar Co: CA 92132–
Landholding Agency: Navy
Property Number: 77200020001

Status: Unutilized
Reason: Secured Area
Bldg. 23027
Marine Corps Air Station
Miramer Co: CA 92132–
Landholding Agency: Navy
Property Number: 77200030002
Status: Unutilized
Reason: Secured Area
Bldg. 731
Naval Air Station
Point Mugu
Oxnard Co: Ventura Ca 93043–4301
Landholding Agency: Navy
Property Number: 77200030003
Status: Excess
Reason: Extensive deterioration
Bldg. 731A
Naval Construction Battalion
Point Hueneme
Oxnard Co: Ventura CA 93043–4301
Landholding Agency: Navy
Property Number: 77200030004
Status: Excess
Reason: Extensive deterioration
Bldg. 865
Naval Air Station
Point Mugu
Oxnard Co: Ventura CA 93043–4301
Landholding Agency: Navy
Property Number: 77200030005
Status: Excess
Reason: Extensive deterioration
Bldg. 868
Naval Air Station
Point Mugu
Oxnard Co: Ventura CA 93043–4301
Landholding Agency: Navy
Property Number: 77200030006
Status: Excess
Reason: Extensive deterioration
Bldg. 474
Naval Air Station
Point Mugu
Oxnard Co: Ventura CA 93043–4301
Landholding Agency: Navy
Property Number: 77200030007
Status: Excess
Reason: Extensive deterioration
Bldg. 5021
Naval Air Station
Point Mugu
Oxnard Co: Ventura CA 93043–4301
Landholding Agency: Navy
Property Number: 77200030008
Status: Excess
Reason: Extensive deterioration
Bldg. 5022
Naval Air Station
Point Mugu
Oxnard Co: Ventura CA 93043–4301
Landholding Agency: Navy
Property Number: 77200030009
Status: Excess
Reason: Extensive deterioration
Bldg. 5025
Naval Air Station
Point Mugu
Oxnard Co: Ventura CA 93043–4301
Landholding Agency: Navy
Property Number: 77200030010
Status: Excess
Reason: Extensive deterioration
Bldg. 5113
Naval Air Station
Point Mugu
Oxnard Co: Ventura CA 93043–4301
Landholding Agency: Navy
Property Number: 77200030011
Status: Excess
Reason: Extensive deterioration
Bldg. 5114
Naval Air Station
Point Mugu
Oxnard Co: Ventura CA 93043–4301
Landholding Agency: Navy
Property Number: 77200030012
Status: Excess
Reason: Extensive deterioration
Bldg. 82 & 84
Naval Air Station
Point Mugu
Oxnard Co: Ventura CA 93043–4301
Landholding Agency: Navy
Property Number: 77200030013
Status: Excess
Reason: Extensive deterioration
Bldg. 6–1
Naval Air Station
Point Mugu
Oxnard Co: Ventura CA 93043–4301
Landholding Agency: Navy
Property Number: 77200030014
Status: Excess
Reason: Extensive deterioration
Bldg. 479
Naval Construction Battalion
Point Hueneme
Oxnard Co: Ventura CA 93043–4301
Landholding Agency: Navy
Property Number: 77200030015
Status: Excess
Reason: Extensive deterioration

Connecticut

Bldg. 308
Naval Submarine Base
Groton Co: New London CT 06349–
Landholding Agency: Navy
Property Number: 77200030016
Status: Unutilized
Reason: Extensive deterioration

Missouri

Steam Line/Support Structure
Marine Corps Support Activity
Kansas City Co: Jackson MO 64147–
Landholding Agency: Navy
Property Number: 77200030017
Status: Unutilized
Reason: Extensive deterioration

Washington

Bldg. 109
Naval Weapons Station
Port Hadlock Co: Jefferson WA 98339–9723
Landholding Agency: Navy
Property Number: 77200030020
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area; Extensive deterioration
Bldg. 157
Naval Weapons Station
Port Hadlock Co: Jefferson WA 98339–9723
Landholding Agency: Navy
Property Number: 77200030021
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area; Extensive deterioration
Bldg. 161
Naval Weapons Station
Port Hadlock Co: Jefferson WA 98339–9723
Landholding Agency: Navy
Property Number: 77200030022
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area; Extensive deterioration
Bldg. 170
Naval Weapons Station
Port Hadlock Co: Jefferson WA 98339–9723
Landholding Agency: Navy
Property Number: 77200030023
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area; Extensive deterioration
Bldg. 262
Naval Weapons Station
Port Hadlock Co: Jefferson WA 98339–9723
Landholding Agency: Navy
Property Number: 77200030024
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area; Extensive deterioration

[FR Doc. 00–18160 Filed 7–20–00; 8:45 am]
BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collection Renewal To Be Submitted to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comments.

SUMMARY: The collection of information listed below has been submitted by the U.S. Fish and Wildlife Service (Service) to the Office of Management and Budget (OMB) for renewal under the provisions of the Paperwork Reduction Act of 1995. Copies of the specific information collection requirements, related forms, and explanatory material may be obtained by contacting the Service's Information Collection Clearance Officer at the address provided below.

DATES: Consideration will be given to all comments received on or before August 21, 2000. OMB has up to 60 days to

approve or disapprove information collection but may respond after 30 days. Therefore, to ensure maximum consideration OMB should receive public comments by August 21, 2000.

ADDRESSES: Comments and suggestions on the requirements should be sent to the Office of Management and Budget, Attention: Department of the Interior Desk Officer, 725 17th Street, NW, Washington, DC 20503, and to Rebecca Mullin, Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS 222–ARLSQ, 1849 C Street, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: To request a copy of the draft of the information collection request, explanatory information and related forms contact Rebecca A. Mullin at 703/358–2287, or electronically to rmullin@fws.gov.

SUPPLEMENTARY INFORMATION: We submitted the following proposed information collection clearance requirement to OMB for review and approval under the Paper work Reduction Act of 1005 (Pub. L. 104–13). OMB has up to 60 days to approve or disapprove information collection. To ensure maximum consideration, OMB should receive public comments by [insert 30 days from date of publication]. We may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. We previously published a 60-day notice inviting public comment on this information collection in the **Federal Register** on May 9, 2000 (65 FR 26849). Only one public comment on the previous notice was received as of June 19, 2000. The Service's response is discussed below:

Issue: The Ornithological Society commented that the wildlife-watching section does not go into adequate detail, specifically that the data on the amount of birding activity and related economic activity were insufficient.

Service Response: Past National Surveys have focused on wildlife watching around the home (residential) and more than a mile from home (nonresidential). The Service has provided participation and trip-related expenditure estimates for nonresidential wildlife (including, but not only, birds) watching and participation estimates for residential bird watching and feeding. With all these data revolving around the recreational enjoyment of birds, there was no one estimate for the overall number of bird watchers. The Service is addressing this issue in the 2001 Survey. The Service will include questions on the nonresidential observation of birds and the residential observation of birds, which will enable the Service to provide estimates of the total number of bird watchers at both the national level and the state level. The Service has added questions on the number of species the bird watcher can identify and whether or not the bird watcher has a birding life list. As for the expenditures of bird watchers, the Service addresses the wildlife-watching expenditure section the same as the hunting and fishing expenditure sections, which means the Service gets expenditures by type of activity (residential, nonresidential, freshwater, saltwater, big game, small game, etc.), not by species sought.

This notice provides an additional 30 days in which to comment on the following information.

The Federal Aid in Sport Fish Restoration Act (16 U.S.C. 777–777K), and the Federal Aid in Wildlife Restoration Act (16 U.S.C. 669–699i) authorizes the Service to provide grants annually to the States for projects to support sport fish and wildlife management and restoration, including the acquisition and improvement of aquatic resources, fishing access, fish stocking, and the acquisition and improvement of wildlife management areas, facilities, and access. Grants also are provided for aquatic education and hunter education, maintenance of completed projects, and research into the problems affecting fish and wildlife resources. Those projects help ensure that the American people have adequate opportunities for wildlife-related recreation. To assist in carrying out its responsibilities, the Service has sponsored national surveys of fishing and hunting at about 5-year intervals sine 1955. The Bureau of the Census conducts the Survey for the Service. The survey data are needed to allow the Service to effectively administer the Sport Fish and Wildlife Restoration Grant Programs, and to help States develop project proposals and conservation programs that meet the needs of their populations. The Survey collects information on the number of people participating in wildlife-related recreation, the number of days and expenditures spent on those activities. Survey data are needed to provide comparable state level information on existing recreation demands and to provide a basis for projecting future demands to effectively meet the needs of the American people. The information is needed to evaluate the effectiveness of existing programs in meeting those needs, formulate new policies, develop programs, and support budget proposals and legislation for the benefit of sport fish and wildlife restoration. Data are needed to evaluate the status and trends of recreational uses, as well as the values and benefits, of fish and wildlife resources. The comprehensive comparable state-level data provided by the Survey are not available from other sources..

We invite your comments on: (1) Whether the collection of information is necessary for the proper performance of the functions of the agency including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the collection information; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents.

Title:: 2001 National Survey of Fishing, Hunting, and Wildlife-Associated Recreation.

Approved Number: 1018–0088.

Service Form Number(s): N/A.

Description and Use: The 2001 National Survey of Fishing, Hunting, and Wildlife-Related will be the 10th one conducted since 1955. It is conducted every 5 years and is requested by the States through the International Association of Fish and Wildlife Agencies. It will be conducted by the Bureau of the Census using computer-assisted telephone or in-person interviews. A sample of sportsmen and non-consumptive participants will be selected from a household screen. Sample persons will be asked about their participation and expenditures. Three detailed interviews will be conducted during the Survey year. The Survey will be similar in scope to past surveys. It will generate information identified as priority data needed by the Federal and State fish and wildlife agencies responsible for administering the Sport Fish and Wildlife Restoration grant programs. Accordingly, the 2001 Survey will be a comprehensive data base of fish and wildlife-related recreation activities and expenditures. It will include the number of persons participating in different types of activities such as freshwater, saltwater, and Great Lakes fishing; and big game, small game, migratory bird, and other animal hunting. Wildlife watching (non-consumptive activities) include wildlife observation, feeding, and photographing around the home and on trips away from home. Information is collected on days of participation, the species of animals sought, and how much money was spent on trips and for equipment. Information on the characteristics of participants will include age, income, sex, education, race, and residency. The

Survey data has State level reliability. Federal and State fish and wildlife agencies use information from the Survey as a basis to formulate management and policy decisions related to sport fish and wildlife restoration. Participation patterns and trend information assist in identifying present and future needs and demands. The information is used for planning the acquisition, development, and enhancement of fish and wildlife resources for the benefit of wildlife-related recreation. Data on expenditures, economic evaluation, and participation are used by land managing agencies to assess the value of fish and wildlife-related uses of natural resources. Expenditure information is used by states to estimate the economic impact of wildlife-related recreation expenditures on their economies and to support the dedication of tax revenues to support fish and wildlife restoration programs. The information collected on resident saltwater fishing will assist coastal States in determining the proper ratio for allocating funds between freshwater and saltwater projects as required by the Federal Aid in Sport Fish Restoration Act, as amended. The information is not readily available elsewhere because few States have saltwater licenses or conduct their own surveys. If the Survey data were not available it would impair the ability of those States to meet their obligations under the Act.

In summary, the information collection is needed to assist the Fish and Wildlife Service and the State fish and wildlife agencies in administering the Sport Fish and Wildlife Restoration grant programs. The Survey will provide up-to-date information on the uses and demands for wildlife-related recreation resources, trends in the uses of those resources, and a basis for developing and evaluating programs and projects to meet existing and future needs. The information collection is subject to the Paperwork Reduction Act requirements for such activity, which includes soliciting comments from the general public regarding the nature and burden imposed by the collection.

Frequency of Collection: Household screen interviews and the first detailed sportsmen and non-consumptive participant interviews will be conducted April–June 2001. The second detailed interviews will be conducted September–October 2001. The third and last detailed interviews will be conducted January–March 2002.

Description of Respondents: Individuals.

Estimated Completion Time: We estimate the average completion time per respondent to be about 7 minutes for the screen and 15 minutes for the detailed interviews. A respondent will average 2 interviews during the survey period. Total estimated respondent burden hours for all respondents are 27,000 hours.

Number of Respondents: It is estimated that there will be 80,000 total respondents.

Dated: July 14, 2000.

Rebecca Mullin,

Fish and Wildlife Service Information Collection Officer.

[FR Doc. 00–18445 Filed 7–20–00; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of an Environmental Assessment and Receipt of Applications for Incidental Take Permits for the Assessment District 161 Habitat Conservation Plan in Western Riverside County, California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability and receipt of applications.

SUMMARY: Three public agencies and nine private entities (the Applicants) have applied to the Fish and Wildlife Service for incidental take permits pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended. The Applicants are: Metropolitan Water District of Southern California; Rancho California Water District; Murrieta Valley Unified School District; Obed Properties, Incorporated; Winchester 700, Limited Liability Company; Pulte Homes Corporation; Butterfield Development Company, Incorporated; Hill Country, Limited; Buie Communities, Limited Liability Company; Crowne Meadows Limited Partnership; Parcel Five, Incorporated; and SDI Communities, Limited Liability Company. We anticipate a future application from the County of Riverside; however, we do not intend to publish a separate notice for receipt of that application because the Assessment District 161 Habitat Conservation Plan (District Plan) and our Environmental Assessment comprehensively address all applications. The Applicants request a 30-year permit that would authorize take of 21 covered species (4 listed species, and 17 unlisted species should they be listed during the term of the permit). Take would be incidental to otherwise lawful activities associated with urban development of 2,028 acres of habitat in western Riverside County, California.

We request comments from the public on the permit applications, and our Environmental Assessment, which are available for review. The permit applications include the proposed District Plan and an accompanying Implementing Agreement (legal contract). The District Plan describes the proposed project, the measures that the Applicants would undertake to minimize and mitigate take of the covered species, and the management program proposed for the conserved habitat.

We provide this notice pursuant to section 10(a) of the Endangered Species Act and National Environmental Policy Act regulations (40 CFR 1506.6). All comments that we receive, including names and addresses, will become part of the official administrative record and may be made available to the public.

DATES: We must receive your written comments on or before September 19, 2000.

ADDRESSES: Send written comments to Mr. Ken Berg, Field Supervisor, Fish and Wildlife Service, 2730 Loker Avenue West, Carlsbad, California 92008; facsimile (760) 431–5902.

FOR FURTHER INFORMATION CONTACT: Ms. Karin Cleary-Rose, Fish and Wildlife Biologist, or Ms. Michelle Shaughnessy, Supervisory Fish and Wildlife Biologist, at the above address or call (760) 431–9440.

SUPPLEMENTARY INFORMATION:

Availability of Documents

You may obtain copies of these documents for review by contacting the above office (see **ADDRESSES**). Documents also will be available for public inspection, by appointment, during normal business hours at the above address and at the following libraries: City of Murrieta Library, 39589 Los Alamos Road, Murrieta, California; and Temecula Branch Library, 41000 County Center Drive, Temecula, California.

Background

Section 9 of the Endangered Species Act and Federal regulation prohibit the ''take'' of fish or wildlife species listed as endangered or threatened, respectively. Take of listed fish or wildlife is defined under the Act to include kill, harm, or harass. The Service may, under limited circumstances, issue permits to authorize incidental take; i.e., take that is incidental to, and not the purpose of, the carrying out of an otherwise lawful activity. Regulations governing

incidental take permits for threatened and endangered species are found in 50 CFR 17.32 and 17.22, respectively.

The take prohibitions of the Act do not apply to listed plants on private land unless their destruction on private land is in violation of State law. Nevertheless, the Applicants consider plants in the District Plan and request permits for them to the extent that State law applies.

The Applicants request a 30-year permit that would authorize take of 4 listed species and 17 unlisted species should they be listed during the term of the permit: endangered California Orcutt grass (*Orcuttia californica*); endangered Riverside fairy shrimp (*Streptocephalus woottoni*); endangered Quino checkerspot butterfly (*Euphydryas editha quino*); threatened coastal California gnatcatcher (*Polioptila californicus californicus*); Palmer's grapplinghook (*Harpagonella palmeri*); long-spined spineflower (*Chorizanthe polygonoides*); western spadefoot toad (*Spea hammondii*); San Diego horned lizard (*Phrynosoma coronatum blainvillei*); orange-throated whiptail lizard (*Cnemidophorus hyperythrus*); burrowing owl (*Speotyto cunicularia*); southern California rufous-crowned sparrow (*Aimophila ruficeps canescens*); Bell's sage sparrow (*Amphispiza belli belli*) grasshopper sparrow (*Ammodramus savannarum*); American peregrine falcon (*Falco peregrinus anatus*); Cooper's hawk (*Accipiter cooperii*); ferruginous hawk (*Buteo regalis*); golden eagle (*Aquila chrysaetos*); long-eared owl (*Asio otis*); merlin (*Falco lineatus*); sharp-shinned hawk (*Accipiter strianus*); and white-tailed kite (*Elanus leucurus*).

The District Plan area is located adjacent to the cities of Temecula and Murrieta within western Riverside County, California. Generally the District Plan area lies to the east of Interstate 15, south of Clinton Keith Road, and adjacent to Highway 79. The Southwestern Riverside Multiple Species Reserve and Lake Skinner Recreation Area are northeast of the District Plan area. Due to already existing development patterns in the County, the District and adjacent lands lie within the only possible landscape linkage between the Lake Skinner Core and the Lake Mathews multiple species reserve system. Maintaining a viable linkage between these areas is key to successful regional reserve design in western Riverside County and will contribute to the proposed Multiple Species Habitat Conservation Plan. Habitat acquisition proposed under the District Plan would contribute regionally to conservation within this viable linkage area. Land uses surrounding the project sites include residential developments, commercial centers, undeveloped land with native vegetation, and agricultural fields.

The District Plan identifies 19 covered projects that could result in take despite the avoidance and minimization measures proposed in the Plan. The covered projects are the residential developments of Crowne Hill, Roripaugh Ranch, SDI Communities, Silver Hawk Specific Plan, Costa-Pulte, Murrieta Springs, Rancho Miramosa, Parcel 5, Lincoln Ranch, Buie Communities, Los Alamos High School, San Diego/Rancho California Water District Pipeline No. 6, EM–20 Turnout and Transmission Main, San Diego Pipeline No.3 Bypass, and Nicholas Reservoir. In addition, in anticipation of an application, the County of Riverside projects have been included in the analysis: the extension of Butterfield Stage Road, widening portions of Winchester and Newport Roads, and the expansion of the French Valley Airport runway and the Southwest Justice Center.

Several of the covered projects have sought or will, in the future, seek a permit from the U.S. Army Corps of Engineers (Corps) pursuant to Section 404 of the Clean Water Act for effects to Corps-jurisdictional wetlands and non-wetland waters of the U.S. The District Plan does not address impacts to Corps jurisdictional areas. Federal wetland permitting would remain subject to the Fish and Wildlife Coordination Act and could result in additional avoidance, minimization and or mitigation measures not contemplated in this Plan.

Riverside County initiated development of the District Plan in coordination with the project proponents within and around Assessment District 161. The County formed the District to fund public infrastructure. The District is encumbered with approximately $85 million of debt. The County initiated a refinancing of the District 161 bond to lower the interest rate; however, the refinancing could not proceed without assurances of development repaying the debt. Therefore, to facilitate these assurances, the affected landowners, along with the County, developed the District Plan to provide for both assurance of conservation and development within the Plan boundary.

Take of covered species would occur during construction of single and multi-family housing, commercial and light industrial facilities, schools, parks, associated infra-structure, and public projects within a 3,094-acre footprint. Collectively, the projects would permanently eliminate 2,028 acres of suitable habitat for the covered species (659 acres of coastal sage scrub, 89 acres of chaparral, 7 acres of coast live oak woodland, 7 acres of riparian habitat, 3 acres of stream bed, 554 acres of non-native grassland, 10 acres of eucalyptus woodland, and 699 acres of agricultural land).

The Applicants propose to conserve 1,450 acres of habitat within the District Plan Area: 627 acres of coastal sage scrub, 61 acres of grassland, 77 acres chaparral, 10 acres of eucalyptus woodland , 568 acres of agricultural lands, 10 acres of coast live oak woodland, 33 acres of riparian habitat, 1 acre of pond, and 4 acres of stream bed. Habitat would be conserved on nine properties in three areas: the Johnson and Roripaugh Ranch area, along Warm Springs Creek, and east of Interstate 215 near Clinton Keith Road. The largest of these areas (674 acres) is on Johnson Ranch, of which 503 acres is used for ongoing agricultural operations. The Applicants propose to continue agriculture in its current footprint as a method of weed control.

The following table shows the anticipated effects to each proposed covered species in terms of acres of habitat destroyed and conserved:

Species	Habitat destroyed	Habitat conserved
California Orcutt grass [1]	4	0
Palmer's grapplinghook	1,213	689
Long-spined spineflower	1,213	689
Riverside fairy shrimp [1]	4	0
Quino checkerspot butterfly	1,695	1,180
Western spadefoot toad	1,230	734
San Diego horned lizard	1,213	689
Orange-throated whiptail lizard	1,213	689

Species	Habitat destroyed	Habitat conserved
Coastal California gnatcatcher	748	703
Burrowing owl	554	61
Southern California rufous-crowned sparrow	660	627
Bell's sage sparrow	748	704
Grasshopper sparrow	554	61
Raptors	1,219	1,341

[1] California Orcutt grass and Riverside fairy shrimp may be adversely affected by destruction of a small portion of the Skunk Hollow vernal pool watershed. We do not anticipate direct loss of individuals.

During the construction and operational phases of the covered projects, the Applicants propose to avoid and minimize impacts to covered species. These measures include best management practices; fire prevention; fuel management; access control; restriction of project footprints; dust control; restriction of lighting; monitoring of construction activities; revegetation of temporary disturbance areas; restrictions on the timing and nature of construction activities in and around occupied habitat; preconstruction surveys; buffers around riparian habitat; restrictions on use of invasive landscape species; and patrol, maintenance, and repair requirements.

The Applicants propose to mitigate for destruction of habitat of the covered species by conserving:

1. Approximately 1,180 acres of habitat for the Quino checkerspot butterfly (1,004 acres in the Skinner-Johnson metapopulation and 176 acres in the Warm Springs metapopulation).

2. Approximately 627 acres of coastal sage scrub and 77 acres of chaparral currently occupied by at least 50 pairs of coastal California gnatcatchers and providing habitat for the San Diego horned lizard, western spadefoot toad, orange-throated whiptail lizard, southern California rufous-crowned sparrow, Bell's sage sparrow, and raptors. The conserved habitat supports known populations of all of these species.

3. Approximately 46 acres of riparian and wetland habitats occupied by western spadefoot toads.

4. Approximately 61 acres of grassland, including areas with clay soils. This would conserve habitat for Palmer's grapplinghook, long-spined spineflower, western spadefoot toad, San Diego horned lizard, orange-throated whiptail lizard, burrowing owl, grasshopper sparrow, and raptors.

In addition, the Applicant's propose a Quino checkerspot butterfly research and propagation program linked to the Vista Murrieta High School curriculum. The District Plan identifies the program goals as: (1) To study Quino checkerspot butterfly habitat and develop management/restoration techniques for application to conservation sites in Riverside County; (2) to propagate Quino checkerspot butterflies for release into conservation areas; and (3) to develop education programs in the Murrieta Valley Unified School District and at the University of California, Riverside, pertaining to Quino checkerspot butterfly biology and habitat. The effort would include a 3-year habitat restoration research program, a perpetual quino checkerspot propagation program, an on-site research facility, and a curriculum program in the Murrieta Valley Unified School District.

The Applicants propose three habitat management phases for conserved lands: Interim, ongoing, and long-term. The interim management period would begin when an Applicant signs the Implementing Agreement and would end when management responsibilities are transferred to a conservation organization. Interim management would primarily involve protection of existing biological values and would be funded and provided by the property owner. The Applicants anticipate that most of the conservation areas would not have an interim management phase.

The ongoing management period would begin when the conservation lands are transferred from individual property owners to a conservation organization and would end when or if management responsibilities are secured through completion and implementation of the Riverside County Multiple Species Habitat Conservation Plan. Ongoing management would include exotic species monitoring and control, access control, monitoring of covered species, identification and ranking of restoration and enhancement opportunities, and implementation of a fire management plan and public outreach. Management of some of the properties would be funded by individual property owners.

Long-term management would begin when or if management of the conservation lands is secured through the Riverside County Multiple Species Habitat Conservation Plan. If the County Multiple Species Plan is not adopted, then the Applicants propose to fund long-term management of the conservation areas through (1) a fee paid by the Applicants, (2) creation of a County Service Area, or (3) creation of a master Home Owners Association. In this contingency, the management effort would be the same as in the ongoing management phase.

The Applicants propose to guarantee funding for ongoing and long-term management of conservation lands by providing a bond, letter of credit, or other financial instrument acceptable to the Fish and Wildlife Service prior to the initiation of ground disturbing activities. The Applicants relied on a Property Analysis Record (a database used by the Center for Natural Lands Management) to estimate ongoing and long-term management costs.

In the Environmental Assessment for our proposed action of issuing incidental take permits to the Applicants, we consider the environmental consequences of six alternatives. These alternatives are Implementation of the District Plan as Proposed, No Action, Reduced Coverage, District 161 Projects Only, District 161 Supplemental Assessment Area-wide Biological Mitigation, and Increased Conservation on Participating Properties.

Under the No Action Alternative, the Applicants would pursue incidental take authorization separately. Under the Reduced Coverage Alternative, burrowing owl and grasshopper sparrow would not be included as covered species on the incidental take permit. Under the District 161 Projects Only Alternative, only projects that lie entirely within Assessment District 161 would be included in the Plan. The District 161 Supplemental Assessment Area-wide Biological Mitigation Alternative contemplates conserving the area identified for conservation in the Subsequent Environmental Impact Report prepared by the County of Riverside in 1992 for District 161. The Increased Conservation on Participating Properties Alternative examines

reduced impacts and a concomitant increase in conservation.

We provide this notice pursuant to section 10(a) of the Endangered Species Act and the National Environmental Policy Act of 1969 regulations (40 CFR 1506.6). We will evaluate the applications, associated documents, and comments submitted thereon to determine whether the applications meets the requirements of the National Environmental Policy Act regulations and section 10(a) of the Endangered Species Act. We will issue permits to the Applicants for incidental take of those species for which the permit issuance criteria are met. Our final permit decisions will be made no sooner than 60 days from the date of this notice.

Dated: July 17, 2000.

Elizabeth H. Stevens,

Deputy Manager, California/Nevada Operations Office, Sacramento, California.

[FR Doc. 00–18485 Filed 7–20–00; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Proposed Finding for Federal Acknowledgment of the Little Shell Tribe of Chippewa Indians of Montana

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of proposed finding.

SUMMARY: Pursuant to 25 CFR 83.10(h), notice is hereby given that the Assistant Secretary—Indian Affairs proposes to acknowledge that the Little Shell Tribe of Chippewa Indians of Montana, P.O. Box 1384, Great Falls, Montana 59403, exists as an Indian tribe within the meaning of Federal law. This notice is based on a determination that the petitioner meets the requirements for a government-to-government relationship with the United States.

DATES: As provided by 25 CFR 83.10(i), any individual or organization wishing to comment on the proposed finding may submit arguments and evidence to support or rebut the proposed finding. This material must be submitted within 180 calendar days from the date of publication of this notice. As stated in the regulations, 25 CFR 83.10(i), interested and informed parties who submit arguments and evidence to the Assistant Secretary must also provide copies of their submissions to the petitioner. The names and addresses of commenters on the proposed finding will be available for public review. Commenters wishing to have their name and/or address withheld must state this request prominently at the beginning of their comments. Such a request will be honored to the extent allowable by law.

ADDRESSES: Comments on the proposed finding or requests for a copy of the report which summarizes the evidence and analyses that are the basis for this proposed finding should be addressed to the Bureau of Indian Affairs, Branch of Acknowledgment and Research, 1849 C Street NW, Mailstop 4660–MIB, Washington, D.C. 20240.

FOR FURTHER INFORMATION CONTACT: R. Lee Fleming, Chief, Branch of Acknowledgment and Research, (202) 208–3592.

SUPPLEMENTARY INFORMATION: This notice is published in accordance with authority delegated by the Secretary of the Interior to the Assistant Secretary by 209 DM 8.

Documentation for this proposed finding was submitted by the Little Shell Tribe of Chippewa Indians of Montana (Little Shell, or petitioner) or obtained by the independent research of the Bureau of Indian Affairs (BIA), Branch of Acknowledgment and Research (BAR).

The evidence shows that a substantial portion of the petitioner's members have ancestry from either the historical Pembina Band of Chippewa Indians prior to a treaty of 1863, or from a successor, the Turtle Mountain Band. The petitioner asserts to have its origins in a Chippewa band which had been led by a succession of three hereditary chiefs, all known as Little Shell. The petitioner is a combination of historical Metis, or ''mixed blood,'' groups. Before 1870, many of the petitioner's ancestors were part of the Metis populations along the Red River of the north at the Red River Settlement (now Winnipeg) in Canada and at Pembina and St. Joseph in North Dakota. These Metis populations of the mid-19th century were described by contemporary observers as socially and culturally distinct from both the European settlers and tribal Indians in the same area, but also as being related to and sometimes acting together with Indian tribes. In the early 1890's, some ancestors were listed on censuses of the Turtle Mountain Band.

In Montana, the petitioner's ancestors settled originally in two regions, migrating there by different routes between the 1860's and 1930's. One settlement region was north-central Montana, including both the Lewistown area and the Highline, the area along the railroad line from Wolf Point to Havre. Some ancestors of the petitioner's members began settling this region as early as the late 1860's and early 1870's. The other settlement region was the Front Range, the area along the eastern edge of the northern Rocky Mountains. Those ancestors of the petitioner who settled in this region arrived mostly after the failure of the Metis rebellion led by Louis Riel in Saskatchewan in 1885. The petitioner's ancestors settled originally in rural areas of Montana. Beginning in the 1910's and continuing into the depression of the 1930's, some of them began moving into neighborhoods on the fringes of the rural towns on the Front Range and along the Highline, or into Great Falls and Helena. Many of the petitioner's ancestors lived in segregated areas of these towns at some time before the mid-1950's or early 1960's. Those areas were not limited to the petitioner's ancestors, except on the Front Range, and other Metis and Indians also lived in these neighborhoods.

An organization was formed in 1927 in Hays, the petitioner's first formally organized predecessor in Montana. Joseph Dussome was elected in 1927 to lead the organization formed that year, and to lead organizations of different names in 1935, 1939, and 1949. The consistent leadership of Dussome and the consistent geographical region represented by his officers and area representatives demonstrate continuity from these organizations to the petitioning group. From the mid-1930's until the mid-1950's, two organizations advocated on behalf of the Montana Metis. Dussome's organization, known as the Landless Indians of Montana after 1939, largely drew support from the Highline and Lewistown area, while the Montana Landless Indians largely drew its support from urban areas and the Front Range. Since approximately 1955, the petitioner's members and ancestors have been part of the common political process of a single organization.

The Little Shell Tribe of Chippewa Indians of Montana adopted its current organizational name and its current constitution in 1977. Its membership requirements provide membership eligibility to individuals who can trace their ancestry to the Roe Cloud Roll, a list of unenrolled Indians in Montana which was prepared by the Office of Indian Affairs about 1938. The Little Shell petitioner had 3,893 members as of 1992. Its members are now geographically dispersed, mostly within Montana. The petitioner currently maintains an office in Great Falls, Montana.

The petitioner has not provided substantial evidence of unambiguous previous Federal acknowledgment. The evidence available for this finding does

not demonstrate that the petitioner meets the requirements of previous Federal acknowledgment in sections 83.1 and 83.8 of the regulations. Therefore, the petitioner was not evaluated under the provisions of section 83.8(d) which modify the mandatory criteria for Federal acknowledgment.

This proposed finding departs from practice in previous acknowledgment decisions in certain respects, principally in giving different amounts of weight to various types of evidence than had been done in prior determinations. Precedent from earlier decisions are not binding on Department conclusions, but are useful as guidance for interpreting the regulations. This finding departs from prior decisions for meeting criteria (b) and (c) which depended upon specific evidence showing the continuity of tribal existence substantially without interruption. This finding departs from prior decisions for meeting criterion (a) which required evidence of specific identification of the petitioner as an Indian entity during each decade. This finding departs from prior decisions in which all previous petitioners who met criterion (e) demonstrated that at least 80 percent of their members descended from a historical tribe.

We believe such departures from previous practice on these matters are permissible and within the scope of the existing acknowledgment regulations. Those regulations do not specifically address these questions. Public comment is invited on these various matters, including the consistency of these proposed findings with the existing regulations. The petitioner and third parties may respond by submitting additional evidence or arguments relating to these matters during the comment period on this proposed finding. Such supplementary evidence may create a different record and a more complete factual basis for the final determination, and thus eliminate or reduce the scope of these contemplated departures from precedent.

Based on a review of the technical report, the charts prepared for each criterion, and some primary documents and background materials, and after consideration of the historical situations faced by this petitioner, the Department proposes to find that, although there is no specific evidence in the documentary record in this case for every time period, the evidence as a whole indicates that the Little Shell petitioner is a tribe.

The available documentation permits a proposed finding that the petitioner meets criterion (a). There are several examples of the identification of a group led by Joseph Dussome during the late 1930's and the decade of the 1940's as an Indian entity. Since 1949, the Little Shell petitioner has been consistently identified by various external observers as an Indian entity. It is noteworthy that several nearby tribes support the recognition of the Little Shell. There is limited evidence that the petitioner's ancestors were identified between 1900 and 1935 by external observers as Indians. This proposed finding accepts as a reasonable likelihood that references to the petitioner's individual ancestors as Indians and references to portions of their ancestors as residents of Indian settlements before the 1930's are consistent with the identifications of these and other ancestors of the petitioner as Indian groups after 1935. In order to have this proposed finding affirmed in the final determination, it would be in the petitioner's interest to provide during the comment period further evidence that external observers identified it as an Indian entity at various times between 1900 and 1935.

The available documentation permits a proposed finding that the petitioner meets criterion (b). The evidence indicates that at present there are portions of the petitioner's members residing within each of the two traditional rural regions of settlement in Montana who have been demonstrated to have social cohesion among themselves, and to have their respective ties to the members residing within the two traditional urban centers of settlement in the state. There is evidence that, after their migration to Montana, the petitioner's ancestors married other ethnic Metis individuals almost exclusively, and that those early intermarriages in Montana formed kinship ties that created social cohesion among the petitioner's ancestors. The available evidence does not show clearly that immigrants to Montana from Dakota or Canada necessarily moved together as a community or in a pattern of migration that maintained old community ties. This proposed finding accepts as a reasonable likelihood that patterns of social relationships among the Metis residents of settlements in North Dakota and Canada during the mid-19th century persisted among their descendants who migrated to Montana and appeared on the Federal census records of Montana for 1910 and 1920. The petitioner is encouraged to provide during the comment period further evidence that their ancestors continuously existed as social communities between the 1860's and 1930's.

The available documentation permits a proposed finding that the petitioner meets criterion (c). The attempt of the Little Shell group in Montana to achieve IRA status during the 1930's indicates its desire to obtain recognized status when the ''landless'' policies of the Federal Government were prohibitive. Many of the petitioner's ancestors participated in the activities of one or the other of two political organizations of ''landless Indians'' between the mid-1930's and the early 1950's. Since the mid-1950's the petitioner's members and ancestors have been part of the common political process of a single organization. The political processes of the petitioner's organization at present draw interest and support from both geographical regions of traditional settlement as well as the two main cities where members reside. Area representatives communicate political information and concerns between the council and the general membership. Several recent internal political conflicts indicate that current members are aware of the actions of the council and officers, and consider those actions to be important. This proposed finding concludes that evidence of some local leadership among a minority of the petitioner's ancestors in the past demonstrates a reasonable likelihood that patterns of political influence existed among many of the petitioner's ancestors before the 1930's. The petitioner is encouraged to provide during the comment period additional evidence to demonstrate more fully its political influence or authority over its members from historical times until the 1930's.

The petitioner meets criterion (d). The petitioner has a constitution, dated September 10, 1977, and resolutions which define its membership criteria and the procedures by which it governs its affairs and its members.

The available documentation permits a proposed finding that the petitioner meets criterion (e). A minority of the petitioner's members descend from individuals who received land scrip as ''mixed-blood'' relatives of the Pembina Band under the provisions of the treaties of 1863 and 1864, and therefore descend from a member of the band in a generation earlier than the treaty. A minority of the petitioner's members were on the judgment roll prepared by the Government in 1994 for the distribution of an Indian Claims Commission award for the taking of Indian territory in North Dakota. The available evidence indicates that about 48 percent of the petitioner's members trace their ancestry back to the historical Pembina Band of Chippewa or to its successor the Turtle Mountain Band. An additional 14 percent of the petitioner's members descend from a member of

Rocky Boy's Band with Chippewa ancestry. If Pembina ancestry is assumed for the Chippewa element of the Rocky Boy's Band, as was done by the Indian Claims Commission and by the BIA in preparing the 1994 judgment roll, then possibly 62 percent of the petitioner's members have Pembina Chippewa descent. Genealogical information is missing for many of the petitioner's newest members, and it would be in the petitioner's interest to provide during the comment period further evidence that additional members descend from ancestors with established Pembina Chippewa descent.

The petitioner meets criterion (f). The evidence shows that less than 1 percent of the members of the petitioning group are members of a federally recognized tribe. Therefore, its membership is composed principally of persons who are not members of any acknowledged Indian tribe.

The petitioner meets criterion (g). There is no evidence that the petitioning group was the subject of congressional legislation that prohibited or terminated a relationship between it and the Federal Government.

For these reasons, the petitioner should be acknowledged to exist as an Indian tribe.

This proposed finding is based on the available evidence and does not preclude the submission of other evidence to the contrary. Such new evidence may result in a change in the conclusions reached in the proposed finding.

A report summarizing the evidence, reasoning, and analyses that are the basis for the proposed decision will be provided to the petitioner and interested parties, and is available to other parties upon written request (83.10(h)).

During the 180-day comment period (83.10(i)), the Assistant Secretary shall provide technical advice concerning the proposed finding and shall make available to the petitioner in a timely fashion any records used for the proposed finding not already held by the petitioner, to the extent allowable by Federal law (83.10(j)(1)). In addition, the Assistant Secretary shall, if requested by the petitioner or any interested party, hold a formal meeting for the purpose of inquiring into the reasoning, analyses, and factual bases for the proposed finding. The proceedings of this meeting shall be on the record. The meeting record shall be available to any participating party and become part of the record considered by the Assistant Secretary in reaching a final determination (83.10(j)(2)).

If third party comments are received during the comment period, the petitioner shall have a minimum of 60 days to respond to these comments. This period may be extended at the Assistant Secretary's discretion if warranted by the extent and nature of the comments (83.10(k)).

At the end of the comment and response periods, the Assistant Secretary shall consult with the petitioner and interested parties to determine an equitable time frame for consideration of written arguments and evidence submitted during the comment and response periods, and notify the petitioner and interested parties of the date such consideration begins (83.10(l)). The Assistant Secretary has the discretion to request additional information from the petitioner or commenting parties, and to conduct additional research (83.10(l)(1)). After consideration of the written arguments and evidence submitted during the comment period and the petitioner's response to the comments, the Assistant Secretary shall make a final determination regarding the petitioner's status. A summary of the final determination will be published in the **Federal Register** (83.10(l)(2)).

Dated: July 14, 2000.

Kevin Gover,

Assistant Secretary-Indian Affairs.

[FR Doc. 00–18490 Filed 7–20–00; 8:45 am]

BILLING CODE 4310–02–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ES–930–08–1310–00–241A; MSES 47328, MSES 47325, MSES 47320]

(Mississippi); Proposed Reinstatement of Terminated Oil and Gas Leases

Under the provisions of Public Law 97–451, petitions for reinstatement of oil and gas leases MSES 47328, MSES 47325, MSES 47320, Wayne County, DeSota N.F., Mississippi were timely filed and accompanied by all required rentals and royalties accruing from August 1, 1999, the date of termination.

No new leases have been issued affecting the lands. The lessee has agreed to new lease terms for rentals and royalties at rates of $10 per acre and 16⅔ percent. Payment of $500 in administrative fees and a $125 publication fee has been made for each of the leases.

The Bureau of Land Management is proposing to reinstate the leases effective August 1, 1999, subject to the original terms and conditions of the leases and the increased rental and royalty rates cited above. This is accordance with section 31(d) and (e) of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 188(d) and (e)).

FOR FURTHER INFORMATION CONTACT: Ann Dickerson at (703) 440–1512.

Dated: July 7, 2000.

Walter Rewinski,

Acting State Director.

[FR Doc. 00–18518 Filed 7–20–00; 8:45 am]

BILLING CODE 4310–84–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–957–00–1420–BJ: GPO–0276]

Filing of Plats of Survey: Oregon/ Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The plats of survey of the following described lands are scheduled to be officially filed in the Oregon State Office, Portland, Oregon, thirty (30) calendar days from the date of this publication.

Williamette Meridian

Oregon

T. 24 S., R. 7 W., accepted June 16, 2000
T. 3 S., R. 14 E., accepted June 19, 2000
T. 16 S., R. 5 E., accepted June 28, 2000

Washington

T. 33 N., R. 36 E., accepted June 1, 2000
T. 32 N., R. 36 E., accepted June 1, 2000

If protests against a survey, as shown on any of the above plat(s), are received prior to the date of official filing, the filing will be stayed pending consideration of the protest(s). A plat will not be officially filed until the day after all protests have been dismissed and become final or appeals from the dismissal affirmed.

The plat(s) will be placed in the open files of the Oregon State Office, Bureau of Land Management, 1515 S.W. 5th Avenue, Portland, Oregon 97201, and will be available to the public as a matter of information only. Copies of the plat(s) may be obtained from the above office upon required payment. A person or party who wishes to protest against a survey must file with the State Director, Bureau of Land Management, Portland, Oregon, a notice that they wish to protest prior to the proposed official filing date given above. A statement of reasons for a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within thirty (30) days after the proposed official filing date.

The above-listed plats represent dependent resurveys, survey, and subdivision.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, (1515 S.W. 5th Avenue) P.O. Box 2965, Portland, Oregon 97208.

Dated: July 10, 2000.

Robert D. DeViney, Jr.,

Branch of Realty and Records Services.

[FR Doc. 00–18453 Filed 7–20–00; 8:45 am]

BILLING CODE 4310–33–M

DEPARTMENT OF THE INTERIOR

National Park Service

60 Day Notice of Intention to Request Clearance of Collection of Information; Opportunity for Public Comment

AGENCY: Department of the Interior, National Park Service.

ACTION: Notice and request for comments.

SUMMARY: The National Park Service (NPS) is proposing in 2001 to conduct a telephone survey of households in western Washington State where the following national parks are located: Olympic National Park and Mount Rainer National Park. In this survey, persons will be asked why they visit or do not visit either national park. This information will identify the reasons former visitors have stopped using the parks and why non-visitors do not go to the parks.

	Estimated numbers of	
	Responses	Burden hours
Western Washington Household Survey ...	1000	250

Under provisions of the Paperwork Reduction Act of 1995 and 5 CFR Part 1320, Reporting and Record Keeping Requirements, the National Park Service is soliciting comments on the need for gathering the information in the proposed survey. The NPS also is asking for comments on the practical utility of the information being gathered; the accuracy of the burden hour estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden to respondents, including use of automated information collection techniques or other forms of information technology.

The NPS goal in conducting this survey is to determine if former visitors have been displaced and if other persons do not go to Olympic and Mount Rainer national parks because of crowding and related factors, including traffic congestion, development, and difficulty in obtaining lodging or campsites in the parks.

DATES: Public comments will be accepted on or before September 19, 2000.

SEND COMMENTS TO: James H. Gramann, Department of Recreation, Park and Tourism Sciences, Texas A&M University, 2261 TAMU, College Station, TX 77843–2261.

FOR FURTHER INFORMATION CONTACT: James H. Gramann. Voice: 979–845–4920, e-mail: jgramann@rpts.tamu.edu.

SUPPLEMENTARY INFORMATION:

Title: Development and Advancement of Carrying Capacity Management Techniques, Western Washington Household Survey.

Bureau Form Number: None.

OMB Number: To be requested.

Expiration date: To be requested.

Type of request: Request for new clearance.

Description of need: The National Park Service needs information from former visitors and non-visitors to advance the application of carrying capacity management techniques in the National Park System.

Automated data collection: At the present time, there is no automated way to gather this information because it includes asking residents for information about use and non-use of specific national parks.

Description of respondents: Persons residing in all counties of Washington State west of the Cascade Mountains, including the Seattle and Tacoma metropolitan areas.

Estimated average number of respondents: 1000 (county sample size proportional county population).

Estimated average number of responses: Each respondent will respond only one time, so the number of responses will be the same as the number of respondents.

Estimated average burden hours per response: 15 minutes.

Frequency of response: 1 time per respondent.

Estimated annual reporting burden: 250 hours.

Dated: July 18, 2000.

Betsy Chittenden,

Information Collection Clearance Officer, WASO Administrative Program Center, National Park Service.

[FR Doc. 00–18544 Filed 7–20–00; 8:45 am]

BILLING CODE 4310–70–M

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion for Native American Human Remains in the Possession of the Ocala National Forest, USDA Forest Service, Tallahassee, FL

AGENCY: National Park Service.

ACTION: Notice.

Notice is hereby given in accordance with provisions of the Native American Graves Protection and Repatriation Act (NAGPRA), 43 CFR 10.9, of the completion of an inventory of human remains in the possession of the Ocala National Forest, USDA Forest Service, Tallahassee, FL. This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 43 CFR 10.2 (c). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations within this notice.

A detailed assessment of the human remains was made by USDA Forest Service professional staff in consultation with representatives of the Miccosukee Tribe of Indians of Florida; the Seminole Nation of Oklahoma; and the Seminole Tribe of Florida, Dania, Big Cypress, Brighton, Hollywood and Tampa Reservations.

In May 1990, human remains representing a minimum of eight individuals were found in a collapsed maintenance shed at Silver Glen Springs, part of the Ocala National Forest. No known individuals were identified. No associated funerary objects are present.

The Silver Glen Springs was acquired by the USDA Forest Service on May 11, 1990. These human remains were discovered prior to the enactment of NAGPRA, and are believed to have been collected from the surrounding area of the maintenance shed during private ownership of the land. The Silver Glen Springs site and surrounding area has been identified as a large, deeply stratified aboriginal occupation site. Based on site location and dental morphology, these individuals have been identified as Native American from the pre-contact period.

Based on the above-mentioned information, officials of the USDA Forest Service have determined that, pursuant to 43 CFR 10.2 (d)(1), the human remains listed above represent

the physical remains of a minimum of eight individuals of Native American ancestry. In accordance with the recommendations of the NAGPRA Review Committee following the April 2–4, 2000 meeting in Juneau, AK, officials of the USDA Forest Service have determined that, pursuant to 43 CFR 10.2 (e), there is no relationship of shared group identity that can reasonably be traced between these Native American human remains and any present-day Indian tribe or group, and the disposition of these Native American human remains will be to the Miccosukee Tribe of Indians of Florida. This notice has been sent to officials of the Miccosukee Tribe of Indians of Florida; the Seminole Nation of Oklahoma; and the Seminole Tribe of Florida, Dania, Big Cypress, Brighton, Hollywood and Tampa Reservations. Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains should contact Rhonda Kimbrough, Heritage Program Manager, National Forests in Florida, 325 John Knox Road, Suite F-100, Tallahassee, FL 32303, telephone (850) 942-9373, before August 21, 2000. Repatriation of the human remains to the Miccosukee Tribe of Indians of Florida may begin after that date if no additional claimants come forward.

Dated: June 22, 2000.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 00–18465 Filed 7–20–00; 8:45 am]

BILLING CODE 4310–70–F

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion for Native American Human Remains in the Possession of the Illinois State Museum, Springfield, IL

AGENCY: National Park Service, DoI.

ACTION: Notice.

Notice is hereby given in accordance with provisions of the Native American Graves Protection and Repatriation Act (NAGPRA), 43 CFR 10.9, of the completion of an inventory of human remains in the possession of the Illinois State Museum, Springfield, IL. This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 43 CFR 10.2 (c). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these Native American human remains. The National Park Service is not responsible for the determinations within this notice.

A detailed assessment of the human remains was made by the Illinois State Museum professional staff in written consultation with representatives of Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California.

Prior to 1962, human remains representing two individuals were collected by an unknown individual in Orange County, CA. The circumstances surrounding the recovery of the remains are unknown. At an unknown date, the remains were donated to the Quincy Museum in Quincy, IL by an unknown individual. In 1991, Dr. John Snow assisted in the transfer of the remains to the Illinois State Museum. No known individuals were identified. No associated funerary objects are present.

The transfer inventory, completed by Dr. Snow, lists one skull (catalog number 100-440) with an associated mandible (catalog number 100-440A) and notes an attached tag. This tag presumably was attached prior to donation to the Quincy Museum. The tag read, ''Shumasha culture Orange Co. Calif.'' The inventory, also completed by Dr. Snow, lists a second skull (catalog number 100-443) with an associated mandible (catalog number 100-443A) and notes an attached tag. This tag also presumably was attached prior to its donation to the Quincy Museum.

The tag read, ''Male Skull Shumash culture Orange, Co. CA.'' The tags are no longer attached to the remains, although one skull has writing on it in several places which reads, ''ORANGE CO. CALIF. 1930.'' The 1930 date may imply the date of the collection.

Based on the above-mentioned information, officials of the Illinois State Museum have determined that, pursuant to 43 CFR 10.2 (d)(1), the human remains listed above represent the physical remains of two individuals of Native American ancestry. Officials of the Illinois State Museum have determined that, pursuant to 43 CFR 10.2 (e), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and the Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California.

This notice has been sent to officials of the Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California. Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains should contact Dr. Robert E. Warren, Associate Curator of Anthropology, Illinois State Museum, 1011 East Ash Street, Springfield, IL, telephone (217) 524-7903, before August 21, 2000. Repatriation of the human remains to the Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California may begin after that date if no additional claimants come forward.

Dated: July 13, 2000.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 00–18461 Filed 7–20–00; 8:45 am]

BILLING CODE 4310–70–F

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion for Native American Human Remains and Associated Funerary Objects From Cass County, IN in the Possession of the Indiana State Museum and Historic Sites, Indianapolis, IN

AGENCY: National Park Service.

ACTION: Notice.

Notice is hereby given in accordance with provisions of the Native American Graves Protection and Repatriation Act (NAGPRA), 43 CFR 10.9, of the completion of an inventory of human remains and associated funerary objects from Cass County, IN in the possession of the Indiana State Museum and Historic Sites, Indianapolis, IN.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 43 CFR 10.2 (c). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these Native American human remains and/or associated funerary objects. The National Park Service is not responsible for the determinations within this notice.

A detailed assessment of the human remains was made by Indiana State Museum and Historic Sites professional staff in consultation with representatives of the Miami Tribe of Oklahoma.

Prior to 1932, human remains representing one individual were recovered from a burial near the town of Walton, Cass County, IN by Noah F. Surface, who donated these human remains to the Indiana State Museum. No known individual was identified. The two associated funerary objects include a pewter pan and a suede leather hair bow with silver discs.

Based on associated funerary objects and skeletal morphology, this

individual has been identified as Native American from the historic period, most likely to the first half of the 19th century. Because the hair bow is typical of the style worn by Miami women during the first half of the 19th century and skeletal morphology, this individual has been identified as an adolescent Miami woman. The burial location, five miles south of the Wabash River, is in an area intensively occupied by the Miami between A.D. 1795-1840.

Based on the above-mentioned information, officials of the Indiana State Museum and Historic Sites have determined that, pursuant to 43 CFR 10.2 (d)(1), the human remains listed above represent the physical remains of one individual of Native American ancestry. Officials of the Indiana State Museum and Historic Sites have also determined that, pursuant to 43 CFR 10.2 (d)(2), the two objects listed above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. Lastly, officials of the Indiana State Museum and Historic Sites have determined that, pursuant to 43 CFR 10.2 (e), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and associated funerary objects and the Miami Tribe of Oklahoma.

This notice has been sent to officials of the Miami Tribe of Oklahoma. Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains and associated funerary objects should contact Bill Wepler, Curator of Anthropology, Indiana State Museum and Historic Sites, 202 North Alabama Street, Indianapolis, IN 46204, telephone (317) 232-8178, before August 21, 2000. Repatriation of the human remains and associated funerary objects to the Miami Tribe of Oklahoma may begin after that date if no additional claimants come forward.

Dated: June 15, 2000.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 00–18464 Filed 7–20–00; 8:45 am]

BILLING CODE 4310–70–F

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion for Native American Human Remains and Associated Funerary Objects in the Control of the Arizona State Office, Bureau of Land Management, Phoenix, AZ

AGENCY: National Park Service, DoI.

ACTION: Notice.

Notice is hereby given in accordance with provisions of the Native American Graves Protection and Repatriation Act (NAGPRA), 43 CFR 10.9, of the completion of an inventory of human remains and associated funerary objects in the control of the Arizona State Office, Bureau of Land Management, Phoenix, AZ. This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 43 CFR 10.2 (c). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations within this notice.

A detailed assessment of the human remains was made by Bureau of Land Management professional staff, Museum of Northern Arizona professional staff, and Arizona State Museum professional staff in consultation with representatives of the Hopi Tribe of Arizona; the Zuni Tribe of the Zuni Reservation, New Mexico; the Navajo Nation, Arizona, New Mexico and Utah; the Yavapai-Prescott Tribe of the Yavapai Reservation, Arizona; the Kaibab Band of Paiute Indians of the Kaibab Indian Reservation, Arizona; the Ak-Chin Indian Community of the Maricopa (Ak-Chin) Indian Reservation, Arizona; the Gila River Indian Community of the Gila River Indian Reservation, Arizona; the Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; the Tohono O'odham Nation of Arizona; the Fort Mohave Indian Tribe of Arizona, California and Nevada; and the Colorado River Indian Tribes of the Colorado River Indian Reservation, Arizona and California.

In 1966, human remains representing 14 individuals were recovered during legally authorized salvage excavations of site AZ A:1:11(MNA) near Littlefield, AZ. No known individuals were identified. The 73 associated funerary objects include ceramics, projectile points, knives, scrapers, a palette, a piece of limonite, and several pieces of worked turquoise, stone, and bone.

Based on ceramics, architecture, and site organization, site AZ A:1:11(MNA) has been identified as a Puebloan habitation occupied during A.D. 1000-1200.

In 1968-1969, human remains representing one individual were recovered during legally authorized salvage excavations of site AZ A:1:12(MNA) near Littlefield, AZ. No known individual was identified. No associated funerary objects are present.

Based on its ceramics, site AZ A:1:12(MNA) has been identified as a Puebloan rock shelter occupied during A.D. 400-1150.

Continuities of ethnographic materials, technology, and architecture indicate affiliation of sites AZ A:1:11(MNA) and AZ A:1:12(MNA) with the present-day Hopi Tribe of Arizona. Oral traditions presented by representatives of the Hopi Tribe of Arizona support affiliation with Puebloan sites in this area of northwestern Arizona.

Based on the above-mentioned information, officials of the Bureau of Land Management have determined that, pursuant to 43 CFR 10.2(d)(1), the human remains listed above represent the physical remains of 15 individuals of Native American ancestry. Officials of the Bureau of Land Management also have determined that, pursuant to 43 CFR 10.2 (d)(2), the 73 objects listed above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. Lastly, officials of the Bureau of Land Management have determined that, pursuant to 43 CFR 10.2 (e), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and associated funerary objects and the Hopi Tribe of Arizona.

In 1977-1978, human remains representing 15 individuals were recovered during legally authorized salvage excavations of sites AZ Q:7:105(MNA) and AZ Q:2:11(MNA) near St. Johns, AZ. No known individuals were identified. The 345 associated funerary objects consist of bone beads and 2 pottery jars.

Based on ceramics, radiocarbon dating, and architecture, these sites have been identified as Puebloan habitations occupied during A.D. 925-1175.

In 1988, human remains representing one individual were recovered during a legally authorized testing and stabilization project at site AZ Q:3:97(ASM), known as Long H Ruin, near St. Johns, AZ. No known

individuals were identified. No associated funerary objects are present.

Based on ceramics, architecture, and site organization, site AZ Q:3:97(ASM) has been identified as a Puebloan habitation dating to approximately A.D. 950-1050.

In 1984–1985, human remains representing three individuals were recovered during legally authorized salvage excavations of sites AZ Q:9:5(ASM), AZ Q:9:26(ASM) and AZ Q:9:30(ASM) near Showlow, AZ. The seven associated funerary objects, all from AZ Q:9:30(ASM), consist of ceramics and a stone axe fragment.

Based on ceramics, architecture, and site organization, these sites have been identified as Puebloan habitations occupied during A.D. 850-1150.

Continuities of ethnographic materials, technology, and architecture indicate affiliation of sites AZ Q:7:105(MNA), AZ Q:2:11(MNA), AZ Q:3:97(ASM), AZ Q:9:5(ASM), AZ Q:9:26(ASM), and AZ Q:9:30(ASM) with the present-day Hopi Tribe of Arizona and the Zuni Tribe of the Zuni Reservation, New Mexico. Oral traditions presented by representatives of the Hopi Tribe of Arizona and the Zuni Tribe of the Zuni Reservation, New Mexico support affiliation with Puebloan sites in this area of northeastern Arizona.

Based on the above-mentioned information, officials of the Bureau of Land Management have determined that, pursuant to 43 CFR 10.2(d)(1), the human remains listed above represent the physical remains of 19 individuals of Native American ancestry. Officials of the Bureau of Land Management also have determined that, pursuant to 43 CFR 10.2 (d)(2), the 352 objects listed above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. Lastly, officials of the Bureau of Land Management have determined that, pursuant to 43 CFR 10.2 (e), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and associated funerary objects and the Hopi Tribe of Arizona and the Zuni Tribe of the Zuni Reservation, New Mexico.

In 1960-1961, human remains representing two individuals were recovered during legally authorized salvage excavations of site AZ T:13:9(ASM) near Gila Bend, AZ. No known individuals were identified. No associated funerary objects are present.

Based on ceramics, architecture, and site organization, site AZ T:13:9(ASM) has been identified as Hohokam.

In 1985, human remains representing six individuals were recovered during legally authorized salvage excavations of sites AZ EE:1:154(ASM) and AZ EE:1:155(ASM) in the Santa Rita Mountains south of Tucson, AZ. No known individuals were identified. The 32 associated funerary objects consist of a pottery jar that contained the remains of one individual at AZ EE:155(ASM), and 22 complete and 9 fragmentary stone disk beads found with the individual at AZ EE:154(ASM).

Based on ceramics, archeomagnetic dating, architecture, and site organization, these sites have been identified as Hohokam habitations occupied during A.D. 700-1000.

Continuities of ethnographic materials, technology, and architecture indicate affiliation of sites AZ T:13:9(ASM), AZ EE:1:154(ASM) and AZ EE:1:155(ASM) with present-day Piman and O'odham cultures. Oral traditions presented by representatives of the Ak-Chin Indian Community of the Maricopa (Ak-Chin) Indian Reservation, Arizona; the Gila River Indian Community of the Gila River Indian Reservation, Arizona; the Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; the Tohono O'odham Nation of Arizona support affiliation with Hohokam sites in southern Arizona.

Based on the above-mentioned information, officials of the Bureau of Land Management have determined that, pursuant to 43 CFR 10.2(d)(1), the human remains listed above represent the physical remains of eight individuals of Native American ancestry. Officials of the Bureau of Land Management also have determined that, pursuant to 43 CFR 10.2 (d)(2), the 32 objects listed above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. Lastly, officials of the Bureau of Land Management have determined that, pursuant to 43 CFR 10.2 (e), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and associated funerary objects and the Ak-Chin Indian Community of the Maricopa (Ak-Chin) Indian Reservation, Arizona; the Gila River Indian Community of the Gila River Indian Reservation, Arizona; the Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; the Tohono O'odham Nation of Arizona.

In 1983 and 1985, human remains representing three individuals were recovered during legally authorized salvage excavations of site AZ U:15:109(ASM) at Florence, AZ. No known individuals were identified. The 72 associated funerary objects include ceramics, a shell pendant, animal bone fragments, a limonite crystal, and stone flakes.

Based on ceramics, site AZ U:15:109(ASM) has been identified as Hohokam. One of the burials was radiocarbon dated at A.D. 955-1135.

Between 1965–1974, human remains representing seven individuals were recovered from site AZ V:13:196(ASM) in the Dripping Spring Mountains south of Globe, AZ. No known individual was identified. No associated funerary objects are present.

Based on ceramics, site AZ V:13:196(ASM) has been recorded as Salado, dating from approximately A.D. 1200-1450.

Continuities of ethnographic materials, technology, and architecture indicate affiliation of sites AZ U:15:109(ASM) and AZ V:13:196(ASM) with present-day Piman, O'odham and Puebloan cultures. Oral traditions presented by representatives of the Ak-Chin Indian Community of the Maricopa (Ak-Chin) Indian Reservation, Arizona; the Gila River Indian Community of the Gila River Indian Reservation, Arizona; the Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; the Tohono O'odham Nation of Arizona; the Hopi Tribe of Arizona; and the Zuni Tribe of the Zuni Reservation, New Mexico support affiliation with Hohokam and Salado sites in central Arizona.

Based on the above-mentioned information, officials of the Bureau of Land Management have determined that, pursuant to 43 CFR 10.2(d)(1), the human remains listed above represent the physical remains of 10 individuals of Native American ancestry. Officials of the Bureau of Land Management also have determined that, pursuant to 43 CFR 10.2 (d)(2), the 72 objects listed above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. Lastly, officials of the Bureau of Land Management have determined that, pursuant to 43 CFR 10.2 (e), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and associated funerary objects and the Ak-Chin Indian Community of the Maricopa (Ak-Chin) Indian Reservation, Arizona; the Gila River Indian Community of the Gila River Indian Reservation, Arizona; the Salt River Pima-Maricopa Indian Community of the Salt River

Reservation, Arizona; the Tohono O'odham Nation of Arizona; the Hopi Tribe of Arizona; and the Zuni Tribe of the Zuni Reservation, New Mexico.

In 1987, human remains representing three individuals were recovered during legally authorized salvage excavations of site AZ EE:9:107(ASM) in Nogales, AZ. No known individuals were identified. No associated funerary object are present.

Based on ceramics and architecture, site AZ EE:9:107(ASM) was identified as a Hohokam village, dating to A.D. 700-1200.

In 1988, human remains representing two individuals were recovered during legally authorized salvage excavations of site AZ EE:4:9(BLM) along the San Pedro River near Fairbank, AZ. No known individuals were identified. No associated funerary objects are present.

Based on artifacts and site organization, site AZ EE:4:9(BLM) was identified as Sobaipuri.

Continuities of ethnographic materials, technology, and architecture indicate affiliation of sites AZ EE:9:107(ASM) and AZ EE:4:9(BLM) with present-day Piman and O'odham cultures. Oral traditions presented by representatives of the Ak-Chin Indian Community of the Maricopa (Ak-Chin) Indian Reservation, Arizona; the Gila River Indian Community of the Gila River Indian Reservation, Arizona; the Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; and the Tohono O'odham Nation of Arizona support affiliation with Hohokam and Sobaipuri sites in southern Arizona.

Based on the above-mentioned information, officials of the Bureau of Land Management have determined that, pursuant to 43 CFR 10.2(d)(1), the human remains listed above represent the physical remains of five individuals of Native American ancestry. Officials of the Bureau of Land Management also have determined that, pursuant to 43 CFR 10.2 (e), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and the Ak-Chin Indian Community of the Maricopa (Ak-Chin) Indian Reservation, Arizona; the Gila River Indian Community of the Gila River Indian Reservation, Arizona; the Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; and the Tohono O'odham Nation of Arizona.

In 1988, human remains representing one individual were recovered during legally authorized salvage excavations of site AZ M:15:5(BLM) near Smith Peak in southwestern Yavapai County, AZ. No known individuals were identified. No associated funerary objects are present.

The remains were radiocarbon dated to A.D. 930-1000. Based on age, location, and artifacts, site AZ M:15:5(BLM) was identified as Patayan.

Continuities of ethnographic materials and technology indicate affiliation of site AZ M:15:5(BLM) with present-day Yuman tribes along the Colorado River. Oral traditions presented by representatives of the Fort Mohave Indian Tribe and the Colorado River Indian Tribes support this affiliation.

Based on the above-mentioned information, officials of the Bureau of Land Management have determined that, pursuant to 43 CFR 10.2(d)(1), the human remains listed above represent the physical remains of one individual of Native American ancestry. Officials of the Bureau of Land Management also have determined that, pursuant to 43 CFR 10.2 (e), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and the Fort Mohave Indian Tribe of Arizona, California and Nevada; and the Colorado River Indian Tribes of the Colorado River Indian Reservation, Arizona and California.

This notice has been sent to officials of the Hopi Tribe of Arizona; the Zuni Tribe of the Zuni Reservation, New Mexico; the Navajo Nation, Arizona, New Mexico and Utah; the Yavapai-Prescott Tribe of the Yavapai Reservation, Arizona; the Kaibab Band of Paiute Indians of the Kaibab Indian Reservation, Arizona; the Ak-Chin Indian Community of the Maricopa (Ak-Chin) Indian Reservation, Arizona; the Gila River Indian Community of the Gila River Indian Reservation, Arizona; the Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; the Tohono O'odham Nation of Arizona; the Fort Mohave Indian Tribe of Arizona, California and Nevada; and the Colorado River Indian Tribes of the Colorado River Indian Reservation, Arizona and California. Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains and associated funerary objects should contact Gary Stumpf, Bureau of Land Management, Arizona State Office, 222 North Central Avenue, Phoenix, AZ 85004, telephone (602) 417-9509, before August 21, 2000. Repatriation of the human remains and associated funerary objects to the respective culturally affiliated Indian tribes may begin after that date if no additional claimants come forward.

Dated: June 13, 2000.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 00–18460 Filed 7–20–00; 8:45 am]

BILLING CODE 4310–70–F

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion for Native American Human Remains and Associated Funerary Objects From Alaska in the Control of the Alaska State Office, Bureau of Land Management, Anchorage, AK

AGENCY: National Park Service.

ACTION: Notice.

Notice is hereby give in accordance with provisions of the Native American Graves Protection and Repatriation Act (NAGPRA) 43 CFR 10.9, of the completion of an inventory of human remains and associated funerary objects in the control of the Alaska State Office, Bureau of Land Management, Anchorage, AK. This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 43 CFR 10.2 (c). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations within this notice.

A detailed assessment of the human remains was made by the Bureau of Land Management and Haffenreffer Museum of Anthropology, Brown University professional staff in consultation with representatives of the Native Village of Kotzebue.

During 1956-61, human remains representing 49 individuals were collected or excavated by Dr. J. Louis Giddings under a Federal permit from a series of burials at Cape Krusenstern, Battle Rock Site vicinity, and the Choris Peninsula. These human remains are curated at the Haffenreffer Museum of Anthropology in Bristol, RI. No known individuals were identified. The 387 associated funerary objects include projectile points, scrapers, knives, flake tools, flakes, side and end blade insets, an adze head, a split bone piercer, an ivory handle, a whale and seal head carving, antler arrowheads and arrowhead fragments, 1 potsherd, 4 wooden mask fragments, 1 walrus bone pick, animal bones and teeth, and 2 blue feathers.

Based on skeletal morphology, geographic location, and associated objects, these individuals have been identified as Native American, affiliated with Inupiat Eskimo culture and specifically with the Native Village of Kotzebue. This determination of cultural affiliation has been based upon the continuity of Native Americans in the Kotzebue area and their oral tradition that the area where the remains were found is within their traditional territory.

Based on the above-mentioned information, officials of the Bureau of Land Management have determined that, pursuant to 43 CFR 10.2 (d)(1), the human remains listed above represent the physical remains of 49 individuals of Native American ancestry. Officials of the Bureau of Land Management also have determined that, pursuant to 43 CFR 10.2 (d)(2), the 387 objects listed above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. Lastly, officials of the Bureau of Land Management have determined that, pursuant to 43 CFR 10.2 (e), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and associated funerary objects and the Native Village of Kotzebue. This notice has been sent to officials of the Native Village of Kotzebue. Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains and associated funerary objects should contact Dr. Robert E. King, Alaska State NAGPRA Coordinator, Bureau of Land Management, 222 West 7th Avenue, ı13, Anchorage, AK 99513-7599, telephone (907) 271-5510, before August 21, 2000. Repatriation of the human remains and associated funerary objects to the Native Village of Kotzebue may begin after that date if no additional claimants come forward.

Dated: June 17, 2000.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 00–18463 Filed 7–20–00; 8:45 am]

BILLING CODE 4310–70–F

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion for Native American Human Remains and Associated Funerary Objects in the Control of the Nevada State Office, Bureau of Land Management, Reno, NV

AGENCY: National Park Service.

ACTION: Notice.

Notice is hereby given in accordance with provisions of the Native American Graves Protection and Repatriation Act (NAGPRA), 43 CFR 10.9, of the completion of an inventory of human remains and associated funerary objects in the control of the Nevada State Office, Bureau of Land Management, Reno, NV. This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 43 CFR 10.2 (c). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations within this notice.

A detailed assessment of the human remains was made by the Nevada State Office Bureau of Land Management professional staff in consultation with representatives of the Pyramid Lake Paiute Tribe of the Pyramid Lake Reservation, Nevada.

In 1961, human remains representing four individuals were recovered from Kramer Cave in Washoe County, NV, during a legally permitted archeological excavation by R. Shutler, Jr. and D. R. Touhy, of the Nevada State Museum. The remains and associated funerary items have been curated at the Nevada State Museum since that time. No known individuals were identified. The four associated funerary items consist of small fragments of tule cordage, grass matting warps and wefts, and basketry warps and wefts.

Historical, ethnographic, and oral records indicate that these human remains and associated funerary objects are reasonably believed to be associated with the Northern Paiute Tribes. Historical documents, ethnographic sources, and consultation with representatives of the Pyramid Lake Paiute Tribe of the Pyramid Lake Reservation, Nevada indicate that the Pyramid Lake Paiute Tribe of the Pyramid Lake Reservation, Nevada has occupied this area since at least the early 19th century. The tribe's oral history supports this affiliation.

Based on the above-mentioned information, officials of the Bureau of Land Management, Nevada State Office have determined that, pursuant to 43 CFR 10.2 (d)(1), the human remains listed above represent the physical remains of four individuals of Native American ancestry. Officials of the Bureau of Land Management, Nevada State Office also have determined that, pursuant to 43 CFR 10.2 (d)(2), the cultural objects listed above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. Lastly, officials of the Bureau of Land Management, Nevada State Office has determined that, pursuant to 43 CFR 10.2 (e), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and associated funerary objects and the Pyramid Lake Paiute Tribe of the Pyramid Lake Reservation, Nevada.

This notice has been sent to officials of the Pyramid Lake Paiute Tribe of the Pyramid Lake Reservation, Nevada; the Paiute-Shoshone Tribe of the Fallon Reservation and Colony, Nevada; the Lovelock Paiute Tribe of the Lovelock Indian Colony, Nevada; the Walker River Paiute Tribe of the Walker River Reservation, Nevada; the Yerington Paiute Tribe of the Yerington Colony and Campbell Ranch, Nevada; and the Fort McDermitt Paiute and Shoshone Tribes of the Fort McDermitt Indian Reservation, Nevada and Oregon. Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains and associated funerary objects should contact Cynthia Ellis, NAGPRA Coordinator, Nevada State Office, Bureau of Land Management, P.O. Box 12000, Reno, NV, 89520-0006, telephone (775) 861-6469, before August 21, 2000. Repatriation of the human remains and associated funerary objects to the Pyramid Lake Paiute Tribe of the Pyramid Lake Reservation, Nevada may begin after that date if no additional claimants come forward.

Dated: June 14, 2000.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 00–18466 Filed 7–20–00; 8:45 am]

BILLING CODE 4310–70–F

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion for Native American Human Remains From Hawaii in the Possession of the Peabody Essex Museum, Salem, MA

AGENCY: National Park Service, DoI.

ACTION: Notice.

Notice is hereby given in accordance with provisions of the Native American Graves Protection and Repatriation Act (NAGPRA), 43 CFR 10.9, of the completion of an inventory of human remains from Hawaii in the possession of the Peabody Essex Museum, Salem, MA. This notice is being published as part of the National Park Service's administrative responsibilities under NAGPRA, 43 CFR 10.2 (c). The determinations within this notice are the sole responsibility of the museum, institution, or Federal Agency who has control of these Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations within this notice.

A detailed assessment of the human remains was made by Peabody Essex Museum professional staff in consultation with representatives of Hui Malama I Na Kupuna O Hawai'i Nei, Ka Lahui Hawai'i, and the Office of Hawaiian Affairs.

In 1800, human remains representing one individual in the form of a fish hook from Hawaii were donated to the Peabody Essex Museum by John Derby. No known individual was identified. No associated funerary objects are present.

In 1802, human remains representing one individual in the form of a fish hook from Hawaii were donated to the Peabody Essex Museum by Captain William Bunker. No known individual was identified. No associated funerary objects are present.

In 1916, human remains representing one individual in the form of a fish hook from Hawaii were donated to the Peabody Essex Museum by the Museum of the American Indian (Heye Foundation). No known individual was identified. No associated funerary objects are present.

In 1922, human remains representing one individual in the form of a fish hook from Hawaii were depositied with the Peabody Essex Museum by the Worcester Historical Society. In 1996, these human remains were gifted to the Peabody Essex Museum by the Worcester Historical Society. No known individual was identified. No associated funerary objects are present.

Before 1868, human remains representing one individual in the form of a fish hook were collected from Hawaii by Rev. Asa Thurston. In 1925, these human remains were donated to the Peabody Essex Museum by Stephen W. Phillips. No known individual was identified. No associated funerary objects are present.

Between 1928–1932, human remains representing three individuals in the forms of two fish hooks and a fishing net needle were collected from Hawaii by F. Walter Bergmann. In 1957, these human remains were donated to the Peabody Essex Museum by F. Walter Bergmann. No known individuals were identified. No associated funerary objects are present.

Consultation evidence presented by representatives of Hui Malama I Na Kupuna O Hawai'i Nei indicates these objects are human remains.

Based on the above mentioned information, officials of the Peabody Essex Museum have determined that, pursuant to 43 CFR 10.2 (d)(1), the human remains listed above represent the physical remains of at least eight individuals of Native American ancestry. Officials of the Peabody Essex Museum have determined that, pursuant to 43 CFR 10.2 (e), there is a relationship of shared group identity which can be reasonably traced between these Native American human remains and Hui Malama I Na Kupuna O Hawai'i Nei, Ka Lahui Hawai'i, and the Office of Hawaiian Affairs.

This notice has been sent to officials of the Hui Malama I Na Kupuna O Hawai'i Nei, Ka Lahui Hawai'i, and the Office of Hawaiian Affairs. Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains should contact Christina Hellmich, Director of Collections Management, Peabody Essex Museum, East India Square, Salem, MA 01970; telephone (978) 745–1876, facimile (978) 744–003, before August 21, 2000. Repatriation of the human remains to Hui Malama I Na Kupuna O Hawai'i Nei, Ka Lahui Hawai'i, and the Office of Hawaiian Affairs may begin after that date if no additional claimants come forward.

Dated: June 13, 2000.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 00–18462 Filed 7–20–00; 8:45 am]

BILLING CODE 4310–70–F

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion for Native American Human Remains in the Possession of the Washington State Historical Society, Tacoma, WA

AGENCY: National Park Service.

ACTION: Notice.

Notice is hereby given in accordance with provisions of the Native American Graves Protection and Repatriation Act (NAGPRA), 43 CFR 10.9, of the completion of an inventory of human remains in the possession of the Washington State Historical Society, Tacoma, WA. This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 43 CFR 10.2 (c). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations within this notice.

A detailed assessment of the human remains was made by Washington State Historical Society professional staff in consultation with representatives of the Puyallup Tribe of the Puyallup Reservation, Washington.

At an unknown date, human remains representing four individuals came into the collection of the Washington State Historical Society through unknown circumstances. No known individuals were identified. No associated funerary objects are present.

No museum documentation exists to identify the origin of these human remains, and all identified possible donors of these human remains are now deceased. Based on skeletal morphology, these individuals have been identified as Native American.

Based on the above-mentioned information, officials of the Washington State Historical Society have determined that, pursuant to 43 CFR 10.2 (d)(1), the human remains listed above represent the physical remains of four individuals of Native American ancestry. Officials of the Washington State Historical Society have further determined that, pursuant to 43 CFR 10.2 (e), there is no relationship of shared group identity that can be reasonably traced between these Native American human remains and any Indian tribe. Pursuant to the NAGPRA Review Committee's recommendations at the April 2–4, 2000 meeting in Juneau, AK, officials of the Washington

State Historical Society are proceeding with the repatriation of these Native American human remains to the Puyallup Tribe of the Puyallup Reservation, Washington. This notice has been sent to officials of the Puyallup Tribe of the Puyallup Reservation, Washington. Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains should contact Lynette Miller, Curator, Washington State Historical Society, 315 North Stadium Way, Tacoma, WA 98403, telephone (253) 798-5925, before August 21, 2000. Repatriation of the human remains to the Puyallup Tribe of the Puyallup Reservation, Washington may begin after that date if no additional claimants come forward.

Dated: June 19, 2000.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 00–18467 Filed 7–20–00; 8:45 am]

BILLING CODE 4310–70–F

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Quarterly Status Report of Water Service, Repayment, and Other Water-Related Contract Negotiations

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice.

SUMMARY: Notice is hereby given of proposed contractual actions that are new, modified, discontinued, or completed since the last publication of this notice on April 19, 2000. The January 21, 2000, notice should be used as a reference point to identify changes. This annual notice should be used as a point of reference to identify changes in future notices. This notice is one of a variety of means used to inform the public about proposed contractual actions for capital recovery and management of project resources and facilities. Additional Bureau of Reclamation (Reclamation) announcements of individual contract actions may be published in the **Federal Register** and in newspapers of general circulation in the areas determined by Reclamation to be affected by the proposed action. Announcements may be in the form of news releases, legal notices, official letters, memorandums, or other forms of written material. Meetings, workshops, and/or hearings may also be used, as appropriate, to provide local publicity. The public participation procedures do not apply to proposed contracts for sale of surplus or interim irrigation water for a term of 1 year or less. Either of the contracting parties may invite the public to observe contract proceedings. All public participation procedures will be coordinated with those involved in complying with the National Environmental Policy Act.

ADDRESSES: The identity of the approving officer and other information pertaining to a specific contract proposal may be obtained by calling or writing the appropriate regional office at the address and telephone number given for each region in the supplementary information.

FOR FURTHER INFORMATION CONTACT: Sandra L. Simons, Manager, Water Contracts and Repayment Office, Bureau of Reclamation, PO Box 25007, Denver, Colorado 80225–0007; telephone 303–445–2902.

SUPPLEMENTARY INFORMATION: Pursuant to section 226 of the Reclamation Reform Act of 1982 (96 Stat. 1273) and 43 CFR 426.20 of the rules and regulations published in 52 FR 11954, Apr. 13, 1987, Reclamation will publish notice of the proposed or amendatory contract actions for any contract for the delivery of project water for authorized uses in newspapers of general circulation in the affected area at least 60 days prior to contract execution. Pursuant to the ''Final Revised Public Participation Procedures'' for water resource-related contract negotiations, published in 47 FR 7763, Feb. 22, 1982, a tabulation is provided of all proposed contractual actions in each of the five Reclamation regions. Each proposed action is, or is expected to be, in some stage of the contract negotiation process in 2000. When contract negotiations are completed, and prior to execution, each proposed contract form must be approved by the Secretary of the Interior, or pursuant to delegated or redelegated authority, the Commissioner of Reclamation or one of the regional directors. In some instances, congressional review and approval of a report, water rate, or other terms and conditions of the contract may be involved.

Public participation in and receipt of comments on contract proposals will be facilitated by adherence to the following procedures:

1. Only persons authorized to act on behalf of the contracting entities may negotiate the terms and conditions of a specific contract proposal.

2. Advance notice of meetings or hearings will be furnished to those parties that have made a timely written request for such notice to the appropriate regional or project office of Reclamation.

3. Written correspondence regarding proposed contracts may be made available to the general public pursuant to the terms and procedures of the Freedom of Information Act (80 Stat. 383), as amended.

4. Written comments on a proposed contract or contract action must be submitted to the appropriate regional officials at the locations and within the time limits set forth in the advance public notices.

5. All written comments received and testimony presented at any public hearings will be reviewed and summarized by the appropriate regional office for use by the contract approving authority.

6. Copies of specific proposed contracts may be obtained from the appropriate regional director or his designated public contact as they become available for review and comment.

7. In the event modifications are made in the form of a proposed contract, the appropriate regional director shall determine whether republication of the notice and/or extension of the comment period is necessary.

Factors considered in making such a determination shall include, but are not limited to: (i) The significance of the modification, and (ii) the degree of public interest which has been expressed over the course of the negotiations. As a minimum, the regional director shall furnish revised contracts to all parties who requested the contract in response to the initial public notice.

Acronym Definitions Used Herein

(BON) Basis of Negotiation
(BCP) Boulder Canyon Project
(CAP) Central Arizona Project
(CUP) Central Utah Project
(CVP) Central Valley Project
(CRSP) Colorado River Storage Project
(D&MC) Drainage and Minor Construction
(FR) Federal Register
(IDD) Irrigation and Drainage District
(ID) Irrigation District
(M&I) Municipal and Industrial
(NEPA) National Environmental Policy Act
(O&M) Operation and Maintenance
(P-SMBP) Pick-Sloan Missouri Basin Program
(PPR) Present Perfected Right
(RRA) Reclamation Reform Act
(R&B) Rehabilitation and Betterment
(SOD) Safety of Dams
(SRPA) Small Reclamation Projects Act
(WCUA) Water Conservation and Utilization Act

(WD) Water District

Pacific Northwest Region: Bureau of Reclamation, 1150 North Curtis Road, Suite 100, Boise, Idaho 83706–1234, telephone 208–378–5346.

Completed contract action:

13. Okanogan ID, Okanogan Project, Washington: SOD contract to repay District's share of cost of dam safety repairs to Salmon Lake Dam. Contract executed July 2000.

Mid-Pacific Region: Bureau of Reclamation, 2800 Cottage Way, Sacramento, California 95825–1898, telephone 916–978–5250.

New contract actions:

38. Banta-Carbona and The West Side IDs, CVP, California: Assignment of 5,000 acre-feet of each district's water service contract to the City of Tracy. The assignment will require approval of the Districts' CVP irrigation water to M&I water.

39. Friant Water Users Authority and San Luis and Delta-Mendota Water Authority, CVP, California: Amendments to the Operation, Maintenance, and Replacement and Certain Financial and Administrative Activities' Agreements to implement certain changes to the Direct Funding provisions to comply with applicable Federal law.

40. Monterey County Water Resources Agency, SRPA, California: Proposed contract amendment to provide for deferral of installments of construction charges under a SRPA loan repayment contract.

41. Monterey Regional Water Pollution Control Agency, SRPA, California: Proposed contract amendment to provide for deferral of installments of construction charges under a SRPA loan repayment contract.

Modified contract actions:

1. Irrigation water districts, individual irrigators, M&I and miscellaneous water users, Mid-Pacific Region projects other than CVP: Temporary (interim) water service contracts for available Project water for irrigation, M&I, or fish and wildlife purposes providing up to 10,000 acre-feet of water annually for terms up to 5 years; temporary Warren Act contracts for use of Project facilities for terms up to 1 year; temporary conveyance agreements with the State of California for various purposes; long-term contracts for similar service for up to 1,000 acre-feet annually. **Note.** Copies of the standard forms of temporary water service contracts for the various types of service are available upon written request from the Regional Director at the address shown above.

3. Redwood Valley County WD, SRPA, California: Restructuring the repayment schedule pursuant to Public Law 100–516.

21. Horsefly, Klamath, Langell Valley, and Tulelake IDs, Klamath Project, Oregon: Repayment contract for SOD work on Clear Lake Dam.

31. Tehama-Colusa Canal Authority, CVP, California: Amendment of existing long-term O&M agreement to also include the O&M of the Red Bluff Diversion Dam and related facilities and to implement certain changes to the Direct Funding provisions of the O&M Agreement to comply with applicable Federal law.

Completed contract action:

28. Contra Costa WD, CVP, California: Amend water service contract No. I75r-3401 for the purpose of renegotiating the provisions of contract Article 12, ''Water Shortage and Apportionment,'' to conform to current CVP M&I water shortage policy. Contract executed February 7, 2000.

Lower Colorado Region: Bureau of Reclamation, PO Box 61470 (Nevada Highway and Park Street), Boulder City, Nevada 89006–1470, telephone 702–293–8536.

New contract actions:

61. Gila River Farms, Arizona: Amendment of SRPA contract to restructure the repayment schedule.

62. Central Arizona Water Conservation District, CAP, Arizona: Agreement for delivery of CAP excess water to the Gila River Indian Community and the San Carlos IDD in exchange for San Carlos reservoir water.

63. Lichfield Park Service Company, CAP, Arizona: Proposed assignments of 5,580 acre-feet of CAP M&I water to the Central Arizona Groundwater Replenishment District and to the cities of Avondale, Carefree, and Goodyear.

64. Shepard Water Company, Inc., Arizona: Contract for the delivery of 50 acre-feet of domestic water.

Modified contract action:

28. Arizona State Land Department, BCP, Arizona: Colorado River water delivery contract for 1,535 acre-feet per year for domestic use.

Discontinued contract action:

50. Litchfield Park Service Company, CAP, Arizona: Assignment of 1,200 acre-feet per year of CAP M&I water to the City of Scottsdale.

Completed contract actions:

35. Bureau of Land Management, BCP, Arizona: Agreement for 4,010 acre-feet per year of Colorado River water in accordance with Secretarial Reservations.

39. McMicken ID, CAP, Arizona: Assignment of 486 acre-feet of M&I water per year to the City of Peoria.

53. Arizona State Land Department, CAP, Arizona: Assignment of 1,500 acre-feet per year of CAP water from the Arizona State Land Department to the City of Mesa.

Upper Colorado Region: Bureau of Reclamation, 125 South State Street, Room 6107, Salt Lake City, Utah 84138–1102, telephone 801–524–4419.

Discontinued contract action:

4. William Nielson, Dolores Project, Colorado: Carriage contract with William Nielson to carry up to 1.5 cfs of non-project water in project facilities under the authority of the Warren Act of 1911. Contract is not being pursued.

Completed contract action:

18. Mancos Water Conservancy District, Mancos Project, Colorado: Amendment to repayment contract with the District to increase the farm unit size (for acreage limitation purposes) from 160 to 750 acres, pursuant to the WCUA of 1939. Amendatory contract signed.

Great Plains Region: Bureau of Reclamation, PO Box 36900, Federal Building, 316 North 26th Street, Billings, Montana 59107–6900, telephone 406–247–7730.

Modified contract actions:

3. Ruedi Reservoir, Fryingpan-Arkansas Project, Colorado: Second round water sales from the regulatory capacity of Ruedi Reservoir. Water service and repayment contracts for up to 17,000 acre-feet annually for M&I use; contract with Colorado Water Conservation Board and the U.S. Fish and Wildlife Service for 10,825 acre-feet for endangered fishes.

9. Angostura ID, Angostura Unit, P-SMBP, South Dakota: The District had a contract for water service which expired on December 31, 1995. An interim 3-year contract provided for a continuing water supply and the District to O&M the dam and reservoir. The proposed long-term contract would provide a continued water supply for the District and the District's continued O&M of the facility. A BON is currently being developed for a long-term contract. Another interim 3-year contract was executed on June 9, 2000, to provide for a continuing water supply and allow adequate time for completion of the Environmental Impact Statement for long-term contract renewal.

11. P–SMBP, Kansas and Nebraska: Anticipate executing the long-term water supply renewal contracts with Kansas-Bostwick, Bostwick in Nebraska, Frenchman Valley, Frenchman-Cambridge, and Almena IDs by the end of July 2000. The renewed long-term water service contracts will take effect January 1, 2001. A Notice of Availability for Draft Contracts was published on May 16, 2000. A Notice of Availability for the FEIS was published on June 19, 2000.

14. P-SMBP, Kansas: Water service contracts with Kirwin and Webster IDs in the Solomon River Basin in Kansas were extended for a period of 4 years in accordance with Public Law 104–326 enacted October 19, 1996. Water service contracts will be renewed prior to expiration.

21. Lower Marias Unit, P-SMBP, Montana: Water service contract expires in July 2000. Initiating renewal of existing contract for 25 years for up to 480 acre-feet of storage from Tiber Reservoir to irrigate 160 acres. Received approved BON from the Commissioner. Currently performing a water availability study and consulting with the Tribes regarding the Water Rights Compact. A 1-year interim contract will be issued to continue delivery of water until the necessary actions can be completed to renew a long-term contract.

22. Lower Marias Unit, P-SMBP, Montana: Initiating 25-year water service contract for up to 750 acre-feet of storage from Tiber Reservoir to irrigate 250 acres. A 1-year temporary contract has been issued to allow additional time to complete necessary actions required for the long-term contract. Another 1-year temporary has been issued to continue delivery of water until the long-term renewal process can be completed.

23. Lower Marias Unit, P-SMBP, Montana: Water service contract expired May 2000. Initiating renewal of existing long-term contract for 25 years for up to 4,570 acre-feet of storage from Tiber Reservoir to irrigate 2,285 acres. Currently performing a water availability study and consulting with the Tribes regarding the Water Rights Compact. A 1-year interim contract has been issued to continue delivery of water until the necessary actions can be completed to renew the long-term contract. Another 1-year temporary will be issued to continue delivery of water until the long-term renewal process can be completed.

25. Savage ID, P-SMBP, Montana: A second interim contract has been entered into with the District. The District is currently seeking Title Transfer. The contract is subject to renewal on an annual basis pending outcome of the title transfer process.

29. Fryingpan-Arkansas Project, Colorado: Pueblo Board of Water Works, long-term storage contract.

31. Canyon Limited Liability (Individual), P-SMBP, Boysen Unit, Wyoming: Contract for up to 16 acre-feet of supplemental irrigation water to service 4 acres.

34. Tom Green County and Improvement District No. 1, San Angelo Project, Texas: The irrigation district has requested a deferment of its 2000 construction payment. The deferment has been approved by the Secretary of the Interior. A public notice for this action was printed in the San Angelo Times. The 60-day comment period ends July 3, 2000.

42. Fryingpan-Arkansas Project, Colorado: Pueblo Board of Water Works, long-term conveyance contract.

4. *Completed contract action:*

13. Fort Shaw ID, Sun River Project, Montana: Contract for SOD costs for repairs to Willow Creek Dam. The proposed contract for the emergency repairs has been combined with the contract for repayment of additional SOD work as outlined in the approval memorandum dated November 17, 1999. Contract executed January 10, 2000.

Dated: July 17, 2000.

Wayne O. Deason,

Associate Director, Office of Policy.

[FR Doc. 00–18488 Filed 7–20–00; 8:45 am]

BILLING CODE 4310–MN–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–395]

In the Matter of Certain Eprom, Eeprom, Flash Memory, and Flash Microcontroller Semiconductor Devices and Products Containing Same; Notice of Commission Determination To Review-in-Part an Initial Determination on Inventorship and Two Orders; Schedule for Filing Written Submissions; Denial of Motion for Leave To File a Reply

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review-in-part the final initial determination (ID) issued by the presiding administrative law judge (ALJ) on May 17, 2000, and two ALJ orders in proceedings to reconsider the Commission's determination on inventorship in the above-captioned investigation, which was instituted pursuant to section 337 of the Tariff Act of 1930, 19 U.S.C. 1337. Specifically, the Commission has determined to review: (1) ALJ Order No. 50, (2) ALJ Order No. 69, (3) the determination in the ID that the Certificate of Correction of U.S. Letters Patent 4,451,903 (the '903 patent) was procured inequitably, and (4) the determination in the ID that the inventors named on the Certificate of Correction of the '903 patent are incorrect. The Commission has also determined to deny complainant Atmel Corp.'s Motion for Leave to File a Reply, dated June 22, 2000.

FOR FURTHER INFORMATION CONTACT: Jean Jackson, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone 202–205–3104. General information concerning the Commission may also be obtained by accessing its Internet server (http://www.usitc.gov). Hearing-impaired persons are advised that information on the matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this patent-based investigation on March 18, 1997, based on a complaint filed by Atmel Corp. 62 FR 13706. The complaint named five respondents: Sanyo Electric Co., Ltd. of Japan; Winbond Electronics Corp. of Taiwan and Winbond Electronics North America Corporation of San Jose, California; and Macronix International Co., Ltd. of Taiwan and Macronix America, Inc. of San Jose, California. Silicon Storage Technology, Inc. was permitted to intervene in the investigation.

In its complaint, Atmel alleged that the respondents violated section 337 by importing into the United States, selling for importation, and/or selling in the United States after importation certain electronic products and/or components that infringe one or more of claim 1 of U.S. Letters Patent 4,511,811, (the '811 patent), claim 1 of U.S. Letters Patent 4,673,829 (the '829 patent), claims 1–9 of the '903 patent, and claim 1 of U.S. Letters Patent 4,974,565 (the '565 patent). The '565 patent was later withdrawn from the investigation by Atmel.

The ALJ issued his final ID on violation on March 19, 1998, in which he found, *inter alia,* no infringement of any of the three patents at issue, and hence no violation of section 337. The Commission reviewed the entire ID, except for the finding that claims 2–8 of the '903 patent are invalid as indefinite. After review, the Commission issued its final determination on July 2, 1998, in which it determined that the '903 patent was unenforceable for failure to name one or more co-inventors. The Commission also found that the '811 and '829 patents were invalid on the basis of collateral estoppel in light of a U.S. district court decision. 69 FR 37139 (July 9, 1998). The Federal Circuit reversed the district court decision on December 28, 1999. *Atmel Corp.* v.

Information Storage Device Inc., Appeal No. 99–1082 (Fed. Cir. 1999). Therefore, the Commission will revisit its decision concerning the '811 and '829 patents in connection with the final disposition of this investigation.

On August 21, 1998, Atmel filed a petition for correction of inventorship of the '903 patent with the U.S. Patent and Trademark Office (PTO) under PTO rule 324, 37 CFR 1.324. Atmel sought to add Anil Gupta as a co-inventor. After an *ex parte* proceeding, the PTO granted Atmel's petition on August 28, 1998. A Certificate of Correction issued from the PTO on October 6, 1998, which states that ''it is hereby certified that the correct inventorship of [the '903] patent is: Larry T. Jordan and Anil Gupta.'' On August 28, 1998, Atmel filed a notice of appeal with the U.S. Court of Appeals for the Federal Circuit from the Commission's July 2, 1998, final determination in this investigation (Appeal No. 98–1580). The appeal was remanded to the Commission on April 16, 1999, *In re Winbond Electronics Corporation and Winbond Electronics North America Corporation,* Misc. Docket No. 579, to consider a motion filed by Atmel for reconsideration of the Commission's inventorship determination in light of the Certificate of Correction of the '903 patent issued by the PTO.

On July 20, 1999, the ALJ issued Order No. 50 which ordered Atmel to produce documents, for which it had claimed privilege, concerning the subject of ''proper inventorship'' of the '903 patent and to provide substantive answers to interrogatories requesting the substance of oral communications between Atmel employees and Atmel's attorneys on the ''proper inventorship'' of the '903 patent. ALJ Order No. 69, which issued on January 13, 2000, held that Atmel bore the burden of proof by clear and convincing evidence that the inventors shown on the Certificate of Correction are the actual inventors.

The ALJ issued his final ID on the inventorship on May 17, 2000. The ID found (1) that Atmel had committed inequitable conduct in the procurement of the Certificate of Correction, (2) that the inventors listed on the Certificate of Correction were not the correct inventors, and (3) that no inequitable conduct was shown to have taken place in the prosecution of the original patent application. On May 30, 2000, Atmel petitioned for review of ALJ Orders Nos. 50 and 69 and the ALJ's refusal in the ID to find that respondents and intervenor were judicially estopped from challenging that Anil Gupta was a co-inventor. Atmel also petitioned for review of the ALJ's rulings in the ID that Atmel had committed inequitable conduct in the PTO correction proceedings and that the inventors listed on the Certificate of Correction were incorrect. Atmel also alleged that the ALJ exhibited such bias against Atmel that it was denied a fair hearing. The Commission investigative attorney (IA) petitioned on the same day for review of ALJ Order No. 69 and the ALJ's rulings in the ID concerning inequitable conduct and inventorship. On June 13, 2000, respondents and intervenor filed a joint response in opposition. The IA filed a response opposing in part Atmel's petition on the same date. Atmel filed a motion for leave to reply to the oppositions on June 22, 2000, which the Commission hereby denies.

Having examined the record in this investigation, including Orders Nos. 50 and 69 and the ALJ's final ID, the petitions for review, and the responses thereto, the Commission has determined to review: (1) ALJ Order No. 50, (2) ALJ Order No. 69, (3) the ALJ's determination that the Certificate of Correction of the '903 patent was procured inequitably, and (4) the ALJ's determination that the inventors named on the Certificate of Correction are incorrect.

The parties are requested to brief the issues under review. The briefs should include a discussion of, but are not restricted to, the following questions:

(1) Which of the ALJ's findings concerning his determination of inequitable conduct, if any, are based on documents in the record as to which Atmel has never claimed privilege? Does any other evidence in the record, as to which Atmel has never claimed privilege, exist that would support a finding of inequitable conduct? Which of the ALJ's findings concerning inequitable conduct are supported by documents in the record as to which Atmel has claimed work product privilege? Which of the ALJ's findings concerning inequitable conduct are supported by documents in the record as to which Atmel has claimed attorney-client privilege only?

(2) Which of the ALJ's findings concerning his determination that the correct inventors are not listed on the Certificate of Correction of the '903 patent are supported by documents in the record as to which Atmel has claimed privilege (please specify whether attorney-client or work product privilege)?

(3) What evidence of record corroborates a finding that Dr. Smarandiou and Mr. Perlogos implemented Silicon Signature in the 5133 EPROM before Mr. Gupta implemented Silicon Signature in the 5213 EEPROM? What evidence of record corroborates a finding that Mr. Gupta implemented Silicon Signature in the 5213 EPROM before Dr. Smarandiou and Mr. Perlogos implemented Silicon Signature in the 5213 EEPROM?

(4) What legal authority or policy considerations support the finding that the burden of coming forward with evidence and the burden of proof by clear and convincing evidence should be applied to patent correction proceedings at the U.S. Patent and Trademark Office?

(5) Under what authority is the Commission required to accord the presumption of validity to a certificate of correction concerning inventorship issued by the U.S. Patent and Trademark Office?

(6) Is the Commission empowered to find that a regulation issued by the U.S. Patent and Trademark Office is *ultra vires*?

The Commission intends to dispose of all outstanding issue in this investigation, including the remaining issues concerning the '811 and '829 patents, at the same time. Accordingly, if the Commission finds in connection with the final disposition of this investigation that there has been a violation of section 337, the Commission may issue (1) an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) cease and desist orders that could result in respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see In the Matter of Certain Devices for Connecting Computers via Telephone Lines, Inv. No. 337–TA–360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the President has 60 days to approve or disapprove the Commission's action. During this period, the subject articles would be entitled to enter the United States under

a bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed.

Written Submissions: The parties to the investigation are requested to file written submissions on the issues under review. The submissions should be concise and, where applicable, thoroughly referenced to the record in this investigation. Respondents and intervenor are encouraged to file a joint submission. Additionally, the parties to the investigation, interested government agencies, and any other interested persons are encouraged to file written submissions on remedy, the public interest, and bonding. Such submissions should address the March 19, 1998, recommended determination of the ALJ. Persons who have already filed such submissions, including the parties, may simply update their previously filed submissions.

Complainant and the Commission investigative attorney are also requested to update the proposed remedial orders that they have already submitted for the Commission's consideration. The written submissions and updated proposed remedial orders must be filed no later than close of business on July 31, 2000. Reply submissions must be filed no later than the close of business on August 7, 2000. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file with the Office of the Secretary the original document and 14 true copies thereof on or before the deadlines stated above. Any person desiring to submit a document (or portion thereof) to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See section 201.6 of the Commission's Rules of Practice and Procedure, 19 CFR 201.6. Documents for which confidential treatment by the Commission is sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

This action is taken under the authority of section 337 of the Tariff Act of 1930, 19 U.S.C. 1337, and sections 210.42–210.51 of the Commission's Rules of Practice and Procedure, 19 CFR 210.42–210.51.

Copies of the public version of the ID, and all other nonconfidential documents filed in connection with this investigation, are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone 202–205–2000. Public documents are also available for downloading from the Commission's website, http://www.usitc.gov.

Issued: July 17, 2000.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 00–18511 Filed 7–20–00; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. TA–204–3]

Lamb Meat: Monitoring Developments in the Domestic Industry

AGENCY: International Trade Commission.

ACTION: Institution and scheduling of an investigation under section 204(a) of the Trade Act of 1974 (19 U.S.C. 2254(a)) (the Act).

SUMMARY: The Commission instituted the investigation for the purpose of preparing the report to the President and the Congress required by section 204(a)(2) of the Trade Act of 1974 on the results of its monitoring of developments with respect to the domestic lamb meat industry since the President imposed a tariff-rate quota on imports of fresh, chilled, or frozen lamb meat [1] effective July 22, 1999.

For further information concerning the conduct of this investigation, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 206, subparts A and F (19 CFR part 206).

Background

Following receipt of a report from the Commission in April 1999 under section 202 of the Trade Act of 1974 (19 U.S.C. 2252) containing an affirmative determination and remedy recommendation, the President, on July 7, 1999, pursuant to section 203 of the Trade Act of 1974 (19 U.S.C. 2253), issued Proclamation 7208 (as amended by Proclamation 7214 of July 30, 1999), imposing import relief in the form of a tariff-rate quota on imports of fresh, chilled, or frozen lamb meat for a period of 3 years and 1 day, effective July 22, 1999. Section 204(a)(1) of the Trade Act of 1974 (19 U.S.C. 2254(a)(1)) requires that the Commission, so long as any action under section 203 of the Trade Act remains in effect, monitor developments with respect to the domestic industry, including the progress and specific efforts made by workers and firms in the domestic industry to make a positive adjustment to import competition. Section 204(a)(2) requires that whenever the initial period of an action under section 203 of the Trade Act exceeds 3 years, the Commission shall submit a report on the results of the monitoring under section 204(a)(1) to the President and the Congress not later than the mid-point of the initial period of the relief, or by January 22, 2001, in this case. Section 204(a)(3) requires that the Commission hold a hearing in the course of preparing each such report.

EFFECTIVE DATE: July 17, 2000.

FOR FURTHER INFORMATION CONTACT: Sioban Maguire (202–708–4721), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server *(http://www.usitc.gov)*.

SUPPLEMENTARY INFORMATION:

Participation in the investigation and service list.—Persons wishing to participate in the investigation as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, not later than 14 days after publication of this notice in the **Federal Register**. The Secretary will prepare a service list containing the names and addresses of all persons, or their representatives, who are parties to this investigation upon the expiration of the period for filing entries of appearance.

Public hearing.—As required by statute, the Commission has scheduled a hearing in connection with this

[1] Lamb meat is classified in subheadings 0204.10.00, 0204.22.20, 0204.23.20, 0204.30.00, 0204.42.20, and 0204.43.20 of the Harmonized Tariff Schedule of the United States.

investigation. The hearing will be held beginning at 9:30 a.m. on November 16, 2000 at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before November 7, 2000. All persons desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on November 13, 2000, at the U.S. International Trade Commission Building. Oral testimony and written materials to be submitted at the hearing are governed by sections 201.6(b)(2) and 201.13(f) of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 days prior to the date of the hearing.

Written submissions.—Each party is encouraged to submit a prehearing brief to the Commission. The deadline for filing prehearing briefs is November 8, 2000. Parties may also file posthearing briefs. The deadline for filing posthearing briefs is November 27, 2000. In addition, any person who has not entered an appearance as a party to the investigation may submit, on or before November 27, 2000, a written statement concerning the matters to be addressed in the Commission's report to the President. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain confidential business information must also conform with the requirements of section 201.6 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means.

In accordance with section 201.16(c) of the Commission's rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by the service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: This investigation is being conducted under the authority of section 204(a) of the Trade Act of 1974; this notice is published pursuant to section 206.3 of the Commission's rules.

Issued: July 17, 2000.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 00–18513 Filed 7–20–00; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigations Nos. 701–TA–178 (Review) and 731–TA–636–638 (Review)]

Stainless Steel Wire Rod From Brazil, France, India, and Spain

Determinations

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission determines, pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)), that revocation of the countervailing duty order on stainless steel wire rod from Spain would not be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time. The Commission further determines [2] that revocation of the antidumping duty orders on stainless steel wire rod from Brazil, France, and India would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted these reviews on July 1, 1999 (64 FR 35697) and determined on October 1, 1999, that it would conduct full reviews (64 FR 55962, October 15, 1999). Notice of the scheduling of the Commission's reviews and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on January 18, 2000 (65 FR 2644). The hearing was held in Washington, DC, on May 23, 2000, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determinations in these reviews to the Secretary of Commerce on July 18, 2000. The views of the Commission are contained in USITC Publication 3321 (July 2000), entitled Stainless Steel Wire Rod from Brazil, France, India, and Spain: Investigations Nos. 701–TA–178 (Review) and 731–TA–636–638 (Review).

By order of the Commission.

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Chairman Koplan and Vice Chairman Okun dissenting with respect to France; Commissioner Askey dissenting with respect to Brazil, France, and India.

Issued: July 17, 2000.

Donna R. Koehnke,

Secretary.

[FR Doc. 00–18512 Filed 7–20–00; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Agency Information Collection Activities: Proposed Collection; Comment Requested

ACTION: Notice of information collection under review; Extension of a currently approved collection; Collection of Laboratory Analysis Data on Drug Samples Tested by Non-Federal (State and Local Government) Crime Laboratories.

Office of Management and Budget (OMB) approval is being sought for the information collection listed below. This proposed information collection was previously published in the Federal Register on May 16, 2000, allowing for a 60-day public comment period.

The purpose of this notice is to allow an additional 30 days for public comment until August 21, 2000. This process is conducted in accordance with 5 CFR 1320.10. Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to 202–395–7285. Comments may also be submitted to the Department of Justice (DOJ), Justice Management Division, Information Management and Security Staff, Attention: Department Clearance Officer, Suite 1221, National Place Building, 1331 Pennsylvania Ave., NW., Washington, DC 20530. Additionally, comments may be submitted to DOJ via facsimile to (202) 514–1590.

Written comments and/or suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the

proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

1. *Type of information collection:* Extension of a currently approved collection.

2. *The title of the form/collection:* Collection of Laboratory Analysis Data on Drug Samples Tested by Non-Federal (State and Local Government) Crime Laboratories.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form No.: None Applicable component of the Department sponsoring the collection: Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Regulatory or Compliance. Other: Research. Abstract: Information is needed from state and local laboratories to provide DEA with additional analyzed drug information for the National Forensic Laboratory Information System.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* 100 respondents, 1200 responses per year, × .25 hours per response.

6. *An estimate of the total public burden (in hours) associated with the collection:* 300 annual burden hours.

Public comments on this proposed information collection are strongly encouraged.

If additional information is required contact: Mr. Robert B. Briggs, Department Clearance Officer, U.S. Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 1221, National Place Building, 1331 Pennsylvania Ave., NW., Washington 20530.

Dated: July 17, 2000.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 00–18545 Filed 7–20–00; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Agency Information Collection Activities: Proposed Collection; Comment Requested

AGENCY: Notice of information collection under review; Extension of a currently approved collection; Report of Mail Order Transactions.

Office of Management and Budget (OMB) approval is being sought for the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 16, 2000, allowing for a 60-day public comment period.

The purpose of this notice is to allow an additional 30 days for public comment until August 21, 2000. This process is conducted in accordance with 5 CFR 1320.10. Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to 202–395–7285. Comments may also be submitted to the Department of Justice (DOJ), Justice Management Division, Information Management and Security Staff, Attention: Deparment Clearance Officer, Suite 1221, National Place Building, 1331 Pennsylvania Ave., NW., Washington, DC 20530. Additionally, comments may be submitted to DOJ via facsimile to (202) 14–1590.

Written comments and/or suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

1. *Type of information collection:* Extension of a currently approved collection.

2. *Their title of the form/collection:* Report of Mail Order Transactions.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form No.: None. Applicable component of the Department sponsoring the collection; Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. Other: None. Abstract: The Comprehensive Methamphetamine Control Act of 1996 (Public Law 104–237) (MCA) amended the Controlled Substances Act to require that each regulated person who engages in a transaction with a non-regulated person which involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing these chemicals) and use or attempts to use the Postal Service or any private or commercial carrier shall, on a monthly basis, submit a report of each such transaction conducted during the previous month to the Attorney General.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* 100 respondents, 12 hour per response.

6. *An estimate of the total public burden (in hours) associated with the collection:* 1200 annual burden hours.

Public comments on this proposed information collection are strongly encouraged.

If additional information is required contact: Mr. Robert B. Briggs, Department Clearance Officer, U.S. Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 1221, National Place Building, 1331 Pennsylvania Ave., NW, Washington, DC 20530.

Dated: July 17, 2000.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 00–18546 Filed 7–20–00; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Agency Information Collection Activities: Proposed Collection; Comment Requested

ACTION: Notice of information collection under review; Extension of a currently approved collection; Annual Reporting Requirement for Manufacturers of Listed Chemicals.

Office of Management and Budget (OMB) approval is being sought for the information collection listed below. This proposed information collection was previously published in the Federal Register on May 16, 2000, allowing for a 60-day public comment period.

The purpose of this notice is to allow an additional 30 days for public comment until August 21, 2000. This process is conducted in accordance with 5 CFR 1320.10. Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to 202–395–7285. Comments may also be submitted to the Department of Justice (DOJ), Justice Management Division, Information Management and Security Staff, Attention: Department Clearance Officer, Suite 1221, National Place Building, 1331 Pennsylvania Ave., NW., Washington, DC 20530. Additionally, comments may be submitted to DOJ via facsimile to (202) 514–1590.

Written comments and/or suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

1. *Type of information collection:* Extension of a currently approved collection.

2. *The title of the form/collection:* Annual Reporting Requirement for Manufacturers of Listed Chemicals.

3 *The agency form number, if any and the applicable component of the department sponsoring the collection:* Form No.: None. Applicable component of the Department sponsoring the collection: Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. Other: None. Abstract: This information collection permits the Drug Enforcement Administration to monitor the volume and availability of domestically manufactured listed chemicals. These listed chemicals may be subject to diversion for the illicit production of controlled substances. This information collection is authorized by the Domestic Chemical Diversion Control Act of 1993 (Pub. L. 103–200; 21 U.S.C. 830(b)). This information is collected from businesses and other for-profit entities which manufacture listed chemicals domestically.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* 100 respondents, 4 hours per response.

6. *An estimate of the total public burden in hours) associated with the collection:* 400 annual burden hours.

Public comments on this proposed information collection are strongly encouraged.

If additional information is required contact: Mr. Robert B. Briggs, Department Clearance Officer, U.S. Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 1221, National Place Building, 1331 Pennsylvania Ave., NW., Washington, DC 20530.

Dated: July 17, 2000.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 00–18547 Filed 7–20–00; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF LABOR

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects or a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276(a) and of other Federal statutes referred to in 29 CFR part 1, appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedes decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register,** or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used

in accordance with the provisions of 29 CFR parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon And Related Acts,'' shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., Room S–3014, Washington, DC 20210.

Withdrawn General Wage Determination Decisions

This is to advise all interested parties that the Department of Labor is withdrawing, from the date of this notice, the following General Wage Determinations:

IA000028—See IA000008
IA000029—See IA000008
IA000030—See IA000008
IA000034—See IA000008
IA000059—See IA000008

Contracts for which bids have been opened shall not be affected by this notice. Also, consistent with 29 CFR 1.6(c)(2)(i)(A), when the opening of bids is less than ten (10) days from the date of this notice, this action shall be effective unless the agency finds that there is insufficient time to notify bidders of the change and the finding is documented in the contract file.

Modifications to General Wage Determination Decisions

The number of decisions listed in the Government Printing Office document entitled ''General Wage Determinations Issued Under the Davis-Bacon and related Acts'' being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

New Jersey
NJ000002 (Feb. 11, 2000)
NJ000003 (Feb. 11, 2000)
NJ000007 (Feb. 11, 2000)

Volume II

Delaware
DE00001 (Feb. 11, 2000)
Pennsylvania
PA000005 (Feb. 11, 2000)
PA000006 (Feb. 11, 2000)
PA000025 (Feb. 11, 2000)
PA000026 (Feb. 11, 2000)
PA000030 (Feb. 11, 2000)
PA000031 (Feb. 11, 2000)

Volume III

Florida
FL000001 (Feb. 11, 2000)
FL000017 (Feb. 11, 2000)
FL000032 (Feb. 11, 2000)

Volume IV

Michigan
MI000060 (Feb. 11, 2000)
MI000062 (Feb. 11, 2000)
MI000063 (Feb. 11, 2000)
MI000064 (Feb. 11, 2000)
MI000066 (Feb. 11, 2000)
MI000067 (Feb. 11, 2000)
MI000068 (Feb. 11, 2000)
MI000069 (Feb. 11, 2000)
MI000070 (Feb. 11, 2000)
MI000071 (Feb. 11, 2000)
MI000072 (Feb. 11, 2000)
MI000073 (Feb. 11, 2000)
MI000074 (Feb. 11, 2000)
MI000075 (Feb. 11, 2000)
Ohio
OH000001 (Feb. 11, 2000)
OH000002 (Feb. 11, 2000)
OH000003 (Feb. 11, 2000)
OH000023 (Feb. 11, 2000)
OH000026 (Feb. 11, 2000)
OH000028 (Feb. 11, 2000)
OH000029 (Feb. 11, 2000)
Wisconsin
WI000028 (Feb. 11, 2000)

Volume V:

Iowa
IA000004 (Feb. 11, 2000)
IA000005 (Feb. 11, 2000)
IA000006 (Feb. 11, 2000)
IA000007 (Feb. 11, 2000)
IA000008 (Feb. 11, 2000)
IA000009 (Feb. 11, 2000)
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IA000024 (Feb. 11, 2000)
IA000038 (Feb. 11, 2000)
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IA000078 (Feb. 11, 2000)
IA000079 (Feb. 11, 2000)
IA000080 (Feb. 11, 2000)
IA000003 (Feb. 11, 2000)
IA000005 (Feb. 11, 2000)
IA000010 (Feb. 11, 2000)
Texas
IA000003 (Feb. 11, 2000)
IA000005 (Feb. 11, 2000)
IA000010 (Feb. 11, 2000)

Volume VI:

Alaska
AK000001 (Feb. 11, 2000)
AK000001 (Feb. 11, 2000)
AK000002 (Feb. 11, 2000)
AK000006 (Feb. 11, 2000)
Oregon
OR000017 (Feb. 11, 2000)
OR000017 (Feb. 11, 2000)
Washington
WA000001 (Feb. 11, 2000)

Volume VII:

Arizona
AZ000001 (Feb. 11, 2000)
AZ000002 (Feb. 11, 2000)
AZ000003 (Feb. 11, 2000)
AZ000004 (Feb. 11, 2000)
AZ000005 (Feb. 11, 2000)
AZ000006 (Feb. 11, 2000)
AZ000012 (Feb. 11, 2000)
AZ000013 (Feb. 11, 2000)
AZ000014 (Feb. 11, 2000)
AZ000015 (Feb. 11, 2000)
AZ000016 (Feb. 11, 2000)
AZ000017 (Feb. 11, 2000)

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under the David-Bacon and Related Acts.'' This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

The general wage determinations issued under the Davis-Bacon and related Acts are available electronically by subscription to the FedWord Bulletin Board System of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at 1–800–363–2068.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC. 20402, (202) 512–1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the seven separate volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage

determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates are distributed to subscribers.

Signed at Washington, DC. this 14th day of July 2000.

John Frank,

Acting Chief, Branch of Construction Wage Determinations.

[FR Doc. 00–18181 Filed 7–20–00; 8:45 am]

BILLING CODE 4510–27–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts; Leadership Initiatives Advisory Panel

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 Leadership Initiatives Advisory Panel, AccessAbility Section (Universal Design) to the National Council on the Arts will be held on August 4, 2000. The panel will meet by teleconference from 2:00 p.m. to 3:00 p.m. in Room 528 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW, Washington, D.C. 20506.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendations on 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. In accordance with the determination of the Chairman of May 12, 2000, 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.

Further information with reference to this meeting can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, D.C. 20506, or call 202/682–5691.

Dated: July 18, 2000.

Kathy Plowitz-Worden,

Panel Coordinator, Panel Operations, National Endowment for the Arts.

[FR Doc. 00–18526 Filed 7–20–00; 8:45 am]

BILLING CODE 7537–01–M

NUCLEAR REGULATORY COMMISSION

Notice of a Public Meeting on Assessing Future Regulatory Research Needs

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of public meeting.

SUMMARY: The U. S. Nuclear Regulatory Commission (NRC) will hold a meeting of nuclear experts from the government, the nuclear industry, academia, and the Public on August 16–17, 2000. The purpose of the meeting is to seek stakeholder input on the role and future direction of nuclear regulatory research. The meeting is open to the public and all interested parties may attend.

DATES: The meeting will be held from 8:00 AM to 5:00 PM on August 16 and 17, 2000 at the Marriott Residence Inn located at 7335 Wisconsin Avenue in Bethesda, Maryland 20804. The telephone number of the hotel is 301–718–0200.

FOR FURTHER INFORMATION CONTACT: Questions with respect to this meeting should be referred to James W. Johnson, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission at (301) 415–6293; fax 301–415–5153; E-mail jwj@nrc.gov or Joseph J. Mate, at (301) 415–6202; fax 301–415–5153; E-mail *jjm@nrc.gov*.

SUPPLEMENTARY INFORMATION: Parking is available in the hotel for a modest cost. Additional parking in Bethesda is somewhat limited. The hotel can also be reached by Metro.

The hotel is located one block south of the Bethesda Metro stop on the Red Line and is on the opposite side of the street from the metro station. Seating for the public is limited and therefore will be on a first-come, first serve basis.

Dated at Rockville, Maryland, this 17th day of July 2000.

For the Nuclear Regulatory Commission.

Ashok C. Thadani,

Director, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission.

[FR Doc. 00–18539 Filed 7–20–00; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35–27200]

Filings Under the Public Utility Holding Company Act of 1935, as amended (''Act'')

July 14, 2000.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated under the Act. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendment(s) is/are available for pubic inspection through the Commission's Branch of Pubic Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by August 7, 2000, to the Secretary, Securities and Exchange Commission, Washington, DC 20549–0609, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in the case of an attorney at law, by certificate) should be filed with the request. Any request for hearing should identify specifically the issues of facts or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After August 7, 2000, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

Indiana Michigan Power Company, Inc. (70–7715)

Indiana Michigan Power Company, Inc. (''I&M''), One Summit Square, Fort Wayne, Indiana 46801, an electric utility subsidiary company of American Electric Power Company, Inc., a registered holding company, has filed a post-effective amendment under sections 6(a), 7, 9(a) and 10 of the Act and rule 54 under the Act, to an application-declaration previously filed under the Act.

By prior Commission order dated December 21, 1990 (HCAR No. 25222) (''Prior Order''), I&M was authorized, among other things, to enter into a Nuclear Material Lease Agreement, dated as of December 1, 1990 (''Existing Lease''), with DCC Fuel Corporation (''DCC''), under which I&M leases certain nuclear material (''Nuclear Fuel'') required for use at its Donald C. Cook Nuclear Plant (''Cook Plant''). Under the terms of the Existing Lease, DCC is required to provide up to $110 million of financing to pay the suppliers, processors and manufacturers of Nuclear Fuel, which is leased to I&M for use in the Cook Plant. Correspondingly, I&M is unconditionally obligated to make monthly lease payments to DCC in amounts sufficient to cover the cost of the Nuclear Fuel, operational and financing costs and other associated fees and expenses, including taxes.

Under the Existing Lease, DCC meets its financing obligations by issuing notes under a credit agreement with PruLease and note purchase agreements

with various note purchasers (together, ''Creditors''). In the Prior Order, the Commission imposed limits on certain fees and rates applicable to borrowings under these agreements that were incorporated in the payments made under the Existing Lease.

On March 1, 1999, the Creditors informed DCC of their election to terminate their loan commitment obligations effective March 1, 2001 or an earlier date that is mutually acceptable to the parties. I&M now proposes to enter into a new financing arrangement with Bank of America and certain other financial institutions for the lease of Nuclear Fuel.

I&M proposes to enter into a new nuclear fuel lease with DCC (''New Lease''), which will be substantially the same as the Existing Lease. Under the terms of the New Lease, DCC would be required to provide up to $140 million of financing to pay the suppliers, processors and manufacturers of Nuclear Fuel for the Cook Plant. Correspondingly, I&M would be unconditionally obligated to make monthly lease payments to DCC in amounts sufficient to cover the cost of the Nuclear Fuel, operational and financing costs and other associated fees and expenses, including taxes. In addition to the monthly lease payments to DCC, I&M would be obligated to pay a quarterly program fee to certain financial institutions providing DCC with back-up funding, discussed below. The fee will be from .175% to .4% of the total loan commitments of those institutions depending on I&M's debt rating.

DCC will finance the acquisition of the Nuclear Fuel to be leased to I&M through borrowings under a revolving loan agreement with Hatteras Funding Corporation, a special purpose commercial paper funding entity administered by Bank of America (''Primary Purchaser''), and one or more financial institutions (''Liquidity Purchasers'') (''Agreement''). Under the Agreement, notes issued by DCC to the Primary Purchaser will bear interest at the commercial paper rate quoted by the Primary Purchaser, including dealer fees. Notes issued to Liquidity Purchasers will bear interest at LIBOR, plus a margin of between .585% and 1.7% depending upon I&M's debt rating at the time of issuance.

All outstanding notes will mature no later than the termination date of the Agreement. The Agreement will have a term of five years, unless otherwise terminated or extended under the terms of the Agreement.

For the Commission by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 00–18492 Filed 7–20–00; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meetings during the week of July 24, 2000.

An open meeting will be held on Tuesday, July 25, 2000 at 10:00 a.m., in Room 1C30.

The subject matter of the open meeting scheduled for Tuesday, July 25, 2000 will be:

(1) The Commission will consider two actions regarding the options markets. First, the Commission will consider approving an intermarket linkage plan for options exchanges. Second, the Commission will consider a rule proposal regarding the quotation obligations of options exchanges and market makers, and disclosure by broker-dealers of executions of customer options orders at prices inferior to the quote. For further information contact: Heather Traeger, Attorney, at (202) 942–0763, Office of Market Supervision, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth St, N.W., Washington, DC 20549–1001; and

(2) Consideration will be given to a rule proposal arising from its request for comments on issues of fragmentation and internalization in the securities markets. The rule proposal would require greater disclosure of order routing and order execution practices by brokers and market centers. For further information, contact: Susie Cho, Attorney, at (202) 942–0748, Office of Market Supervision, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth St, N.W., Washington, DC 20549–1001.

Hearings will be held on Tuesday, July 26, 2000 at 9:00 a.m., in Room 1C30.

The Commission will hold public hearings on its proposed rule amendments concerning auditor independence. The purpose of the hearings is to give the Commission the benefit of the views of interested members of the public regarding the issues raised and questions posed in the Proposing Release (33–7870). For further information, contact: John M. Morrissey, Deputy Chief Accountant or W. Scott Bayless, Associate Chief Accountant, Office of the Chief Accountant at (202) 942–4400.

A closed meeting will be held on Thursday, July 27, 2000 at 11:00 a.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4), (8), (9)(A) and (10) and 17 CFR 200.402(a)(4), (8), (9)(A) and (10), permit consideration for the scheduled matters at the closed meeting.

The subject matters of the closed meeting scheduled Thursday, July 27, 2000 will be:

Institution and settlement of injunctive actions; and

Institution and settlement of administrative proceedings of an enforcement nature

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: The Office of the Secretary at (202) 942–7070.

Dated: July 18, 2000.

Jonathan G. Katz,

Secretary.

[FR Doc. 00–18586 Filed 7–18–00; 4:31 pm]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43030; File No. SR–NASD–99–42]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the National Association of Securities Dealers, Inc. Relating to Performance Fee Arrangements

July 12, 2000.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 2, 1999, the National Association of Securities Dealers, Inc. (''NASD'' or ''Association''), through its wholly owned subsidiary NASD Regulation, Inc. (''NASD'' or ''Association''), through its wholly owned subsidiary NASD Regulation, Inc. (''NASD Regulation'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by NASD Regulation. The Commission is publishing this notice to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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

NASD Regulation is proposing to amend NASD Rule 2330(f)(2), in order to make it consistent with recent amendments by the Commission to Rule 205–3 under the Investment Advisers Act of 1940 (''Advisers Act''). Below is the text of the proposed rule change. Proposed new language is in italics; proposed deletions are in brackets.

* * * * *

Rules of the Association

* * * * *

2300. Transactions With Customers

2330. Customers' Securities or Funds

(a) through (e) (No change).

(f) Sharing in Accounts; Extent Permissible.

(1)(A) and (B) (No change).

(2) Notwithstanding the prohibition of paragraph (f)(1), a member or person associated with a member may receive compensation based on a share in profits or gains in an account if [all of] the following conditions are satisfied:*

(A) The member or person associated with a member seeking such compensation obtains prior written authorization from the member carrying the account; *and*

(B) The compensation arrangement complies with the conditions set forth in any applicable rule promulgated by the Commission.

[(B) The customer has at the time the account is opened either a net worth which the member or person associated with a member reasonably believes to be not less than $1,000,000, or the minimum amount invested in the account is not less than $500,000;

(C) The member or person associated with a member reasonably believes the customer is able to understand the proposed method of compensation and its risks prior to entering into the arrangement;

(D) The compensation arrangement is set forth in a written agreement executed by the customer and the member;

(E) The member or person associated with a member reasonably believes, immediately prior to entering into the arrangement, that the agreement represents an arm's-length arrangement between the parties;

(F) The compensation formula takes into account both gains and losses realized or accrued in the account over a period of at least one year; and

(G) The member has disclosed to the customer all material information relating to the arrangement including the method of compensation and potential conflicts of interest which may result from the compensation formula.]

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis of, the Proposed Rule Change

In its filing with the Commission, NASD Regulation included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NASD Regulation 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

I. Purpose

Description of Proposed Rule Change. NASD Rule 2330(f) prohibits members and persons associated with members form sharing in customer account profits and gains except under certain conditions. Subparagraph (f)(1)(A) permits sharing in customer account profits and gains where the firm has authorized it and the sharing is proportionate to the member's or associated person's contributions to the account. Subparagraph (f)(2) permits, under certain conditions, members or registered representatives to charge a performance fee (an advisory fee based on a percentage of the capital gains or capital appreciation of an account). Currently, NASD Rule 2330(f)(2) permits the receipt of a performance fee only if: (1) The member or associated person reasonably believes that the customer account meets certain minimum net worth ($1,000,000) or amount invested ($500,000) requirements; (ii) the member or associated person obtains the prior written authorization of the arrangement from the member carrying the account; (iii) the member or associated person reasonably believes that the customer is able to understand the compensation arrangement and its risks; (iv) the compensation agreement is in writing; (v) the member or associated person reasonably believes that the agreement is an arm's length agreement; (vi) the compensation formula takes into account realized and accrued gains and losses over a period of at least one year; and (vii) the member discloses all material information relating to the agreement, including method of compensation and potential conflicts of interest.

The requirements of NASD Rule 2330(f)(2) have always closely tracked the requirements of Rule 205–3 under the Advisers Act. However, effective August 20, 1998, the Commission amended Rule 205–3 to provide greater flexibility in structuring performance fee arrangements with clients who are financially sophisticated or have the resources to obtain sophisticated financial advice regarding these arrangements.[3] The amendments to Rule 205–3 changed and eliminated many of the requirements tracked in NASD Rule 2330(f)(2). As a result of these changes, NASD Rule 2330(f)(2) is now inconsistent with Rule 205–3 under the Advisers Act. In order to restore consistency, the proposed rule change will permit members and their associated persons to share in customer account profits and gains subject to the provisions of Rule 205–3 under the Advisers Act. Thus, in the future, the proposed rule will conform to any subsequent amendments by the Commission to Rule 205–3.

2. Statutory Basis

NASD Regulation believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[4] which requires, among other things, that the Association's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. NASD Regulation believes that the proposed rule change will protect investors and the public interest by ensuring that performance fee arrangements are consistent with Commission rules and are structured with clients who are

* It is the position of the Division of Investment Management of the Commission that compensation received by a member or person associated with a member under t his Rule would constitute ''special compensation'' for purposes of th e broker/dealer exception to the definition of ''investment adviser'' in Section 202(a)(11)(C) of the Investment Advisers Act of 1940 (Advisers Act). Any member or person associated with a member, required to be registered under the Advisers Act, or state law, who receives compensation based on a share of profits or capital appreciation of a customer's account must comply with Section 205(1) and Rule 205–3 under the Advisers Act, or applicable state law, with respect to such compensation. (SEC Release 34–24355, 52 FR 13778, April 24, 1987).

[3] *See* Investment Advisors Act Release No. 1731 (July 15, 1998), 63 FR 39022 (July 21, 1998).

[4] 15 U.S.C. 78o–3(b)(6).

financially sophisticated or have the resources to obtain sophisticated financial advice regarding the terms of these arrangements.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASD Regulation does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

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 NASD Regulation 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, including whether the proposed rule change is consistent with the Act. In particular, the Commission seeks comment on how a broker-dealer can best meet its fiduciary obligation to ensure that its customers fully understand the performance fee arrangement. In formulating comments on this proposal, commenters are advised to refer to Advirsors Act Release No. 1731.[5] Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to the File No. SR–NASD–99–42 and should be submitted by August 11, 2000.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Jonathan G. Katz,

Secretary.

[FR Doc. 00–18493 Filed 7–20–00; 8:45 am]

BILLING CODE 8010–01–M

[5] 63 FR 39022 (July 21, 1998).

[6] 17 CFR 200.30–3(a)(12)

SOCIAL SECURITY ADMINISTRATION

Ticket to Work and Work Incentives Advisory Panel Meeting

AGENCY: Social Security Administration (SSA).

ACTION: Notice of meeting (Emergency Location Change).

DATES: July 24, 2000, 1:30 p.m.–5:00 p.m. and July 25, 2000, 9:00 a.m.–4:30 p.m.

ADDRESSES: Sheraton Crystal City, 1800 Jefferson Davis Highway, Arlington, VA 22202.

SUPPLEMENTARY INFORMATION:

Type of meeting: The meeting is open to the public.

Purpose: In accordance with section 10(a)(2) of the Federal Advisory Committee Act, the Social Security Administration (SSA) announces the first meeting of the Ticket to Work and Work Incentives Advisory Panel (the Panel). Section 101(f) of the Ticket to Work and Work Incentives Improvement Act of 1999 (TWWIIA), Public Law 106–170, establishes the Panel to advise the Commissioner of Social Security, the President, and the Congress on issues related to work incentives programs, planning, and assistance for individuals with disabilities as provided under section 101(f)(2)(A) of TWWIIA. The Panel is also to advise the Commissioner on matters specified in section 101(f)(2)(B) of that Act, including certain issues related to the Ticket to Work and Self-Sufficiency Program established under section 101(a) of that Act.

This is the first deliberative meeting of the Panel. No public testimony will be heard at this meeting. However, interested parties are invited to attend the meeting. The Panel will meet to hear presentations on the status of TWWIIA implementation, review their charter, and discuss their organization and upcoming agenda.

Agenda: The Panel will meet commencing Monday, July 24, 2000 at, 1:30 p.m.–5:00 p.m. and Tuesday, July 25, 2000, at 9:00 a.m.–4:30 p.m. At this meeting, the Panel will use this time to hear presentations on the Status of TWWIIA implementation, review their charter, and discuss their organization and upcoming agenda. Since seating may be limited, persons interested in attending this meeting should contact the Panel staff by E-mailing Reggie Sajauskas, Designated Federal Officer, at ''reggie.sajauskas@ssa.gov'' or calling (410) 965–5381 by July 21, 2000.

The agenda for the meeting is posted on the Internet at the web site of SSA' Office of Employment Support Programs at ''http://*www.ssa.gov/work.*'' A copy of the agenda also may be obtained in advance of the meeting by contacting the Panel staff at the mailing address, Email address, telephone or FAX number shown below. Requests for materials in alternate formats, *i.e.,* large print, Braille, computer disc, etc. may be made to the Panel staff at the addresses and numbers shown below.

Records are being kept of all Panel proceedings and will be available for public inspection at the Office of Employment Support Programs' web site at ''*http://www.ssa.gov/work''* or by appointment at the office of the Ticket to Work and Work Incentives Advisory Panel staff, 107 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235. Anyone requiring information regarding the Panel should contact the Panel staff by:

- Mail addressed to Social Security Administration, Ticket to Work and Work Incentives Advisory Panel Staff, 107 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235;
- Telephone at (410) 965–5381;
- FAX at (410) 966–8597; or
- Email to Reggie Sajauskas, Designated Federal Officer, at ''reggie.sajauskas@ssa.gov.''

Michael S. Greenberg,

Acting Deputy Associate Commissioner, Office of Employment Support Programs, Social Security Administration.

[FR Doc. 00–18601 Filed 7–20–00; 8:45 am]

BILLING CODE 4191–02–U

DEPARTMENT OF STATE

[Public Notice 3368]

Culturally Significant Objects Imported for Exhibition Determinations: ''Charlotte Salomon: Life? Or Theatre?''

DEPARTMENT: Department of State.

ACTION: Notice.

SUMMARY: Notice is hereby given of the following determinations:

Pursuant to the authority vested in me by the Act of October 19, 1965 [79 Stat. 985, 22 U.S.C. 2459], the Foreign Affairs Reform and Restructuring Act of 1998 [112 Stat. 2681 *et seq.*], Delegation of Authority No. 234 of October 1, 1999 [64 FR 56014], and Delegation of Authority No. 236 of October 19, 1999, as amended by Delegation of Authority No. 236–1 of November 9, 1999, I hereby determine that the objects to be included in the exhibit, ''Charlotte Salomon: Life? Or Theatre?,'' imported from abroad for the temporary exhibition without profit within the United States, are of cultural significance. These objects are imported pursuant to a loan agreement with a foreign lender. I also determine that the temporary exhibition or display of the exhibit objects at the Museum of Fine Arts, Boston, Massachusetts from on or about August 9, 2000, to on or about October 29, 2000, and thenceforth at the Jewish Museum in New York for an undetermined period, is in the national interest. Public Notice of these determinations is ordered to be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of exhibit objects, contact Paul W. Manning, Attorney-Adviser, Office of the Legal Adviser, 202/619–5997, and the address is Room 700, United States Department of State, 301 4th Street, S.W., Washington, DC 20547–0001.

Dated: July 14, 2000.

Helena Kane Finn,

Acting Assistant Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. 00–18532 Filed 7–18–00; 4:48 pm]

BILLING CODE 4710–08–U

DEPARTMENT OF STATE

[Public Notice 3367]

Bureau of Oceans, International Environmental and Scientific Affairs; Public Meeting To Discuss Progress on International Harmonization of Chemical Hazard Classification and Labeling

SUMMARY: The United States government, through an interagency working group, is preparing for a series of international meetings to further develop a globally harmonized system (GHS) of chemical hazard classification and labeling. The Department of State will hold a public meeting to provide an update on recent activities and a preview of upcoming international meetings.

The public meeting will take place on Thursday, August 10, 2000, from 10:00 AM until noon in Room C5521 at the U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC. Attendees should use the entrance at C and Third Streets NW. Attendees should bring picture identification with them. No advance registration is necessary. For further information, please contact Marie Ricciardone, U.S. Department of State, Office of Environmental Policy (OES/ENV), Room 4325, 2201 C Street NW, Washington, DC 20520; telephone (202) 647–9799; fax (202) 647–5947; e-mail RicciardoneMD@state.gov.

SUPPLEMENTARY INFORMATION: The U.S. Department of State is issuing this notice to help ensure that interested organizations and individuals are aware of and knowledgeable about the effort to internationally harmonize chemical hazard classification and labeling, and have an opportunity to offer comments. Agencies participating in the U.S. government interagency group include: Department of State, Environmental Protection Agency, Department of Transportation, Occupational Safety and Health Administration, Consumer Product Safety Commission, Food and Drug Administration, Department of Commerce, Department of Agriculture, Office of the U.S. Trade Representative, and National Institute of Environmental Health Sciences. For more complete information on the GHS process, please refer to State Department Public Notice 2526, pages 15951–15957 of the **Federal Register** of April 3, 1997.

This meeting will provide an update on GHS activities since the previous public meeting on April 27, 2000 (see Department of State Public Notice 3276 on pages 19036–19037 of the **Federal Register** of April 10, 2000):

—Fifth Meeting of the Inter-Organization Program for the Sound Management of Chemicals (IOMC)/ International Labor Organization (ILO) Working Group of Hazard Communication, May 22–24, Geneva, Switzerland.

—Sixteenth Consultation of the IOMC Coordinating Group for the Harmonization of Chemical Classification Systems, May 25–26, Geneva, Switzerland.

—Sixth Meeting of the Organization for Economic Cooperation and Development (OECD) Expert Group on Classification Criteria for Chemical Mixtures, May 29–31, Paris, France.

—Eighteenth Session of the UN Subcommittee on Experts on the Transport of Dangerous Goods, July 3–13, Geneva, Switzerland.

Members of the interagency working group will also provide an overview of the U.S. preparations for upcoming international meetings:

— The Seventh Meeting of the OECD Extended Expert Group on Aquatic Environmental Hazards (Paris, September 4–5) will develop guidance for applying harmonized hazard classification criteria for aquatic toxicity of chemical substances, decide on a work plan for a Dissolution Protocol, and develop harmonized hazard classification criteria for aquatic toxicity of chemical mixtures.

— The Tenth Meeting of the OECD Task Force on Harmonization of Classification and Labeling (Paris, September 6–8) will consider harmonized hazard classification criteria for chemical mixtures, examine hazard classification criteria for target organ/systemic toxicity, and review the work of the Extended Expert Group on Aquatic Environmental Hazards.

Interested organizations and individuals are invited to present their views orally and/or in writing at the public meeting. Participants may address other topics relating to harmonization of chemical hazard classification and labeling systems, and identify issues of concern. Those organizations/individuals that cannot attend the August 10 meeting, but wish to submit a written comment, should provide Eunice Mourning of the Office of Environmental Policy, U.S. Department of State (telephone 202–647–9266; fax 202–647–5947) with their statement and/or name, organization, address, telephone and fax numbers, and e-mail address. All written comments will be placed in the OSHA public docket (H–022H), which is open

Monday through Friday, from 10 AM until 4 PM, at the Department of Labor, Room 2625, 200 Constitution Avenue NW, Washington, DC; telephone 202–219–7894; fax: 202–219–5046. Interested organizations/individuals that wish to receive future notifications of GHS-related developments by email should contact Mary Frances Lowe of the U.S. Environmental Protection Agency at ''lowe.maryfrances@epa.gov''.

Dated: July 17, 2000.

Daniel T. Fantozzi,

Director, Office of Environmental Policy, U.S. Department of State.

[FR Doc. 00–18553 Filed 7–20–00; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

[USCG–2000–7642]

Lifesaving Equipment

AGENCY: Coast Guard, DOT.

ACTION: Notice of meetings.

SUMMARY: The Coast Guard is hosting four workshops on the implementation of new lifesaving system rules for large passenger vessels operating in domestic waters. The meetings will be informal workshops open to the public and will be held in cities near high concentrations of passenger vessels affected by the new rules. The new rules apply to large passenger vessels in lakes, bays, and sounds and to rivers service; and require them to carry lifesaving equipment for all persons on board, or to develop a safety assessment in lieu of retrofitting lifesaving equipment. The workshops will help passenger vessel operators and Coast Guard inspection offices create a consistent process for the development and approval of the safety assessment alternative. This notice announces the dates, time, and locations of the four workshops.

DATES: The workshops will be held from 9 a.m. to 5 p.m., with registration at 8:30 a.m., on the following dates, but will close early if all business is finished.

St. Louis, MO, August 29, 2000
Seattle, WA, September 8, 2000
Staten Island, NY, September 26, 2000
New Orleans, LA, December 6, 2000

ADDRESSES: The workshops will be held at the following locations:

St. Louis, MO—Room 2–308, Robert A. Young Federal Building, 1222 Spruce Street, St. Louis, MO 63103.

Seattle, WA—Bear Conference Room, Building 5, 1519 Alaskan Way S., Seattle, WA 98103.

Staten Island, NY—Fr. Capodanno Memorial Chapel, Activities New York, 203 New York Avenue, Fort Wadsworth, Staten Island, NY 10305–5005.

New Orleans, LA—Basement Conference Room, Hale Boggs Federal Building, 500 Camp Street, New Orleans, LA 70130–3396.

FOR FURTHER INFORMATION CONTACT: LCDR Kevin Kiefer, Lifesaving and Fire Safety Division (G–MSE–4), U.S. Coast Guard Headquarters, telephone 202–267–1444, fax 202–267–4816, or email KKiefer@comdt.uscg.mil.

SUPPLEMENTARY INFORMATION:

Background

The Lifesaving Equipment Final Rule [CGD 84–069], including changes to 46 CFR part 199, Lifesaving Systems For Certain Inspected Vessels, in subchapter W, Lifesaving Appliances and Arrangements, was published on October 1, 1998 (63 FR 52802), with an effective date of November 2, 1998.

Subchapter W requires existing passenger vessels certificated under 46 CFR subchapter H in lakes, bays, and sounds service or in rivers service, to carry additional survival craft with a compliance date of October 1, 2003. As an alternative to the survival craft requirements listed in subchapter W, in 46 CFR 199.201(b), vessel operators may have a safety assessment approved by their local Officer in Charge, Marine Inspection (OCMI). New passenger vessels or recently built vessels may also consider the safety assessment alternative to possibly reduce the number of required survival craft.

The safety assessment must include:

(1) the navigation and vessel safety conditions within the vessel's planned operating area; and

(2) a comprehensive shipboard safety management and contingency plan, including an evacuation plan that is tailored to the particular vessel, is easy to use, is understood by vessel management personnel both on board and ashore, and is updated regularly.

Paragraph (f) of 46 CFR 199.630 contains additional information about the contents of the safety assessment.

The Coast Guard recognizes that this performance-based regulation, designed to allow for flexibility, will inevitably involve some inconsistencies and differences of opinion. The implementation workshops will provide opportunities for the Coast Guard and vessel operators to work together to minimize these problems. The workshop participants will create a consistent process for the development and approval of safety assessments, which include Shipboard Safety Management and Contingency Plans. The workshops will consider risk management principles such as the types of contingencies that need to be planned for, the probabilities of various types of emergencies, given the characteristics of the waterway, and to what degree ship characteristics and alternative equipment can substitute for lifesaving equipment.

The product of the workshops, which will be distributed to vessel operators and OCMIs after the completion of all four workshops, is the development of the criteria that will be used by the OCMI in the safety assessment approval process.

Format of Subchapter W Implementation Workshops

The subchapter W implementation workshops are open to the public and will consist of briefings and facilitated breakout sessions.

The morning sessions of the one-day workshops will provide background information and outline the Coast Guard view on the safety assessment approval process.

The afternoon sessions will be facilitated to tailor the safety assessment approval process and to develop criteria that will be used by the OCMI in the approval process. Members of the public attending the meetings are welcome to participate in all sessions. The workshops will begin at 9 a.m. with registration at 8:30 a.m.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact LCDR Kevin Kiefer, Lifesaving and Fire Safety Division (G–MSE–4), U.S. Coast Guard Headquarters, telephone 202–267–1444, fax 202–267–4816, or email KKiefer@comdt.uscg.mil, as soon as possible.

Dated: July 14, 2000.

Joseph J. Angelo,

Director of Standards, Marine Safety and Environmental Standards.

[FR Doc. 00–18554 Filed 7–20–00; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Lincoln County, Oregon

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Intent.

SUMMARY: The FHWA is issuing this notice to advise the public that a supplement to an Environmental Impact Statement (EIS) will be prepared for a proposed highway project in Lincoln County, Oregon. The Oregon Department of Transportation (ODOT) initially started the project development process for the proposed Pioneer Mountain-Eddyville project with the intent to use their own funds to construct the project. They published a Draft Environmental Impact Statement (DEIS) in September 1993 and held a Public Hearing in October 1993. ODOT did not complete the final EIS for the proposed project. ODOT is now proposing to request federal aid participation for the project. As a result, FHWA is reviewing the DEIS, public hearing testimony, and comments received on the DEIS to determine if all federal regulations and processing requirements have been met.

FOR FURTHER INFORMATION CONTACT: Anthony Boesen, Region 2 Liaison Engineer, Federal Highway Administration, Equitable Center, Suite 100, 530 Center Street NE, Salem, Oregon 97301, Telephone (503) 399–5749.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with ODOT and after evaluation of the DEIS, public hearing testimony and written comments, will prepare a Supplemental Environmental Impact Statement for the project, and hold additional public hearing as necessary.

The proposed project will realign a 10 mile, 2-lane roadway section from mile point 14.5 to 24.75 of the Corvallis-Newport Highway (US 20). Two Build Alternatives and a No-Build Alternative were considered in the DEIS. Build Alternative number one generally followed the existing roadway and the Yaquina River. Build Alternative number two is on new alignment and overall reduces the highway length by 2.5 miles. An option common to both Build Alternatives was considered for a short segment on the west end of the project; this design option was a channel change of Simpson Creek. Based on public input, agency comments and coordination, and overall environmental impacts, Build Alternative number two without the channel change of Simpson Creek is the preferred alternative determined by ODOT. Lincoln County has strongly supported Alternative 2 and has now included the proposed project in their county comprehensive land use plans.

The project is considered necessary to improve the highway to current safety standards, eliminate numerous sharp curves, reduce a higher than average accident rate that occurs on this segment of highway, and is part of an overall upgrade of this highway between the Willamette Valley and the Oregon Coast.

There have been no significant changes in development/conditions in the area since the DEIS was prepared, as the proposed route is predominately through underdeveloped large timber company holdings that have been logged within recent years. The project has been developed with consideration for the proposed listings of the salmon by the National Marine Fisheries Service (NMFS). Since then the salmon has been formally listed by NMFS. There appears to be no Section 4(f) eligible properties that would be impacted by this proposed project.

The DEIS describing the proposed action and solicitation of comments was sent to all appropriate federal, state, and local agencies by ODOT. Public meetings and a public hearing were held for the project. ODOT published a Hearing Study Report/Decision Document in March 1994 that summarized and responded to all comments received at the public hearing and on the DEIS. As a result of comments received, minor changes are being considered for inclusion in the proposed project and subsequent environmental documents. Since ODOT formally circulated the DEIS, we propose to develop a supplemental EIS and circulate it with a copy of the summary of the DEIS as part of our normal distribution. Copies of the entire DEIS will be made available upon request. Additional public meetings/public hearing will be held as needed.

To ensure that the full range of issues related to this proposed action are addressed and significant issues identified, comments, and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued on: July 12, 2000.

Elton Chang,

Environmental Engineer, Oregon Division.

[FR Doc. 00–18454 Filed 7–20–00; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–00–7570]

Highway Safety Programs; Model Specifications for Devices To Measure Breath Alcohol

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice.

SUMMARY: This notice amends the Conforming Products List for instruments that conform to the Model Specifications for Evidential Breath Testing Devices (58 FR 48705).

EFFECTIVE DATE: July 21, 2000.

FOR FURTHER INFORMATION CONTACT: Dr. James F. Frank, Office of Traffic Injury Control Programs, Impaired Driving Division (NTS–11), National Highway Traffic Safety Administration, 400 Seventh Street, SW, Washington, D.C. 20590; Telephone: (202) 366–5593.

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 a conforming Products List (CPL) of instruments that were found to conform to the Model Specifications as Appendix D to that notice (49 FR 48864).

On September 17, 1993, NHTSA published a notice (58 FR 48705) to amend the Model Specifications. The notice changed the alcohol concentration levels at which instruments are evaluated, from 0.000, 0.050, 0.101, and 0.151 BAC, to 0.000, 0.020, 0.040, 0.080, and 0.160 BAC; added a test for the presence of acetone; and expanded the definition of alcohol to include other low molecular weight alcohols including methyl or isopropyl. On June 4, 1999, the most recent amendment to the Conforming Products List (CPL) was published (64 FR 30097), identifying those instruments found to conform with the Model Specifications.

Since the last publication of the CPL, two (2) instruments have been evaluated and found to meet the model specifications, as amended on September 17, 1993, for mobile and

non-mobile use. They are: (1) Intoxilyzer 400PA manufactured by CMI, Inc. of Owensboro, KY. This device is a hand-held breath tester with a fuel cell alcohol sensor. (2) Alco Sensor IV–XL manufactured by Intoximeters, Inc. of St. Louis, MO. This device is a hand-held breath tester with a fuel cell alcohol sensor that is microprocessor controlled. It is designed to minimize operator involvement in performing the test and processing the test data.

The CPL has been amended to add these two instruments to the list.

In accordance with the foregoing, the CPL is therefore amended, as set forth below.

CONFORMING PRODUCTS LIST OF EVIDENTIAL BREATH MEASUREMENT DEVICES

Manufacturer and model	Mobile	Nonmobile
Alcohol Countermeasure Systems Corp., Mississauga, Ontario, Canada:		
Alert J3AD*	X	X
PBA3000C	X	X
BAC Systems, Inc., Ontario, Canada: Breath Analysis Computer*	X	X
CAMEC Ltd., North Shields, Tyne and Ware, England: IR Breath Analyzer*	X	X
CMI, Inc., Owensboro, KY:		
Intoxilyzer Model:		
200	X	X
200D	X	X
300	X	X
400	X	X
400PA	X	X
1400	X	X
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 (w3/8″ ID Hose option)	X	X
5000CD	X	X
5000CD/FG5	X	X
5000EN	X	X
5000 (CAL DOJ)	X	X
5000VA	X	X
PAC 1200*	X	X
S–D2	X	X
Decator Electronics, Decator, IL: Alco-Tector model 500*		X
Draeger Safety, Inc., Durango, CO:		
Alcotest Model:		
7010*	X	X
7110*	X	X
7110 MKIII	X	X
7110 MKIII–C	X	X
7410	X	X
7410 Plus	X	X
Breathalyzer Model:		
900*	X	X
900A*	X	X
900BG*	X	X
7410	X	X
7410–II	X	X
Gall's Inc., Lexington, KY: Alcohol Detection System-A.D.S. 500	X	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
3000 (rev B2A) w/FM option*	X	X
3000 (Fuel Cell)*	X	X
3000 D*	X	X
3000 DFC*	X	X
Alcomonitor		X
Alcomonitor CC	X	
Alco-Sensor III	X	X
Alco-Sensor IV	X	X
Alco-Sensor IV–XL	XL	X
Alco-Sensor AZ	X	X
RBT–AZ	X	X
RBT III	X	X
RBT III–A	X	X
RBT IV	X	X

CONFORMING PRODUCTS LIST OF EVIDENTIAL BREATH MEASUREMENT DEVICES—Continued

Manufacturer and model	Mobile	Nonmobile
RBT IV with CEM (cell enhancement module)	X	X
Intox EC/IR	X	X
Portable Intox EC/IR	X	X
Komyo Kitagawa, Kogyo, K.K.:		
Alcolyzer DPA–2*	X	X
Breath Alcohol Meter PAM 101B*	X	X
Lifeloc Technologies, Inc., (formerly Lifeloc, Inc.), Wheat Ridge, CO:		
PBA 3000B	X	X
PBA 3000–P*	X	X
PBA 3000C	X	X
Alcohol Data Sensor	X	X
Phoenix	X	X
Lion Laboratories, Ltd., Cardiff, Wales, UK:		
Alcolmeter Model:		
300	X	X
400	X	X
AE–D1*	X	X
SD–2*	X	X
EBA*	X	X
Auto-Alcolmeter*	X	
Intoxilyzer Model:		
200	X	X
200D	X	X
1400	X	X
5000 CD/FG5	X	X
5000 EN	X	X
Luckey Laboratories, San Bernadino, CA:		
Alco-Analyzer Model:		
1000*		X
2000*	X	
National Draeger, Inc., Durango, CO:		
Alcotest Model:		
7010*	X	X
7110*	X	X
7110 MKIII	X	X
7110 MKIII–C	X	X
7410	X	X
7410 Plus	X	X
Breathalyzer Model:		
900*	X	X
900A*	X	X
900BG*	X	X
7410	X	X
7410–II	X	X
National Patent Analytical Systems, Inc., Mansfield, OH:		
BAC DataMaster (with or without the Delta-1 accessory)	X	X
BAC Verifier Datamaster (with or without the Delta-1 accessory)	X	X
DataMaster cdm (with or without the Delta-1 accessory)	X	X
Omicron Systems, Palo Alto, CA:		
Intoxilyzer Model:		
4011*	X	X
4011AW*	X	X
Plus 4 Engineering, Minturn, CO: 5000 Plus4*	X	X
Seres, Paris, France:		
Alco Master	X	X
Alcopro	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 (non-Humidity Sensor)*	X	X
Sound-Off, Inc., Hudsonville, MI:		
AlcoData	X	X
Seres Alco Master	X	X
Seres Alcopro	X	X
Stephenson Corp.: Breathalyzer 900*	X	X
U.S. Alcohol Testing, Inc./Protection Devices, Inc., Rancho Cucamonga, CA:		
Alco-Analyzer 1000		X

CONFORMING PRODUCTS LIST OF EVIDENTIAL BREATH MEASUREMENT DEVICES—Continued

Manufacturer and model	Mobile	Nonmobile
Alco-Analyzer 2000		X
Alco-Analyzer 2100	X	X
Verax Systems, Inc., Fairport, NY:		
BAC Verifier*	X	X
BAC Verifier Datamaster	X	X
BAC Verifier Datamaster II*	X	X

*Instruments marked with an asterisk (*) meet the Model Specifications detailed in 49 FR 48854 (December 14, 1984) (*i.e.,* instruments tested at 0.000, 0.050, 0.101, and 0.151 BAC.) Instruments not marked with an asterisk meet the Model Specifications detailed in 58 FR 48705 (September 17, 1993), and were tested at BACs = 0.000, 0.020, 0.040, 0.080, and 0.160. All instruments that meet the Model Specifications currently in effect (dated September 17, 1993) also meet the Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids.

(23 U.S.C. 402; delegations of authority at 49 CFR 1.50 and 501.1)

Issued on: July 17, 2000.

Rose A. McMurray,

Associate Administrator for Traffic Safety Programs.

[FR Doc. 00–18455 Filed 7–20–00; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–99–6187; Notice 2]

Athey Products Corporation, Grant of Application for Decision That Noncompliance Is Inconsequential to Motor Vehicle Safety

Athey Products Corporation (Athey) determined that certain Mobil model Street Sweepers it produced are not in full compliance with 49 CFR 571.105, Federal Motor Vehicle Safety Standard (FMVSS) No. 105, ''Hydraulic and Electric Brake Systems,'' and filed an appropriate report pursuant to 49 CFR Part 573, ''Defect and Noncompliance Reports.'' Athey also applied to be exempted from the notification and remedy requirements of 49 U.S.C. Chapter 301—''Motor Vehicle Safety'' on the basis that the noncompliance is inconsequential to motor vehicle safety.

Notice of receipt of an application was published, with a 30-day comment period, on October 21, 1999 in the **Federal Register** (64 FR 56835). NHTSA received no comments on this application during the comment period.

Paragraph S5.5 of FMVSS No. 105 requires each vehicle with a gross vehicle weight rating greater than 10,000 pounds, except for a vehicle with a speed attainable in 2 miles of not more than 33 mph, to be equipped with an antilock brake system (ABS) that directly controls the wheels of at least one front axle and the wheels of at least one rear axle of the vehicle. Vehicles that do not comply with the requirements of a FMVSS are subject to the notification and remedy requirements of Chapter 301, unless exempted pursuant to 49 U.S.C. 30118(d) and 30120(h) on the basis that the noncompliance is inconsequential to motor vehicle safety. The effective date of the requirement for ABS on medium and heavy duty hydraulically-braked trucks was March 1, 1999.

Between March 1, 1999 and July 31, 1999 Athey manufactured, sold and/or distributed 21 Athey Mobil M8A model street sweepers and 56 Mobil M9D model street sweepers which were not equipped with ABS as required by FMVSS No. 105. To the best of Athey's knowledge, there were no other vehicles manufactured by the company that are noncompliant with the ABS requirements.

Athey supported its application by stating that the agency recognized that vehicle stopping distances and stability would not be substantially improved with ABS during maximum braking at speeds below 33 mph. According to Athey, the noncompliant vehicles are capable of speeds in excess of 33 mph, but spend the majority of their operating time at speeds below 33 mph. A review of information from its customers indicated that these street sweepers spend 80% to 90% of their operation time at speeds that are most effective at removal of road debris, speeds in the 3 to 7 mph range. In Athey's opinion, due to the low speed operation of these vehicles and the type of road use of street sweepers, maximum brake application does not normally cause lockup and the subsequent loss of vehicle control or jack knifing. Athey also stated that these street sweeper models are seldom operated in inclement weather thereby reducing the need for ABS.

Athey further stated that the hydraulic service brake system with which the noncompliant street sweepers are equipped is capable of providing substantially more brake torque than necessary to meet the 30 mph and 60 mph stopping performance requirements in FMVSS No. 105.

In addition to information supporting its arguments that the noncompliance with FMVSS No. 105 is inconsequential, Athey cited several other developments and circumstances that it considered relevant to its application. Athey stated that it attempted to secure the necessary ABS equipment from suppliers in order to meet the March 1, 1999 effective date for ABS installation, but experienced delays in receiving ABS equipment from suppliers due to a backlog of orders for ABS components. Further, immediately upon becoming aware of the consequences of the noncompliance, Athey halted all further sales and/or distribution of the Mobil model M8A and M9D street sweepers until compliance with the ABS requirements was achieved.

According to Athey, the importance of the service provided by street sweepers on public and private roadways should not be overlooked. The removal of waste material such as broken glass and other sharp, potentially dangerous objects from the roadway is a health and safety benefit.

Athey also noted that the agency granted a temporary exemption to the Johnson Sweeper Company (JSC) under 49 CFR part 555 from the ABS requirements of FMVSS No. 105. The agency cited the low speed operation of the JSC street sweepers and a reduction in the number of sweepers to fill the need of municipalities if JSC sweepers were not available, as important factors in its decision.

Upon its review of this petition, the agency believes that the true measure of inconsequentiality to motor vehicle safety is the effect of the noncompliance on the operation of the vehicles. Athey has described the effect of the absence of ABS on the operational characteristics, the braking capacity, and the braking stability of these specialized vehicles. The street sweepers spend the majority of their operating time at speeds in the 3 to 7 mph range for maximum debris removal effectiveness, speeds well below the vehicle speed capability for which ABS

installation is required or effective. During low speed operation, maximum braking does not generally result in wheel lockup and the subsequent potential for loss of vehicle control. These street sweepers are seldom operated in inclement weather, which further reduces the need for ABS.

Athey stated that the company has reviewed its manufacturing process, determined the cause of the noncompliance with the ABS requirements of FMVSS No. 105, and taken corrective measures to eliminate this type of noncompliance in the future.

In consideration of the foregoing, NHTSA has decided that the applicant has met its burden of persuasion that the noncompliance it describes is inconsequential to safety. Accordingly, its application is granted, and the applicant is exempted from providing the notification of the noncompliance that is required by 49 U.S.C. 30118, and from remedying the noncompliance, as required by 49 U.S.C. 30120.

(49 U.S.C. 30118, 30120; delegations of authority of 49 CFR 1.50 and 501.8)

Issued on: July 17, 2000.

Stephen R. Kratzke,

Associate Administrator for Safety Performance Standards.

[FR Doc. 00–18514 Filed 7–20–00; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33897]

Arkansas-Oklahoma Railroad Company—Lease and Operation Exemption—Union Pacific Railroad Company

Arkansas-Oklahoma Railroad Company, a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to lease and operate 35.5 miles of rail line from Union Pacific Railroad Company between milepost 446.5, near Shawnee, OK, and milepost 482.0, near Oklahoma City, OK.

The transaction was scheduled to be consummated within seven days following the July 7, 2000 effective date of the exemption.

If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke does not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 33897, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, NW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Edward W. Landreth, Arkansas-Oklahoma Railroad Company, P.O. Box 485, Wilburton, OK 74578.

Board decisions and notices are available on our website at ''WWW.STB.DOT.GOV.''

Dated:Decided: July 13, 2000.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 00–18429 Filed 7–20–00; 8:45 am]

BILLING CODE 4915–00–P

Corrections

Federal Register

Vol. 65, No. 141

Friday, July 21, 2000

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); TRICARE Prime Enrollment

Correction

In rule document 00–16263 beginning on page 39804 in the issue of Wednesday, June 28, 2000, make the following correction:

§199.17 [Corrected]

On page 39805, in the third column, in the third paragraph, in §199.17 ''(o)(6)'' should read ''(o)(7)''.

[FR Doc. C0–16263 Filed 7–20–00; 8:45 am]

BILLING CODE 1505–01–D

FEDERAL HOUSING FINANCE BOARD

[No. 2000-N-4]

Federal Home Loan Bank Members Selected for Community Support Review

Correction

In notice document 00–17134, beginning on page 43752, in the issue of Friday, July 14, 2000, make the following corrections:

1.On page 43754, in the table, the sixth line from the bottom, remove the entire entry for '' Delaware National Bank''.

2. On page 43756, in the table, above the fifth line from the bottom, add the heading '' **Federal Home Loan Bank of Indianapolis— District 6**''.

[FR Doc. C0–17134 Filed 7–20–00; 8:45 am]

BILLING CODE 1505–01–D

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–42908; File No. SR–NASD–00–22]

Self Regulatory Organizations: Notice of Filing of Proposed Rule Change by the National Association of Securities Dealers, Inc. Relating to Limit Order Protection for OTC Bulletin Board Securities

Correction

In notice document 00–15242, beginning on page 37808, in the issue of Friday, June 16, 2000, make the following correction:

On page 37810, in the third column, under the heading '' 2. Statutory Basis'', in the ninth line, ''protest'' should read ''protect''.

[FR Doc. C0–15242 Filed 7–20–00; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00-AGL-03]

Modification of Class D Airspace: Rapic City, SD; Modification of Class D Airspace; Rapid City Ellsworth AFB, SD; and Modification of Class E Airspace; Rapid City, SD

Correction

In rule document 00–12164 beginning on page 30878 in the issue of Monday, May 15, 2000, make the following corrections:

§71.1 [Corrected]

1. On page 30878, in §71.1, in the third column, under **AGL SD D Rapid City, SD [Revised]** ,in the sixth line, ''5,7000'' should read '' 5,700''.

2. On the same page, in the same column, in the same paragraph, in the 11th line, ''Ellsworth AFB SC'' should read ''Ellsworth AFB SD''.

3. On the same page, in the same column, in last italicized heading, ''*Paragraph 6003*'' should read ''*Paragraph 6004*''.

[FR Doc. C0–12164 Filed 7–20–00; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Friday,
July 21, 2000

Part II

Department of Health and Human Services

Food and Drug Administration

Annual Comprehensive List of Guidance Documents at the Food and Drug Administration; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0046]

Annual Comprehensive List of Guidance Documents at the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing an annual comprehensive list of all guidance documents currently in use at the agency. We committed to publishing this list in our February 1997 ''Good Guidance Practices'' (GGP's), which set forth our policies and procedures for developing, issuing, and using guidance documents. This list is intended to inform the public of the existence and availability of all our current guidance documents.

DATES: We welcome general comments on this list and on agency guidance documents at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. We have provided information on where to obtain a single copy of any of the guidance documents listed in the specific Center's list of guidance documents.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy, Planning, and Legislation (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 27, 1997 (62 FR 8961), we announced our GGP's—our policies and procedures for developing, issuing, and using guidance documents. We adopted the GGP's to ensure your involvement in the development of guidance documents and to enhance your understanding of the availability, nature, and legal effect of such guidance.

As part of our effort to ensure meaningful interaction with the public regarding guidance documents, we committed to publish an annual comprehensive list of guidance documents and quarterly updates that list all guidance documents that were issued and withdrawn during that quarter, including ''Level 2'' guidance documents.

A. Plain Language in Guidance Documents

On June 1, 1998, the President instructed all Federal agencies to ensure the use of ''plain language'' in all new documents. As part of this initiative, We use the principles of ''plain language'' set forth by the President when writing our guidance documents. We seek your comments on the clarity of our guidances.

B. How the List is Organized

The following comprehensive list of guidance documents represents all guidances currently in effect. This comprehensive list is maintained on the FDA Internet home page. We will update and publish this list in the **Federal Register** every year. We organized the guidance documents in this comprehensive list by the issuing Center or Office within FDA, and we further grouped them by the pertinent intended users or regulatory activities. The dates in the list refer to the date we issued the guidances or, where applicable, the last date we revised a document. We also provide document numbers when they are available.

II. Guidance Documents Issued by the Center for Biologics Evaluation and Research (CBER)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Interpretative Guidelines of the Source Plasma (Human) Standards	October 2, 1973	FDA Regulated Industry	Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 1–800–835–4709 or 301–827–1800, FAX Information System: 1–888–CBER–FAX (within U.S.) or 301–827–3844 (outside U.S. and local to Rockville, MD). Internet access: http://www.fda.gov/cber
Guidelines for Reviewing Amendments to Include Plasmapheresis of Hemophiliacs	July 20, 1976	Do	Do
Package Insert: Immune Serum Globulin (Human)	March 30, 1978	Do	Do
Guidelines for Interpretation of Potency Test Results for All Forms of Adsorbed Diphtheria and Tetanus Toxoids	April 12, 1979	Do	Do
Guidelines for Immunization of Source Plasma (Human) Donors with Blood Substances	June 1, 1980	Do	Do
Collection of Human Leukocytes for Further Manufacturing (Source Leukocytes)	January 28, 1981	Do	Do
Platelet Testing Guidelines—Approval of New Procedures and Equipment	July 1, 1981	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Revised Guideline for Adding Heparin to Empty Containers for Collection of Heparinized Source Plasma (Human)	August 1, 1981	Do	Do
Requirements for Infrequent Plasmapheresis Donors	August 27, 1982	Do	Do
Recommendations to Decrease the Risk of Transmitting AIDS from Plasma Donors	March 24, 1983	Do	Do
PTC in the Manufacture of In Vitro Monoclonal Antibody Products Subject to Licensure	June 20, 1983	Do	Do
Draft PTC in the Production and Testing of Interferon Intended for Investigational Use in Humans (Interferon Test Procedures)	July 28, 1983	Do	Do
Interstate Shipment of Interferon for Investigational Use in Laboratory Research Animals or Tests in Vitro	November 21, 1983	Do	Do
Deferral of Blood Donors Who Have Received the Drug Accutane (isotretinoin/Roche); 13-cis-retinoic acid)	February 28, 1984	Do	Do
Equivalent Methods for Compatibility Testing	December 14, 1984	Do	Do
Plasma Derived from Therapeutic Plasma Exchange	December 14, 1984	Do	Do
Draft PTC in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology	April 10, 1985	Do	Do
Guidelines for Meningococcal Polysaccharide Vaccines	July 17, 1985	Do	Do
Guideline for the Uniform Labeling of Blood and Blood Components	August 1, 1985	Do	Do
Recommended Methods for Short Ragweed Pollen Extracts	November 1, 1985	Do	Do
Reduction of the Maximum Platelet Storage Period to 5 Days in an Approved Container	June 2, 1986	Do	Do
To In Vitro Diagnostic Reagent Manufacturers: Guidance On the Labeling of Human Blood Derived In Vitro Diagnostic Devices In Regard to Labeling for HTLV–III/LAV Antibody Testing	December 6, 1986	Do	Do
Guideline for Submitting Documentation for the Stability of Human Drugs and Biologics	February 1, 1987	Do	Do
Guideline for Submitting Documentation for Packaging for Human Drugs and Biologics	February 1, 1987	Do	Do
Guideline On General Principles of Process Validation	May 1, 1987	Do	Do
Guideline On Sterile Drug Products Produced by Aseptic Processing	June 1, 1987	Do	Do
Deferral of Donors Who Have Received Human Pituitary-Derived Growth Hormone	November 25, 1987	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guideline On Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices	December 1, 1987	Do	Do
Recommendations for the Management of Donors and Units That Are Initially Reactive for Hepatitis B Surface Antigen (HBsAg)	December 2, 1987	Do	Do
Extension of Dating Period for Storage of Red Blood Cells, Frozen	December 4, 1987	Do	Do
To Licensed In-Vitro Diagnostic Manufacturers: Handling of Human Blood Source Materials	December 23, 1987	Do	Do
Recommendations for Implementation of Computerization in Blood Establishments	April 6, 1988	Do	Do
Control of Unsuitable Blood and Blood Components	April 6, 1988	Do	Do
Discontinuance of Prelicensing Inspection for Immunization Using Licensed Tetanus Toxoid and Hepatitis B and Rabies Vaccines	July 7, 1988	Do	Do
Physician Substitutes	August 15, 1988	Do	Do
To Licensed Manufacturers of Blood Grouping Reagents: Criteria for Exemption of Lot Release	August 26, 1988	Do	Do
Revised Guideline for the Collection of Platelets, Pheresis	October 7, 1988	Do	Do
To Manufacturers of HTLV–I Antibody Test Kits: Antibody to Human T–Cell Lymphotropic Virus, Type I (HTLV–I) Release Panel I	October 18, 1988	Do	Do
Draft Guideline for the Design of Clinical Trials for Evaluation of Safety and Efficacy of Allergenic Products for Therapeutic Uses	November 1, 1988	Do	Do
HTLV–1 Antibody Testing	November 29, 1988	Do	Do
Use of Recombigen HIV–1 LA Test	February 1, 1989	Do	Do
Guidelines for Release of Pneumococcal Vaccine, Polyvalent	February 1, 1989	Do	Do
Guidance for Autologous Blood and Blood Components	March 15, 1989	Do	Do
HTLV–I Antibody Testing	July 6, 1989	Do	Do
Use of Recombigen HIV–1 Latex Agglutination (LA) Test	August 1, 1989	Do	Do
Draft PTC in the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Antibodies to Human Immunodeficiency Virus Type 1 (1989)	August 8, 1989	Do	Do
PTC in the Collection, Processing and Testing of Ex Vivo Activated Mononuclear Leukocytes for Administration to Humans	August 22, 1989	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Information Relevant to the Manufacture of Acellular Pertussis Vaccine	August 23, 1989	Do	Do
FDA Regulated Industries for Drug Master Files	September 1, 1989	Do	Do
Requirements for Computerization of Blood Establishments	September 8, 1989	Do	Do
Abbott Laboratories' HIVAG–1 Test for HIV–1 Antigen(s) Not Recommended for Requirements for Computerization of Blood Establishments	October 4, 1989	Do	Do
Guideline for Collection of Blood or Blood Products from Donors With Positive Tests for Infectious Disease Markers (''High Risk'' Donors)	October 26, 1989	Do	Do
Guideline for Determination of Residual Moisture in Dried Biological Products	January 1, 1990	Do	Do
Autologous Blood Collection and Processing Procedures	February 12, 1990	Do	Do
Cytokine and Growth Factor Pre-Pivotal Trial Information Package	April 2, 1990	Do	Do
Use of Genetic Systems HIV–2 EIA	June 21, 1990	Do	Do
PTC in the Safety Evaluation of Hemoglobin-Based Oxygen Carriers	August 21, 1990	Do	Do
Guideline on the Preparation of Investigational New Drug Products (Human & Animal)	March 1, 1991	Do	Do
FDA Request for Information on Blood Storage Patterns and Red Cell Contamination by Yersinia Enterocolitica	March 15, 1991	Do	Do
Revision to October 26, 1989 Guideline for Collection of Blood or Blood Products from Donors with Positive Tests for Infectious Disease Markers (High Risk Donors)	March 17, 1991	Do	Do
Deficiencies Relating to the Manufacture of Blood and Blood Components	March 20, 1991	Do	Do
Responsibilities of Blood Establishments Related to Errors & Accidents in the Manufacture of Blood and Blood Components	March 20, 1991	Do	Do
To Biologic Product Manufacturers—Controlling Materials of Bovine or Ovine Origin	May 3, 1991	Do	Do
FDA Recommendations Concerning Testing for Antibody to Hepatitis B Core Antigen (Anti-HBc)	September 10, 1991	Do	Do
Disposition of Blood Products Intended for Autologous Use That Test Repeatedly Reactive for Anti–HCV	September 11, 1991	Do	Do
Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing	December 12, 1991	Do	Do
Recommended Methods for Blood Grouping Reagents Evaluation	March 1, 1992	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Recommended Methods for Evaluating Potency, Specificity and Reactivity of Anti-Human Globulin	March 1, 1992	Do	Do
PTC in the Design and Implementation of Field Trials for Blood Grouping Reagents and Anti-Human Globulin	March 1, 1992	Do	Do
PTC in the Manufacture of In Vitro Monoclonal Antibody Products for Further Manufacturing into Blood Grouping Reagents and Anti-Human Globulin	March 1, 1992	Do	Do
Supplement to the PTC in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology: Nucleic Acid Characterization and Genetic Stability	April 6, 1992	Do	Do
Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products	April 23, 1992	Do	Do
Use of Fluorognost HIV–1 Immunofluorescent Assay (IFA)	April 23, 1992	Do	Do
Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)	April 23, 1992	Do	Do
Exemptions to Permit Persons with a History of Viral Hepatitis Before the Age of Eleven Years to Serve as Donors of Whole Blood and Plasma; Alternative Procedures, 21 CFR 640.120	April 23, 1992	Do	Do
Changes in Equipment for Processing Blood Donor Samples	July 21, 1992	Do	Do
Nomenclature for Monoclonal Blood Grouping Reagents	September 28, 1992	Do	Do
Volume Limits for Automated Collection of Source Plasma	November 4, 1992	Do	Do
FDA's Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics	November 25, 1992	Do	Do
Revision of October 7, 1988 Memo Concerning Red Blood Cell Immunization Programs	December 16, 1992	Do	Do
Draft PTC in the Characterization of Cell Lines Used to Produce Biologicals	July 12, 1993	Do	Do
CBER Refusal to File (RTF) Guidance for Product and Establishment License Applications	July 12, 1993	Do	Do
Alternatives to Lot Release	July 20, 1993	Do	Do
Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products	July 22, 1993	Do	Do
Deferral of Blood and Plasma Donors based on Medications	July 28, 1993	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti–HCV)	August 19, 1993	Do	Do
Changes in administrative procedures	September 9, 1993	Do	Do
To Sponsors of IND's using Retroviral Vectors	September 20, 1993	Do	Do
Draft Guideline for the Validation of Blood Establishment Computer Systems	September 28, 1993	Do	Do
Methods of the Allergenic Products Testing Laboratory	October 1, 1993	Do	Do
Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products; Notice	October 14, 1993	Do	Do
Guideline for Adverse Experience Reporting for Licensed Biological Products	October 15, 1993	Do	Do
Guidance Regarding Post Donation Information Reports	December 10, 1993	Do	Do
To Manufacturers: Bovine Derived Materials (BSE)	December 17, 1993	Do	Do
Donor Suitability Related to Laboratory Testing for Viral Hepatitis and a history of Viral Hepatitis	December 22, 1993	Do	Do
Compliance Program Guidance Manual (Drugs and Biologics)	1994	Do	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, 703–605–6050, (Publication No. 94–920699)
Recommendations for the Invalidation of Test Results When Using Licensed Viral Marker Assays to Screen Donors	January 3, 1994	Do	Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 1–800–835–4709 or 301–827–1800, FAX Information System: 1–888–CBER–FAX (within U.S.) or 301–827–3844 (outside U.S. and local to Rockville, MD). Internet access: http://www.fda.gov/cber
To Blood Establishment Computer Software Manufacturers	March 31, 1994	Do	Do
To Sponsors of IND's for Human Immunoglobulin Products	May 23, 1994	Do	Do
To Manufacturers of Licensed Anti-HIV Test Kits	May 26, 1994	Do	Do
Recommendations for Deferral of Donors for Malaria Risk	July 26, 1994	Do	Do
ICH Guideline for Industry: Studies in Support of Special Populations	August 1, 1994	Do	Do
OELPS, Advertising and Promotional Labeling Staff Procedural Guidance Document (Draft)	August 1, 1994	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Use of and FDA Cleared or Approved Sterile Docking Device (STCD) in Blood Bank Practices (transmittal memo 8/12/94) (corrects 7/29/94 Memo)	August 5, 1994	Do	Do
ICH Guideline for Industry: Stability Testing of New Drug Substances and Products	September 1, 1994	Do	Do
Guide to Inspections of Blood Banks, Division of Field Investigations, Office of Regional Operations, Office of Regulatory Affairs	September 1, 1994	FDA Personnel	Do
Letter to Manufacturers of Immune Globulin Intravenous (Human)(IGIV), Aseptic Meningitis Syndrome	October 3, 1994	FDA Regulated Industry	Do
Guidance on Alternatives to Lot Release for Licensed Biological Products	October 27, 1994	Do	Do
Guidance for Industry: For the Submission of Chemistry, Manufacturing, and Controls Information for Synthetic Peptide Substances	November 1994	Do	Do
Recommendations to Users of Medical Devices That Test for Infectious Disease Markers by Enzyme Immunoassay (EIA) Test Systems	December 20, 1994	Do	Do
To Manufacturers of Immune Globulin Products: Testing for Hepatitis C Virus RNA Immunoglobulin	December 27, 1994	Do	Do
Timeframe for Licensing Irradiated Blood Products	February 3, 1995	Do	Do
To Blood Establishment Computer Software Manufacturers	February 10, 1995	Do	Do
Home Specimen Collection Kit Systems Intended for Human Immunodeficiency Virus (HIV–1 and/or HIV–2) Antibody Testing; Revisions to Previous Guidance	February 23, 1995	Do	Do
ICH Guideline for Industry: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting	March 1, 1995	Do	Do
To Manufacturers of Intramuscular Immune Globulin Products: HCV RNA Testing by PCR	March 3, 1995	Do	Do
Revision of August 27, 1982 FDA Memo: Requirements for Infrequent Plasmapheresis Donors	March 10, 1995	Do	Do
To Manufacturers of Intramuscular Immune Globulin Products: additional information regarding HCV RNA testing by PCR	March 13, 1995	Do	Do
To Health Professionals: Implementation of Testing for HCV RNA by PCR for Immune Globulin Products for Intramuscular Administration	March 14, 1995	Do	Do
To All Establishments Performing Red Blood Cell Immunizations: Revised Recommendations for Red Blood Cell Immunization Programs for Source Plasma	March 14, 1995	Do	Do
Reviewer Guidance, Computer Software	March 26, 1995	FDA Personnel	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Recommendations for the Deferral of Current and Recent Inmates of Correctional Institutions as Donors of Whole Blood, Blood Components, Source Leukocytes and Source Plasma	June 8, 1995	FDA Regulated Industry	Do
Guideline for Quality Assurance in Blood Establishments	July 11, 1995	Do	Do
FDA Guidance Document Concerning Use of Pilot Manufacturing Facilities for the Development and Manufacture of Biological Products	July 11, 1995	Do	Do
Disposition of Products Derived from Donors Diagnosed with, or at Known HighRisk for, Creutzfeldt-Jakob Disease	August 8, 1995	Do	Do
Recommendations for Labeling and Use of Units of Whole Blood, Blood Components, Source Plasma, Recovered Plasma or Source Leukocytes Obtained from Donors with Elevated Levels of Alanine Aminotransferase (ALT)	August 8, 1995	Do	Do
Precautionary Measures to Further Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease by Blood and Blood Products	August 8, 1995	Do	Do
Recommendations for Donor Screening with a Licensed Test for HIV-1 Antigen	August 8, 1995	Do	Do
PTC in the Manufacture and Testing of Therapeutic Products for Human Use Derived from Transgenic Animals	August 22, 1995	Do	Do
Informed Consent for Plasmapheresis/Immunization	October 1, 1995	FDA Personnel	Do
Draft Reviewers' Guide: Changes in Personnel	October 1, 1995	FDA Personnel	Do
Disease Associated Antibody Collection Program	October 1, 1995	FDA Personnel	Do
Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products	November 1, 1995	FDA Regulated Industry	Do
Guidance Concerning Conversion to FDA-Reviewed Software Products	November 13, 1995	Do	Do
Donor Deferral Due to Red Blood Cell Loss During Collection of Source Plasma by Automated Plasmapheresis	December 4, 1995	Do	Do
Interim Definition and Elimination of Lot-by-Lot Release for Well-Characterized Therapeutic Recombinant DNA-Derived and Monoclonal Antibody Biotechnology Products	December 8, 1995	Do	Do
Dear Colleague: Regarding Reverse Transcriptase Activity in Viral Vaccines Produced in Chicken Cells	January 4, 1996	Do	Do
Requesting All Manufacturers Immediately to Revise Warning Section for Package Insert on Thrombin	January 4, 1996	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
ICH Final Guideline: Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Dervied Protein Products	February 23, 1996	Do	Do
ICH Final Guideline on the Need for Long-Term Rodent Carcinogenicity Study of Pharmaceuticals	March 1, 1996	Do	Do
Additional Recommendations for Donor Screening With a Licensed Test for HIV–1 Antigen	March 14, 1996	Do	Do
FDA Guidance Concerning Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-Derived Products	March 26, 1996	Do	Do
ICH Guideline on the Detection of Toxicity to Reproduction for Medicinal Products; Addendum on Toxicity to Male Fertility	April 5, 1996	Do	Do
ICH Guidance on Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals	April 24, 1996	Do	Do
To Manufacturers of FDA–Regulated Drug/Biological/Device Products, Bovine Spongiform Encephalopathy (BSE)	May 9, 1996	Do	Do
Additional Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leucocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)	May 16, 1996	Do	Do
Guidance for Industry—The Content and Format for Pediatric Use Supplements	May 23, 1996	Do	Do
Guidance on Applications for Products Comprised of Living Autologous Cells Manipulated Ex Vivo and Intended for Structural Repair of Reconstruction	May 24, 1996	Do	Do
Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products	May 29, 1996	Do	Do
Guide to Inspections of Infectious Disease Marker Testing Facilities	June 1, 1996	FDA Personnel	Do
To Manufacturers: Implementation of testing for Hepatitis C virus RNA by Manufacturers: Implementation of testing for Hepatitis C virus RNA by polymerase chain reaction (PCR) of intramuscular immune globulin preparations	June 13, 1996	FDA Regulated Industry	Do
ICH Final Guidelines on Stablity Testing of Biotechnological/Biological Products	July 10, 1996		
ICH Guideline on Structure and Content of Clinical Study Reports	July 17, 1996	Do	Do
Recommendations for the Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human T–Lymphotropic Virus Type I (HTLV–I)	July 19, 1996	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
To Manufacturers: HIV–1 Group O	July 31, 1996	Do	Do
Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA–Derived Product or a Monoclonal Antibody Product for In Vivo Use	August 15, 1996	Do	Do
ICH Revised Guidance: Single Dose Acute Toxicity Testing for Pharmaceuticals	August 26, 1996	Do	Do
Draft Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation; Notice	September 23, 1996	Do	Do
ICH Draft Guideline on Data Elements for Transmission of Individual Case Reports	October 1, 1996	Do	Do
To All Plasma Derivative Manufacturers and to ABRA: Warning Statement for Plasma Derivative Product Labeling	October 7, 1996	Do	Do
Advertising and Promotion; Guidance; Notice	October 8, 1996	Do	Do
To Biologic Product Manufacturers: Revised Procedures for Internal Labeling Review Number Assignment	December 3, 1996	Do	Do
Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection	December 11, 1996	Do	Do
PTC on Plasmid DNA Vaccines for Preventive Infectious Disease Indications	December 22, 1996	Do	Do
Guidance for the Submission of Chemistry, Manufacturing, and Controls Information and Establishment Description for Autologous Somatic Cell Therapy Products	January 1997	Do	Do
Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software	January 13, 1997	FDA Personnel	Do
The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents	February 27, 1997	FDA Regulated Industry	Do
Proposed Approach to Regulation of Cellular and Tissue-Based Products	February 27, 1997	Do	Do
PTC in the Manufacture and Testing of Monoclonal Antibody Products for Human Use	February 28, 1997	Do	Do
Tables 1 and 2 from Proposed Approach to Regulation of Cellular and Tissue-Based Products	March 4, 1997	Do	Do
Preclearance of Promotional Labeling; Clarification	March 5, 1997	Do	Do
Guidance for Industry for the Evaluation of Combination Vaccines for Preventable Diseases: Production, Testing and Clinical Studies	April 1997	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
ICH Draft Guideline on Dose Selection for Carcinogenicity Studies for Pharmaceuticals: Addendum on the Limit Dose	April 2, 1997	Do	Do
ICH Draft Guideline on the Timing of Nonclinical Studies for the Conduct of Human Clinical Trials for Pharmaceuticals	May 2, 1997	Do	Do
ICH Draft Guideline on Impurities: Residual Solvents	May 2, 1997 (Correction May 19, 1997)	Do	Do
ICH Guideline on Stability Testing for New Dosage Forms	May 9, 1997	Do	Do
ICH Draft Guideline on Statistical Principles for Clinical Trials, Part III	May 9, 1997	Do	Do
ICH Good Clinical Practice: Consolidated Guideline, Part II	May 9, 1997	Do	Do
ICH Guideline for the Photostability Testing of New Drug Substances and Products, Part II	May 16, 1997	Do	Do
ICH Guideline on Impurities in New Drug Products, Part IV	May 19, 1997	Do	Do
ICH Guideline on Clinical Safety Data Management: Periodic Safety Update Reports for marketed Drugs, Part VI	May 19, 1997	Do	Do
ICH Guideline on the Validatioin of Analytical Procedures: Methodology, Part V	May 19, 1997	Do	Do
To Plasma Fractionators—CBER's View on Product Recalls Conducted by the Plasma Fractionation Industry	May 29, 1997	Do	Do
ICH Draft Guideline on General Considerations for Clinical Trials	May 30, 1997	Do	Do
Guide to Inspections of Source Plasma Establishments (Division of Field Investigations, Office of Regional Operations, Office of Regulatory Affairs)	June 1, 1997	FDA Personnel	Do
Draft Guidance for Industry: Computerized Systems Used in Clinical Trials; Availability	June 18, 1997	FDA Regulated Industry	Do
Guidance for Industry—Changes to an Approved Application: Biological Products	July 1997	Do	Do
Guidance for Industry—Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products	July 1997	Do	Do
Guidance for Industry—Screening and Testing of Donors of Human Tissue Intended for Transplantation	July 1997	Do	Do
Guidance for Industry—Donor Screening for Antibodies to HTLV-II	August 1997	Do	Do
Draft Guidance for Industry on Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts	August 1997	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance for Industry—Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report	August 1997	Do	Do
Draft Guidance for Industry Efficacy Evaluation of Hemoglobin-and Perfluorocarbon-Based Oxygen Carriers	September 1997	Do	Do
Guidance for Industry -The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) in FDA-Regulated Products for Human Use	September 1997	Do	Do
Notification Process for Transfusion Related Fatalities and Donation Related Deaths (revised telephone number)	October 7, 1997	Do	Do
Submission Requirements for Requesting Certificates for Exporting Products to Foreign Countries	October 15, 1997	Do	Do
ICH Guidance on Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals	November 18, 1997	Do	Do
ICH Guidance on Genotoxicity: A Standard Battery for Genotoxicity Testing for Pharmaceuticals	November 21, 1997	Do	Do
ICH Guidance on Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals	November 25 1997	Do	Do
ICH Draft Guidance on Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances	November 25, 1997	Do	Do
Guidance for FDA and Industry: Direct Final Rule Procedures	November 21, 1997	FDA Personnel and Regulated Industry	Do
Draft Guidance for Industry: Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMS)	December 1997	FDA Regulated Industry	Do
Guidance for Industry: Industry-Supported Scientific and Educational Activities	December 3, 1997	Do	Do
ICH Guidance on Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on a Limit Dose and Related Notes	December 4, 1997	Do	Do
To Biologic Product Manufacturers—Withdrawal of Human Blood-Derived Materials Because Donors Diagnosed With, or At Increased Risk For, CJD	December 11, 1997	Do	Do
To Allergenic Extract Manufacturers—Standardized Grass Pollen Extracts	December 23, 1997	Do	Do
ICH Guidance on Data Elements for Transmission of Individual Case Safety Reports	January 15, 1998		

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance for Industry: Year 2000 Date Change for Computer Systems and Software Applications Used in the Manufacture of Blood Products	January 1998	Do	Do
Draft Guidance for Industry: Container and Closure Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products	January 1998	Do	Do
ICH Guidance on Testing for Carncinogenicity of Pharmaceuticals	February 28, 1998		
Draft Guidance for Industry: Manufacturing, Processing or Holding Active Pharmaceutical Ingredients	March 1998	Do	Do
Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy	March 1998	Do	Do
Draft Guidance for Industry: Instructions for Submitting Electronic Lot Release Protocols to the Center for Biologics Evaluation and Research	May 1998	Do	Do
Draft Guidance for Industry: Pilot Program for Electronic Investigational New Drug (eIND) Applications for Biological Products	May 1998	Do	Do
Guidance for Industry: Submitting and Reviewing Complete Responses to Clinical Holds	May 1998	Do	Do
Guidance for Industry: Classifying Resubmissions in Response to Action Letters	May 1998	Do	Do
Guidance for Industry: Pharmacokinetics in Patients with Impaired Renal Function—Study Design, Data Analysis and Impact on Dosing and Labeling	May 1998	Do	Do
Guidance for Industry: Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements	May 1998	Do	Do
Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products	May 1998	Do	Do
Draft Guidance for Industry: Stability Testing of Drug Substances and Drug Products	June 1998	Do	Do
Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug and Cosmetic Act	June 1998	Do	Do
Guidance for Industry: Errors and Accidents Regarding Saline Dilution of Samples Used for Viral Marker Testing	June 1998	Do	Do
ICH Draft Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	June 9, 1998	Do	Do
ICH Guidance on Ethnic Factors in the Acceptability of Foreign Clinical Data	June 10, 1998	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Draft Guidance for Industry: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996	June 12, 1998	Do	Do
Guidance for Industry: Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997—Elimination of Certain Labeling Requirements	July 1998	Do	Do
Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications	July 1998	Do	Do
Draft Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods	July 1998	Do	Do
Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV	September 1998	Do	Do
Draft Guidance for Industry: Submitting Debarment Certification Statements	September 1998	Do	Do
Guidance for Industry: How to Complete the Vaccine Adverse Reporting System Form (VAERS–1)	September 1998	Do	Do
Guidance for Industry: Fast Track Drug Development Programs—Designation, Development, and Application Review	September 1998	Do	Do
ICH Guidance on Statistical Principles for Clinical Trials	September 16, 1998	Do	Do
ICH Guidance on Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products	September 21, 1998	Do	Do
ICH Guidance on Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin	September 24, 1998	Do	Do
Draft Guidance for Industry: Developing Medical Imaging Drugs and Biologics	October 1998	Do	Do
Guidance for Industry: on Advisory Committees: Implementing Section 120 of the Food and Drug Administration Act of 1997	October 1998	Do	Do
Draft Document: United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128	December 1997 (Released November 1998)	Do	Do
Draft Guidance for Industry: General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products	November 1998	Do	Do
To Viral Vaccine IND Sponsors—Use of PCR-based Reverse Transcriptase Assay	December 18, 1998	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products	December 1998	Do	Do
Draft Guidance for Industry: Content and Format of Geriatric Labeling	December 1998	Do	Do
Draft Guidance for Industry: Product Name Placement, Size and Prominence in Advertising and Promotional Labeling	January 1999	Do	Do
Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product	January 1999	Do	Do
Guidance on Amended Procedures for Advisory Panel Meetings	January 1999	Do	Do
Guidance for Industry: Providing Regulatory Submissions in Electronic Format—General Considerations	January 1999	Do	Do
Guidance for Industry: Population Pharmacokinetics	February 1999	Do	Do
Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological Products, Animal Plasma or Serum-Derived Products	February 1999	Do	Do
Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological Products, Animal Plasma or Serum-Derived Products	February 1999	Do	Do
Draft Guidance for Industry: INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products, Chemistry Manufacturing and Controls Content and Format	February 1999	Do	Do
Draft Guidance for Industry: Accelerated Approval Products—Submission of Promotional Materials	March 1999	Do	Do
Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product	March 1999	Do	Do
Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans	April 1999	Do	Do
Guidance for Industry On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test	April 1999	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance for Industry For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the Form FDA 356h ''Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use''	May 1999	Do	Do
Guidance for Industry For Platelet Testing and Evaluation of Platelet Substitute Products	May 1999	Do	Do
Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use	May 1999	Do	Do
Draft Guidance for Industry: Monoclonal Antibodies Used as Reagents in Drug Manufacturing	May 1999	Do	Do
Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Documentation	May 1999	Do	Do
Draft Guidance for Industry: Establishing Pregnancy Registries	June 1999	Do	Do
Draft Reviewer Guidance: Evaluation of Human Pregnancy Outcome Data	June 1999	FDA Personnel	Do
Draft Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections from donors with Repeatedly Reactive Screening Tests for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of donor Test Results for Antibody to HCV (Anti-HCV)	June 1999	FDA Regulated Industry	Do
ICH Guidance on the Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing)	June 25, 1999	Do	Do
Draft Guidance for Industry: Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA)	July 1999	Do	Do
Draft Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations	July 1999	Do	Do
Draft Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics	August 1999	Do	Do
Guidance for Industry: Consumer-Directed Broadcast Advertisements	August 1999	Do	Do
Draft Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act	August 1999	Do	Do
Guidance for Industry: Possible Dioxin/PCB Contamination of Drug and Biological Products	August 1999	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance for Industry: Submission of Abbreviated Reports and Synopses in Support of Marketing Applications	August 1999	Do	Do
ICH Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	August 18, 1999	Do	Do
Draft Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors	September 1999	Do	Do
Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug and Cosmetic Act	September 1999	Do	Do
International Conference on Harmonisation Draft Guidance; Choice of Control Group in Clinical Trials	September 24, 1999	Do	Do
Draft Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors	November 1999	Do	Do
Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format—Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA)/ Establishment License Application (ELA) and New Drug Application (NDA)]—Revised	November 1999	Do	Do
Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products	November 1999	Do	Do
Guidance for Industry: In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis and Recommendations for Dosing and Labeling	November 1999	Do	Do
Draft Guidance for Industry: Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma	November 1999	Do	Do
Draft Guidance for Industry: Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis and Impact on Dosing and Labeling	November 1999	Do	Do
International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use M4: Common Technical Document	November 8, 1999	Do	Do
Guidance for Industry: In the Manufacture and Clinical Evaluation of *In Vitro* Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2	December 1999	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Contacts	December 1999	Do	Do
Draft Guidance for Industry: Special Protocol Assessment	December 1999	Do	Do
Draft Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture	January 2000	Do	Do
Draft Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol	February 2000	FDA Personnel	Do
Draft Guidance for Industry: IND Meetings for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information	February 2000	FDA Regulated Industry	Do
Guidance for Industry: Formal Meetings With Sponsors and Applicants for PDUFA Products	February 2000	Do	Do
Guidance for Industry: Formal Dispute Resolution: Appeals Above the Division Level	February 2000	Do	Do
Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing	February 2000	Do	Do
Draft Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank	March 2000	Do	Do
International Conference on Harmonisation; E11: Clinical Investigation of Medicinal Products in the Pediatric Population	April 12, 2000	Do	Do
International Conference on Harmonisation; Draft Revised Guidance on Q1A(R) Stability Testing of New Drug Substances and Products	April 21, 2000	Do	Do

III. Guidance Documents Issued by the Center for Drug Evaluation and Research (CDER)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Accelerated Approval Products—Submission of Promotional Materials	March 26, 1999	Advertising Draft	http://www.fda.gov/cder/guidance/index.htm
Product Name, Placement, Size, and Prominence in Advertising and Promotional Labeling	March 12, 1999	Do	Do
Promoting Medical Products in a Changing Healthcare Environment; Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs)	January 5, 1998	Do	Do
Aerosol Steroid Product Safety Information in Prescription Drug Advertising and Promotional Labeling	January 12, 1998	Advertising	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Consumer-Directed Broadcast Advertisements	August 9, 1999	Do	Do
Antifungal (topical)	February 24, 1990	Biopharmaceutic Draft	Do
Antifungal (vaginal)	February 24, 1990	Do	Do
Average, Population, and Individual Approaches to Establishing Bioequivalence	August 27, 1999	Do	Do
Bioanalytical Methods Validations for Human Studies	January 5, 1999	Do	Do
Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action	June 2, 1999	Do	Do
Bioavailability and Bioequivalence Studies for Orally Administered Drug Products	August 27, 1999	Do	Do
Conjugated Estrogens, USP: LC–MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence	March 9, 2000	Do	Do
Food-Effect Bioavailability and Bioequivalence Studies	December 20, 1997	Do	Do
Topical Dermatological Drug Product NDA's and ANDA's—In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies	June 18, 1998	Do	Do
Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Containing Certain Active Moieties/Active Ingredients	February 17, 1999	Do	Do
Buspirone Hydrochloride Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	May 15, 1998	Biopharmaceutic	Do
Cholestyramine Powder In Vitro Bioequivalence	July 15, 1993	Do	Do
Cimetidine Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	June 12, 1992	Do	Do
Clozapine (Tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	November 15, 1996	Do	Do
Corticosteroids, Dermatologic (topical) In Vivo	June 2, 1995	Do	Do
Diclofenac Sodium (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	October 6, 1994	Do	Do
Dissolution Testing of Immediate Release Solid Oral Dosage Forms	August 25, 1997	Do	Do
Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations	September 26, 1997	Do	Do
Glipizide (Tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do
Glyburide Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do
Metaproterenol Sulfate and Albuterol Metered Dose Inhalers In Vitro	June 27, 1989	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Oral Extended (Controlled) Release Dosage Forms In Vivo Bioequivalence and In Vitro Dissolution Testing	September 9, 1993	Do	Do
Phenytoin/Phenytion Sodium (capsules, tablets, suspension) In Vivo Bioequivalence and In Vitro Dissolution Testing	March 4, 1994	Do	Do
Potassium Chloride (slow-release tablets and capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 6, 1994	Do	Do
Statistical Procedure for Bioequivalence Studies Using a Standard Two-Treatment Crossover Design	July 1, 1992	Do	Do
BACPAC I: Intermediates in Drug Substance Synthesis (Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation)	November 30, 1998	Chemistry Draft	Do
IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information	February 4, 2000	Do	Do
IND's for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products; Chemistry, Manufacturing, and Controls Content and Format	April 20, 1999	Do	Do
Metered Dose Inhalers (MDI) and Dry Powder Inhalers (DPI) Drug Products; Chemistry, Manufacturing, and Controls Documentation	November 19, 1998	Do	Do
Monoclonal Antibodies Used as Reagents in Drug Manufacturing	June 24, 1999	Do	Do
Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products	June 2, 1999	Do	Do
Stability Testing of Drug Substances and Drug Products	June 8, 1998	Do	Do
Submitting Supporting Chemistry Documentation in Radiopharmaceutical Drug Applications	November 1, 1991	Do	Do
SUPAC–SS: Nonsterile Semisolid Dosage Forms Manufacturing Equipment Addendum	January 5, 1999	Do	Do
Tracking of NDA and ANDA Reformulations for Solid, Oral, Immediate Release Drug Products		Do	Do
Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products	July 24, 1997	Chemistry	Do
Changes to an Approved NDA or ANDA	November 23, 1999	Do	Do
Container Closure Systems for Packaging Human Drugs and Biologics	July 7, 1999	Do	Do
Drug Master Files	September 1, 1989	Do	Do
Drug Master Files for Bulk Antibiotic Drug Substances	November 29, 1999	Do	Do
Environmental Assessment of Human Drugs and Biologics Applications	July 27, 1998	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
FDA's Policy Statement for the Development of New Stereoisomeric Drugs	May 1, 1992	Do	Do
Format and Content for the CMC Section of an Annual Report	September 1, 1994	Do	Do
Format and Content of the Chemistry, Manufacturing and Controls Section of an Application	February 1, 1987	Do	Do
Format and Content of the Microbiology Section of an Application	February 1, 1987	Do	Do
NDAs: Impurities in Drug Substances	February 25, 2000	Do	Do
PAC–ALTS: Postapproval Changes—Analytical Testing Laboratory Sites	April 28, 1998	Do	Do
Reviewer Guidance: Validation of Chromatographic Methods	November 1, 1994	Do	Do
Submission of Chemistry, Manufacturing and Controls Information for Synthetic Peptide Substances	November 1, 1994	Do	Do
Submission of Documentation for Sterilization Process Validation Applications for Human and Veterinary Drug Products	November 1, 1994	Do	Do
Submitting Documentation for the Manufacturing of and Controls for Drug Products	February 1, 1987	Do	Do
Submitting Documentation for the Stability of Human Drugs and Biologics	February 1, 1987	Do	Do
Submitting Samples and Analytical Data for Methods Validation	February 1, 1987	Do	Do
Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances	February 1, 1987	Do	Do
Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances	February 1, 1987	Do	Do
SUPAC IR- Immediate-Release Solid Oral Dosage Forms: Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing	November 30, 1995	Do	Do
SUPAC IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum	February 26, 1999	Do	Do
SUPAC–IR Questions and Answers	February 18, 1997	Do	Do
SUPAC–MR: Modified Release Solid Oral Dosage Forms: Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation	October 6, 1997	Do	Do
SUPAC–SS—Nonsterile Semisolid Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation	June 13, 1997	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Acute Bacterial Exacerbation of Chronic Bronchitis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Clinical Antimicrobial Draft	Do
Acute Bacterial Meningitis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Acute Bacterial Sinusitis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Acute Otitis Media; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Bacterial Vaginosis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Catheter-Related Bloodstream Infections—Developing Antimicrobial Drugs for Treatment	October 18, 1999	Do	Do
Clinical Considerations for Accelerated and Traditional Approval of Antiretroviral Drugs Using Plasma HIV RNA Measurements	September 1, 1999	Do	Do
Community Acquired Pneumonia; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Complicated Urinary Tract Infections and Pylonephritis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Developing Antimicrobial Drugs-General Considerations for Clinical Trials	July 22, 1998	Do	Do
Empiric Therapy of Febrile Neutropenia; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Evaluating Clinical Studies of Antimicrobials in the Division of Anti-Infective Drug Products	February 17, 1997	Do	Do
Lyme Disease; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Nosocomial Pneumonia; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Secondary Bacterial Infections of Acute Bronchitis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Streptococcal Pharyngitis and Tonsillitis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Uncomplicated and Complicated Skin and Skin Structure Infections; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Uncomplicated Gonorrhea—Cervical, Urethral, Rectal, and/or Pharyngeal; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Uncomplicated Urinary Tract Infections; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Vuvlovaginal Candidiasis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Clinical Development and Labeling of Anti-Infective Drug Products	October 26, 1992	Clinical Antimicrobial	Do
Clinical Evaluation of Anti-Infective Drugs (Systemic)	September 1, 1977	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Preclinical Development of Antiviral Drugs	November 1, 1990	Do	Do
Abuse Liability Assessment	July 1, 1990	Clinical Medical Draft	Do
Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA)	July 15, 1999	Do	Do
Clinical Evaluation of Anti-Anginal Drugs	January 1, 1989	Do	Do
Clinical Evaluation of Anti-Arrhythmic Drugs	July 1, 1985	Do	Do
Clinical Evaluation of Antihypertensive Drugs	May 1, 1988	Do	Do
Clinical Evaluation of Drugs for the Treatment of Congestive Heart Failure	December 1, 1987	Do	Do
Clinical Evaluation of Drugs for Ulcerative Colitis (3rd draft)		Do	Do
Clinical Evaluation of Lipid-Altering Agents in Adults and Children	September 1, 1990	Do	Do
Clinical Evaluation of Motility-Modifying Drugs		Do	Do
Clinical Evaluation of Weight-Control Drugs	September 24, 1996	Do	Do
Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review	November 22, 1996	Do	Do
Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review	October 13, 1998	Do	Do
Development and Evaluation of Drugs for the Treatment of Psychoactive Substance Use Disorders	February 12, 1992	Do	Do
Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis	June 14, 2000	Do	Do
Establishing Pregnancy Registries	June 4, 1999	Do	Do
Evaluation of Human Pregnancy Outcome Data	June 4, 1999	Do	Do
Female Sexual Dysfunction: Clinical Development of Drug Products for Treatment	May 19, 2000	Do	Do
In Vivo Pharmacokinetics and Bioavailability Studies and In Vitro Dissolution Testing for Levothyroxine Sodium Tablets	June 10, 1999	Do	Do
Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research	March 30, 2000	Do	Do
Levothyroxine Sodium	August 18, 1999	Do	Do
OTC Treatment of Herpes Labialis with Antiviral Agents	March 8, 2000	Do	Do
Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis	April 1, 1994	Do	Do
Preparation of IND Applications for New Drugs Intended for the Treatment of HIV–Infected Individuals	September 1, 1991	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
System Inflammatory Response Syndrome (SIRS) 1st Draft		Do	Do
Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA)	February 17, 1999	Clinical Medical	Do
Clinical Development Programs for MDI and DPI Drug Products	September 19, 1994	Do	Do
Clinical Evaluation of Analgesic Drugs	December 1, 1992	Do	Do
Clinical Evaluation of Antacid Drugs	April 1, 1978	Do	Do
Clinical Evaluation of Anti-Inflammatory and Antirheumatic Drugs (adults and children)	April 1, 1988	Do	Do
Clinical Evaluation of Antianxiety Drugs	September 1, 1977	Do	Do
Clinical Evaluation of Antidepressant Drugs	September 1, 1977	Do	Do
Clinical Evaluation of Antidiarrheal Drugs	September 1, 1977	Do	Do
Clinical Evaluation of Antiepileptic Drugs (adults and children)	January 1, 1981	Do	Do
Clinical Evaluation of Combination Estrogen/Progestin-Containing Drug Products Used for Hormone Replacement Therapy of Postmenopausal Women	March 20, 1995	Do	Do
Clinical Evaluation of Gastric Secretory Depressant (GSD) Drugs	September 1, 1977	Do	Do
Clinical Evaluation of General Anesthetics	May 1, 1982	Do	Do
Clinical Evaluation of Hypnotic Drugs	September 1, 1977	Do	Do
Clinical Evaluation of Laxative Drugs	April 1, 1978	Do	Do
Clinical Evaluation of Local Anesthetics	May 1, 1982	Do	Do
Clinical Evaluation of Psychoactive Drugs in Infants and Children	July 1, 1979	Do	Do
Clinical Evaluation of Radiopharmaceutical Drugs	October 1, 1981	Do	Do
Content and Format for Pediatric Use Supplements	May 24, 1996	Do	Do
Content and Format of Investigational New Drug Applications (IND's) for Phase Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products	November 20, 1995	Do	Do
Development of Vaginal Contraceptive Drugs (NDA)	April 19, 1995	Do	Do
FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products	February 2, 1999	Do	Do
FDA Requirements for Approval of Drugs to Treat Non-Small Cell Lung Cancer	January 21, 1991	Do	Do
FDA Requirements for Approval of Drugs to Treat Superficial Bladder Cancer	June 20, 1989	Do	Do
Format and Content of the Clinical and Statistical Sections of an Application	July 1, 1988	Do	Do
Format and Content of the Summary for New Drug and Antibiotic Applications	February 1, 1987	Do	Do

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Formatting, Assembling and Submitting New Drug and Antibiotic Applications	February 1, 1987	Do	Do
General Considerations for the Clinical Evaluation of Drugs	February 1, 1978	Do	Do
General Considerations for the Clinical Evaluation of Drugs in Infants and Children	September 1, 1977	Do	Do
Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Ovarian Cancer	April 13, 1988	Do	Do
Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Colon and Rectal Cancer	April 19, 1988	Do	Do
OTC Treatment of Hypercholesterolemia	October 27, 1997	Do	Do
Postmarketing Adverse Experience Reporting for Human Drugs and Licensed Biological Products; Clarification of What to Report	August 27, 1997	Do	Do
Postmarketing Reporting of Adverse Drug Experiences	March 1, 1992	Do	Do
Preclinical Development of Immunomodulatory Drugs for the Treatment of HIV Infection and Associated Disorders	September 4, 1992	Do	Do
Preparation of Investigational New Drug Products (Human and Animal)	November 1, 1992	Do	Do
Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products	May 15, 1998	Do	Do
Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs	July 22, 1993	Do	Do
Study of Drugs Likely to be Used in the Elderly	November 1, 1989	Do	Do
Submission of Abbreviated Reports and Synopses in Support of Marketing Applications	September 13, 1999	Do	Do
General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products	November 30, 1998	Clinical Pharmacology Draft	Do
Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies In Vitro	April 7, 1997	Clinical Pharmacology	Do
Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application	February 1, 1987	Do	Do
In Vivo Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling	November 24, 1999	Do	Do
Pharmacokinetics and Pharmacodynamics in Patients with Impaired Renal Function: Study Design, Data Analysis, and Impact on Dosing and Labeling	May 15, 1998	Do	Do
Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling	December 7, 1999	Do	Do
Population Pharmacokinetics	February 10, 1999	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production	November 30, 1998	Compliance Draft	Do
Manufacture, Processing or Holding of Active Pharmaceutical Ingredients	April 17, 1998	Do	Do
Repackaging of Solid Oral Dosage Form Drug Products	February 1, 1992	Do	Do
A Review of FDA's Implementation of the Drug Export Amendments of 1986		Compliance	Do
Compressed Medical Gases	February 1, 1989	Do	Do
Computerized Systems Used in Clinical Trials	May 10, 1999	Do	Do
Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron	June 27, 1997	Do	Do
General Principles of Process Validation	May 1, 1987	Do	Do
Good Laboratory Practice Regulations Questions and Answers		Do	Do
Monitoring of Clinical Investigations	January 1, 1988	Do	Do
Nuclear Pharmacy Guideline Criteria for Determining When to Register as a Drug Establishment	May 1, 1984	Do	Do
Possible Dioxin/PCB Contamination of Drug and Biological Products	August 23, 1999	Do	Do
Sterile Drug Products Produced by Aseptic Processing	May 1, 1987	Do	Do
Validation of Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices	December 1, 1987	Do	Do
Regulatory Submissions in Electronic Format; General Considerations	January 28, 1999	Electronic Submissions	Do
Regulatory Submissions in Electronic Format; New Drug Applications	January 28, 1999	Do	Do
ANDA's: Blend Uniformity Analysis	August 26, 1999	Generic Drug Draft	Do
ANDA's: Impurities in Drug Products	January 5, 1999	Do	Do
Abbreviated New Drug Application (ANDA)—Positron Emission Tomography (PET) Drug Products—With specific information for ANDA's for Fludeoxyglucose F18 Injection	April 18, 1997	Do	Do
ANDA's: Impurities in Drug Substances	December 3, 1999	Generic Drug	Do
Letter announcing that the OGD will now accept the ICH long-term storage conditions as well as the stability studies conducted in the past	August 18, 1995	Do	Do
Letter describing efforts by the CDER & the ORA to clarify the responsibilities of CDER chemistry review scientists and ORA field investigators in the new & abbreviated drug approval process in order to reduce duplication or redundancy in the process	October 14, 1994	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Letter on incomplete Abbreviated Applications, Convictions Under GDEA, Multiple Supplements, Annual Reports for Bulk Antibiotics, Batch Size for Transdermal Drugs, Bioequivalence Protocols, Research, Deviations from OGD Policy	April 8, 1994	Do	Do
Letter on the provision of new information pertaining to new bioequivalence guidelines and refuse-to-file letters	July 1, 1992	Do	Do
Letter on the provision of new procedures and policies affecting the generic drug review process	March 15, 1989	Do	Do
Letter on the request for cooperation of regulated industry to improve the efficiency and effectiveness of the generic drug review process, by assuring the completeness and accuracy of required information and data submissions	November 8, 1991	Do	Do
Letter on the response to December 20, 1984 letter from the Pharmaceutical Manufacturers Association about the Drug Price Competition and Patent Term Restoration Act	March 26, 1985	Do	Do
Letter to all ANDA and AADA applicants about the Generic Drug Enforcement Act of 1992 (GDEA), and the Office of Generic Drugs intention to refuse to file incomplete submissions as required by the new law	January 15, 1993	Do	Do
Letter to regulated industry notifying interested parties about important detailed information regarding labeling, scale-up, packaging, minor/major amendment criteria, and bioequivalence requirements	August 4, 1993	Do	Do
Major, Minor, Facsimile, and Telephone Amendments to Original Abbreviated New Drug Applications (Revised)	May 1, 2000	Do	Do
Organization of an ANDA	March 2, 1999	Do	Do
Revising ANDA Labeling Following Revision of the RLD Labeling	April 25, 2000	Do	Do
Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products	February 3, 2000	Do	Do
Variations in Drug Products that May Be Included in a Single ANDA	January 27, 1999	Do	Do
E10—Choice of Control Group in Clinical Trials	September 24, 1999	ICH Draft—Efficacy	Do
E11 Clinical Investigation of Medicinal Products in the Pediatric Population	April 12, 2000	Do	Do
M4 Common Technical Document: Request for comments on Initial Components	February 11, 2000	ICH Draft—Joint Safety/Efficacy	Do
Q1A(R) Stability Testing of New Drug Substances and Products	April 21, 2000	ICH Draft—Quality	Do
Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances	November 25, 1997	Do	Do

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E1A The Extent of Population Exposure to Assess Clinical Safety: for Drugs Intended for Long-Term Treatment of Non-Life-Threatening Conditions	March 1, 1995	ICH—Efficacy	Do
E2A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting	March 1, 1995	Do	Do
E2B Data Elements for Transmission of Individual Case Safety Reports	January 15, 1998	Do	Do
E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs	May 19, 1997	Do	Do
E3 Structure and Content of Clinical Study Reports	July 17, 1996	Do	Do
E4 Dose-Response Information to Support Drug Registration	November 9, 1994	Do	Do
E5 Ethnic Factors in the Acceptability of Foreign Clinical Data	June 10, 1998	Do	Do
E6 Good Clinical Practice: Consolidated Guideline	May 9, 1997	Do	Do
E7 Studies in Support of Special Populations: Geriatrics	August 2, 1994	Do	Do
E8 General Considerations for Clinical Trials	December 24, 1997	Do	Do
E9 Statistical Principles for Clinical Trials	September 16, 1998	Do	Do
M3 Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals	November 25, 1997	ICH—Joint Safety/Efficacy	Do
Q1A Stability Testing of New Drug Substances and Products	September 22, 1994	ICH—Quality	Do
Q1B Photostability Testing of New Drug Substances and Products	May 16, 1997	Do	Do
Q1C Stability Testing for New Dosage Forms	May 9, 1997	Do	Do
Q2A Text on Validation of Analytical Procedures	May 1, 1995	Do	Do
Q2B Validation of Analytical Procedures: Methodology	May 19, 1997	Do	Do
Q3A Impurities in New Drug Substances	January 4, 1996	Do	Do
Q3B Impurities in New Drug Products	May 19, 1997	Do	Do
Q3C Impurities: Residual Solvents	December 24, 1997	Do	Do
Q5A Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin	September 24, 1998	Do	Do
Q5B Quality of Biotechnology Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products	February 23, 1996	Do	Do
Q5C Quality of Biotechnological Products: Stability Testing of Biotechnology/Biological Products	July 10, 1996	Do	Do

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Q5D Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products	September 21, 1998	Do	Do
Q6B—Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	August 18, 1999	Do	Do
S1A The Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals	March 1, 1996	ICH—Safety	Do
S1B Testing for Carcinogenicity in Pharmaceuticals	February 23, 1998	Do	Do
S1C Dose Selection for Carcinogenicity Studies of Pharmaceuticals	March 1, 1995	Do	Do
S1C(R) Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on a Limit Dose and Related Notes	December 4, 1997	Do	DO
S2A Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals	December 4, 1997	Do	Do
S2B Genotoxicity: Standard Battery Testing	November 21, 1997	Do	Do
S3A Toxicokinetics: The Assessment of systemic Exposure in Toxicity Studies	March 1, 1995	Do	Do
S3B Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies	March 1, 1995	Do	Do
S4A Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing)	June 25, 1999	Do	Do
S5A Detection of Toxicity to Reproduction for Medicinal Products	September 22, 1994	Do	Do
S5B Detection of Toxicity to Reproduction for Medicinal Products: Addendum on Toxicity to Male Fertility	April 5, 1996	Do	Do
S6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals	November 18, 1997	Do	Do
A Revision in Sample Collection Under the Compliance Program Pertaining to Pre-Approval Inspections	July 15, 1996	Industry Letters	o
Certification Requirements for Debarred Individuals in Drug Applications	July 27, 1992	Do	Do
Continuation of a series of letters communicating interim and informal generic drug policy and guidance. Availability of Policy and Procedure Guides, and further operational changes to the generic drug review program	June 1, 1990	Do	Do
Fifth of a series of letters providing informal notice about the Act, discussing the statutory mechanism by which ANDA applicants may make modifications in approved drugs where clinical data is required	April 10, 1987	Do	Do
Fourth of a series of letters providing informal notice to all affected parties about policy developments and interpretations regarding the Act. Three year exclusivity provisions of Title I	October 31, 1986	Do	Do

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Implementation of the Drug Price Competition and Patent Term Restoration Act. Preliminary Guidance	October 11, 1984	Do	Do
Implementation Plan USP injection nomenclature	October 2, 1995	Do	Do
Instructions for Filing Supplements Under the Provisions of SUPAC-IR	April 11, 1996	Do	Do
Seventh of a series of letters about the Act providing guidance on the ''180-day exclusivity'' provision of section 505(j)(4)(B)(iv) of the FD&C	July 29, 1988	Do	Do
Sixth of a series of informal notice letters about the Act discussing 3- and 5-year exclusivity provisions of sections 505(c)(3)(D) and 505(j)(4)(D) of the FD&C Act	April 22, 1988	Do	Do
Streamlining Initiatives	December 24, 1996	Do	Do
Supplement to 10/11/84 letter about policies, procedures and implementation of the Act (Q & A format)	November 16, 1984	Do	Do
Third of a series of letters regarding the implementation of the Act	May 1, 1985	Do	Do
Content and Format for Geriatric Labeling	January 21, 1999	Labeling Draft	Do
Non-Contraceptive Estrogen Drug Products—Physician and Patient Labeling	January 8, 1999	Do	Do
Noncontraceptive Estrogen Class Labeling	September 27, 1999	Do	Do
OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis)	July 16, 1998	Do	Do
Therapeutic Equivalence Code Placement on Prescription Drug Labels and Labeling	January 28, 1999	Do	Do
Acetaminophen and Codeine Phosphate Oral Solution/Suspension	December 1, 1993	Labeling	Do
Acetaminophen and Codeine Phosphate Tablets/Capsules	December 1, 1993	Do	Do
Acetaminophen, Aspirin and Codeine Phosphate Tablets/Capsules	December 1, 1993	Do	Do
Alprazolam Tablets USP	August 1, 1996	Do	Do
Amiloride Hydrochloride and Hydrochlorothiazide Tablets USP	September 1, 1997	Do	Do
Amlodipine Besylate Tablets	September 1, 1997	Do	Do
Astemizole Tablets	September 1, 1997	Do	Do
Atenolol Tablets USP	August 1, 1997	Do	Do
Barbiturate, Single Entity-Class Labeling	March 1, 1981	Do	Do
Butalbital, Acetaminophen and Caffeine Capsules/Tablets USP	September 1, 1997	Do	Do
Butalbital, Acetaminophen, Caffeine and Hydocodone Bitartrate Tablets	September 21, 1997	Do	Do
Butorphanol Tartrate Injection USP	October 1, 1992	Do	Do

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Captopril and Hydrochlorothiazide Tablets USP	April 1, 1995	Do	Do
Captopril Tablets	February 1, 1995	Do	Do
Carbidopa and Levodopa Tablets USP	February 1, 1992	Do	Do
Chlordiazepoxide Hydrochloride Capsules	January 1, 1988	Do	Do
Cimetidine Hydrochloride Injection	September 1, 1995	Do	Do
Cimetidine Tablets	September 1, 1995	Do	Do
Cisapride Oral Suspension	September 1, 1997	Do	Do
Cisapride Tablets	September 1, 1997	Do	Do
Clindamycin Phosphate Injection USP	September 1, 1998	Do	Do
Clorazepate Dipotassium Capsules/Tablets	March 1, 1993	Do	Do
Combination Oral Contraceptives—Physician and Patient Labeling	January 1, 1994	Do	Do
Cyproheptadine Hydrochloride Tablets/Syrup	December 1, 1986	Do	Do
Diclofenac Sodium Delayed-Release Tablets	January 1, 1997	Do	Do
Diltiazem Hydrochloride Extended-Release Capsules	September 1, 1995	Do	Do
Diphenoxylate Hydrochloride and Atropine Sulfate Oral Solution USP	April 1, 1995	Do	Do
Diphenoxylate Hydrochloride and Atropine Sulfate Tablets USP	April 1, 1995	Do	Do
Dipivefrin Hydrochloride Ophthalmic Solution, 0.1%	November 2, 1998	Do	Do
Ergoloid Mesylates Tablets	January 1, 1988	Do	Do
Fludeoxyglucose F18 Injection	January 1, 1997	Do	Do
Flurbiprofen Tablets USP	January 1, 1994	Do	Do
Fluvoxamine Maleate Tablets	September 1, 1997	Do	Do
Gentamicin Sulfate Ophthalmic Ointment and Solution USP	April 1, 1992	Do	Do
Heparin Sodium Injection USP	March 1, 1991	Do	Do
Hydrocodone Bitartrate and Acetaminophen Tablets USP	April 1, 1994	Do	Do
Hydroxyzine Hydrochloride Injection	December 1, 1989	Do	Do
Hypoglycemic Oral Agents—Federal Register	April 1, 1984	Do	Do
Indomethacin Capsules USP	September 1, 1995	Do	Do
Informal Labeling Guidance Texts for Estrogen Drug Products—Patient Labeling	August 1, 1992	Do	Do
Informal Labeling Guidance Texts for Estrogen Drug Products—Professional Labeling	August 1, 1992	Do	Do
Isoetharine Inhalation Solution	March 1, 1989	Do	Do
Itraconazole Capsules, USP	September 1, 1998	Do	Do
Leucovorin Calcium for Injection	July 1, 1996	Do	Do

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Leucovorin Calcium Tablets, USP	July 1, 1996	Do	Do
Local Anesthetics—Class Labeling	September 1, 1982	Do	Do
Meclofenamate Sodium Capsules	July 1, 1992	Do	Do
Medroxyprogesterone Acetate Tablets, USP	September 1, 1998	Do	Do
Metaproterenol Sulfate Inhalation Solution USP	May 1, 1992	Do	Do
Metaproterenol Sulfate Syrup USP	May 1, 1992	Do	Do
Metaproterenol Sulfate Tablets	May 1, 1992	Do	Do
Metoclopramide Tablets USP/Oral Solution	February 1, 1995	Do	Do
Naphazoline Hydrochloride Ophthalmic Solution	March 1, 1989	Do	Do
Naproxen Sodium Tablets, USP	September 1, 1997	Do	Do
Naproxen Tablets, USP	September 1, 1997	Do	Do
Niacin Tablets	July 1, 1992	Do	Do
Paclitaxel Injection	February 1, 1991	Do	Do
Phendimetrazine Tartrate Capsules/Tablets, and Extended-Release Capsules	February 1, 1991	Do	Do
Phentermine Hydrochloride Capsules/Tablets	August 1, 1988	Do	Do
Promethazine Hydrochloride Tablets	March 1, 1990	Do	Do
Propantheline Bromide Tablets	August 1, 1988	Do	Do
Pyridoxine Hydrochloride Injection	June 1, 1984	Do	Do
Quinidine Sulfate Tablets/Capsules USP	October 1, 1995	Do	Do
Ranitidine Tablets USP	November 1, 1993	Do	Do
Risperidone Oral Solution	September 1, 1997	Do	Do
Risperidone Tablets	September 1, 1997	Do	Do
Sulfacetamide Sodium and Prednisolone Acetate Ophthalmic Suspension and Ointment	January 1, 1995	Do	Do
Sulfacetamide Sodium Ophthalmic Solution/ Ointment	August 1, 1992	Do	Do
Sulfamethoxazole and Phenazopyridine Hydrochloride Tablets	February 1, 1992	Do	Do
Sulfamethoxazole and Trimethoprim Tablets and Oral Suspension	August 1, 1993	Do	Do
Theophylline Immediate-Release Dosage Forms	February 1, 1995	Do	Do
Theophylline Intravenous Dosage Forms	September 1, 1995	Do	Do
Thiamine Hydrochloride Injection	February 1, 1988	Do	Do
Tobramycin Sulfate Injection USP	May 1, 1993	Do	Do
Venlafaxine Hydrochloride Tablets	October 1, 1997	Do	Do
Verapamil Hydrochloride Tablets	October 1, 1991	Do	Do
Vitamin A Capsules	February 1, 1992	Do	Do

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Zolpidem Tartrate Tablets	September 1, 1997	Do	Do
Labeling OTC Human Drug Products Using a Column Format	December 1, 1997	OTC Draft	Do
OTC Actual Use Studies	July 22, 1994	Do	Do
OTC Nicotine Substitutes	March 1, 1994	Do	Do
Enforcement Policy on Marketing OTC Combination Products (CPG 7132b.16)			
General Guidelines for OTC Combination Products		Do	Do
Upgrading Category III Antiperspirants to Category I (43 FR 46728–46731)		Do	Do
Photosafety Testing	January 10, 2000	Pharmacology/Toxicology Draft	Do
Format and Content of the Nonclinical Pharmacology/Toxicology Section of an Application	February 1, 1987	Pharmacology/Toxicology	Do
Nonclinical Pharmacology/Toxicology Development of Topical Drugs Intended to Prevent the Transmission of Sexually Transmitted Diseases (STD) and/or for the Development of Drugs Intended to Act as Vaginal Contraceptives		Do	Do
Reference Guide for the Nonclinical Toxicity Studies of Antiviral Drugs Indicated for the Treatment of N/A Non-Life Threatening Disease: Evaluation of Drug Toxicity Prior to Phase I Clinical Studies	February 1, 1989	Do	Do
Single Dose Acute Toxicity Testing Toxicity Testing for Pharmaceuticals	August 26, 1996	Do	Do
Applications Covered by Section 505(b)(2)	December 8, 1999	Procedural Draft	Do
Content and Format of New Drug Applications and Abbreviated New Drug Applications for Certain Positron Emission Tomography Drug Products	March 10, 2000	Do	Do
Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by CDER, Beginning January 1, 2000	December 22, 1999	Do	Do
Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank	March 29, 2000	Do	Do
Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act	August 17, 1999	Do	Do
Special Protocol Assessment	February 9, 2000	Do	Do
Submitting Debarment Certification Statements	October 2, 1998	Do	Do
180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act	July 14, 1998	Procedural	Do
Advisory Committees: Implementing Section 120 of the Food and Drug Modernization Act of 1997	November 2, 1998	Do	Do

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Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act	March 30, 2000	Do	Do
Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000	November 30, 1999	Do	Do
Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act	November 23, 1998	Do	Do
Fast Track Drug Development Programs: Designation, Development, and Application Review	November 18, 1998	Do	Do
Formal Dispute Resolution: Appeals Above the Division Level	March 7, 2000	Do	Do
Formal Meetings With Sponsors and Applicants For PDUFA Products	March 7, 2000	Do	Do
Implementation of Section 126 of the FDA Modernization Act of 1997—Elimination of Certain Labeling Requirements	July 21, 1998	Do	Do
National Uniformity for Nonprescription Drugs Ingredient Labeling for OTC Drugs	April 9, 1998	Do	Do
Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act—Revised	October 1, 1999	Do	Do
Refusal to File	July 12, 1993	Do	Do
Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act	June 15, 1998	Do	Do
Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements	May 15, 1998	Do	Do
Street Drug Alternatives	April 3, 2000	Do	Do
Women and Minorities Guidance Requirements	July 28, 1998	Do	Do
Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act	August 17, 1999	User Fee Draft	Do
Classifying Resubmissions in Response to Action Letters	May 14, 1998	User Fee	Do
Submitting and Reviewing Complete Responses to Clinical Holds	May 14, 1998	Do	Do

IV. Guidance Documents Issued by the Center for Devices and Radiological Health (CDRH)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Compliance Program Guidance Manual: Inspection of Medical Devices; Draft	August 12, 1999	Office of Compliance (OC)	Division of Small Manufacturers Assistance; 1–800–638–2041 or 301–827–0111 or (FAX) Facts-on-Demand at 1–800–899–0381 or Internet at http://www.fda.gov/cdrh/ggpmain.html

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Procedures for Laboratory Compliance Testing of Television Receivers-part of TV Packet	May 1, 1986	Do	Do
A Pocket Guide to Device GMP Inspections-Inspections of Medical Device Manufacturers and GMP Regulation Requirements	November 1, 1991	Do	Do
General Principles of Software Validation; Draft Guidance	June 9, 1997	Do	Do
Global Harmonization Task Force Study Group 3-Process Validation Guidance; Final Draft	February 1, 1999	Do	Do
Civil Money Penalty Policy; Guidance for FDA Staff	June 8, 1999	Do	Do
Guidance on Medical Device Tracking; Guidance for Industry and FDA Staff [FDAMA]	January 24, 2000	Do	Do
Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals, Draft Guidance-Not for Implementation; Guidance for Industry and for FDA Staff	February 8, 2000	Do	Do
Cover Letter/Guidance Document on the Performance Standard for Electrode Lead Wires and Patient Cable	March 9, 1998	Do	Do
Commercial Distribution/Exhibit Letter	April 10, 1992	Do	Do
Working Draft of the Current Good Manufacturing Practice (CGMP) Final Rule	July 1, 1995	Do	Do
Regulating In Vitro Diagnostic Device (IVD) Studies; Guidance; Guidance for FDA Staff	December 17, 1999	Office of Compliance (OC)/ Division of Bioresearch Monitoring (DBM)	Do
Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects	March 19, 1999	Do	Do
A Guide for the Submission of Abbreviated Radiation Safety Reports on Cephalometric X–Ray Devices: Defined as Dental Units with an Attachment for Mandible Work that Holds a Cassette and Beam Limiting Device	March 1, 1996	Office of Compliance (OC)/ Division of Enforcement I (DOEI)	Do
A Guide for the Submission of Abbreviated Radiation Safety Reports on Image Receptor Support Devices for Mammographic X–Ray Systems	March 1, 1996	Do	Do
A Guide for the Submission of an Abbreviated Radiation Safety Report on X–Ray Tables, Cradles, Film Changers or Cassette Holders Intended for Diagnostic Use	March 1, 1996	Do	Do
Clarification of Radiation Control Regulations for Diagnostic X–Ray Equipment (FDA 89–8221)	March 1, 1989	Do	Do
CPG 7133.19: Retention of Microwave Oven Test Record/Cover Letter: August 24, 1981 Retention of Records Required by 21 CFR 1002	August 24, 1981	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Exemption from Reporting and Recordkeeping Requirements for Certain Sunlamp Product Manufacturers	September 16, 1981	Do	Do
Compliance Program Guidance Manual; Field Compliance Testing of Diagnostic (Medical) X-ray Equipment; Guidance for FDA Staff	March 15, 2000	Do	Do
Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems; Guidance for Industry	October 18, 1999	Do	Do
Guidance on Electrosurgical Devices and the Application of the Performance Standard for Electrode Lead Wires and Patient Cables	November 15, 1999	Do	Do
Guide for the Submission of Initial Reports on Diagnostic X–Ray Systems and their Major Components	January 1, 1982	Do	Do
Guideline for the Manufacture of In Vitro Diagnostic Products	January 10, 1994	Do	Do
Letter to Medical Device Industry on Endoscopy and Laparoscopy Accessories (Galdi)	May 17, 1993	Do	Do
Manufacturers/Assemblers of Diagnostic X-ray Systems: Enforcement Policy for Positive-Beam Limitation (PBL) Requirements in 21 CFR 1020.31(g)	October 13, 1993	Do	Do
Abbreviated Reports on Radiation Safety for Microwave Products (Other Than Microwave Ovens)- E.G. Microwave Heating, Microwave Diathermy, RF Sealers, Induction, Dielectric Heaters, Security Systems	August 1, 1995	Office of Compliance (OC)/ Division of Enforcement I & III (DOEI & III)	Do
Abbreviated Reports on Radiation Safety of Non-Medical Ultrasonic Products	August 1, 1995	Do	Do
Guide for Filing Annual Reports for X-Ray Components and Systems	July 1, 1980	Do	Do
Guide for Preparing Abbreviated Reports of Microwave and RF Emitting Electronic Products Intended for Medical Use	September 1, 1996	Do	Do
Guide for Preparing Product Reports for Medical Ultrasound Products	September 1, 1996	Do	Do
Guide for Preparing Reports on Radiation Safety of Microwave Ovens	March 1, 1985	Do	Do
Guide for Submission of Information on Accelerators Intended to Emit X–Radiation Required Pursuant to 21 CFR 1002.10	April 1, 1971	Do	Do
Letter to Manufacturers and Importers of Microwave Ovens: Information Requirements for Cookbooks and User and Service Manuals	October 31, 1988	Do	Do
Reporting and Compliance Guide for Television Products including Product Report, Supplemental Report, Radiation Safety Abbreviated Report, Annual Report, Information and Guidance	October 1, 1995	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Reporting Guide for Laser Light Shows and Displays (21 CFR 1002) (FDA 88–8140)	September 1, 1995	Do	Do
Revised Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products (replaces FDA 82–8127)	September 1, 1995	Do	Do
All U.S. Condom Manufacturers, Importers and Repackagers	April 7, 1987	Office of Compliance (OC)/ Division of Enforcement II (DOEII)	Do
Compliance Guide for Laser Products (FDA 86–8260)	September 1, 1985	Do	Do
Condoms: Inspection and Sampling at Domestic Manufacturers and of all Repackers; Sampling from all Importers (Damaska Memo to Field on April 8, 1987)	April 8, 1987	Do	Do
Dental Handpiece Sterilization (Dear Doctor Letter)	September 28, 1992	Do	Do
Ethylene Oxide; Ethylene Chlorohydrin; and Ethylene Glycol; Proposed Maximum Residue Limits and Maximum Levels of Exposure	June 23, 1978	Do	Do
Guidance on Quality System Regulation Information for Various Premarket Submissions; Guidance for Industry; Draft	August 3, 1999	Do	Do
Guidance on Quality System Regulation Information for Various Premarket Submissions; Guidance for Industry; Draft	August 3, 1999	Do	Do
Guide for Preparing Product Reports for Lasers and Products Containing Lasers	September 1, 1995	Do	Do
Hazards of Volume Ventilators and Heated Humidifiers	September 15, 1993	Do	Do
Latex Labeling Letter (Johnson)	March 18, 1993	Do	Do
Letter—Condom Manufacturers and Distributors	April 5, 1994	Do	Do
Letter—Manufacturers, Distributors and Importers of Condom Products	February 23, 1994	Do	Do
Letter—Manufacturers, Importers, and Repackagers of Condoms for Contraception or Sexually-Transmitted Disease Prevention (Holt)	February 13, 1989	Do	Do
Letter to All Foreign Manufacturers and Importers of Electronic Products for Which Applicable FDA Performance Standards Exist	May 28, 1981	Do	Do
Letter to Industry, Powered Wheelchair Manufacturers from RMJohnson	May 10, 1993	Do	Do
Letter to Manufacturers/Repackers Using Cotton	April 22, 1994	Do	Do
Letter to: Manufacturers and Users of Lasers for Refractive Surgery [excimer]	October 10, 1996	Do	Do
Manufacturers and Initial Distributors of Hemodialyzers	May 23, 1996	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Manufacturers and Initial Distributors of Sharps Containers and Destroyers Used by Health Care Professionals	February 3, 1994	Do	Do
Pesticide Regulation Notice 94–4: Interim Measures for the Registration of Antimicrobial Products/Liquid Chemical Germicides with Medical Device Use Claims Under the Memorandum of Understanding Between EPA and FDA	June 30, 1994	Do	Do
Application for a Variance from 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device [form FDA 3147]	July 1, 1998	Office of Compliance (OC)/ Division of Enforcement III (DOEIII)	Do
Computerized Devices/Processes Guidance—Application of the Medical Device GMP to Computerized Devices and Manufacturing Processes	May 1, 1992	Do	Do
Design Control Guidance for Medical Device Manufacturers	March 11, 1997	Do	Do
Final Design Control Report and Guidance	June 1, 1998	Do	Do
Guidance for the Submission of Cabinet X–Ray System Reports Pursuant to 21 CFR 1020.40	February 1, 1975	Do	Do
Guide for Preparing Annual Reports for Ultrasonic Therapy Products	September 1, 1996	Do	Do
Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products (replaces FDA 82–8127)	September 1, 1995	Do	Do
Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps (replaces FDA 82–8127)	September 1, 1995	Do	Do
Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General)	October 1, 1987	Do	Do
Guide for Preparing Product Reports for Ultrasonic Therapy Products (physical therapy only)	August 1, 1996	Do	Do
Guide for Preparing Product Reports on Sunlamps and Sunlamp Products (21 CFR 1002)	September 1, 1995	Do	Do
Guide for Submission of Information on Analytical X–Ray Equipment Required Pursuant to 21 CFR 1002.10	April 30, 1974	Do	Do
Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer Equipment Pursuant to 21 CFR 1002.10 and 1002.12 (FDA 81–8137)	September 1, 1980	Do	Do
Guide for Submission of Information on Industrial X–Ray Equipment Required Pursuant to 21 CFR 1002.10	March 1, 1973	Do	Do
Guide for the Submission of Initial Reports on Computed Tomography X–Ray Systems	September 1, 1984	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Impact Resistant Lenses: Questions and Answers (FDA 87–4002)	September 1, 1987	Do	Do
Keeping Medical Devices Safe from Electromagnetic Interference	July 1, 1995	Do	Do
Keeping Up With the Microwave Revolution (FDA Pub No. 91–4160)	March 1, 1990	Do	Do
Laser Light Show Safety—Who's Responsibility (FDA 86–8262)	May 1, 1986	Do	Do
Letter to Manufacturers and Importers of Microwave Ovens—Open Door Operation of Microwave Ovens as a Result of Oven Miswiring	March 28, 1980	Do	Do
Letter to Trade Association: ReUse of Single-use or Disposable Medical Devices	December 27, 1995	Do	Do
Letter: Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products	August 21, 1986	Do	Do
Medical Device Electromagnetic Interference Issues, Problem Reports, Standards, and Recommendations		Do	Do
Medical Devices and EMI: The FDA Perspective	January 1, 1995	Do	Do
Policy on Lamp Compatability (sunlamps)	September 2, 1986	Do	Do
Policy on Warning Label Required on Sunlamp Products	June 25, 1985	Do	Do
Quality Assurance Guidelines for Hemodialysis Devices	February 1, 1991	Do	Do
Quality Control Guide for Sunlamp Products (FDA 88–8234)	March 1, 1988	Do	Do
Quality Control Practices for Compliance with the Federal Mercury Vapor Lamp Performance Standard	May 1, 1980	Do	Do
Reporting Guide for Product Reports on High Intensity Mercury Vapor Discharge Lamps (21 CFR 1002)	September 1, 1995	Do	Do
Reporting of New Model Numbers to Existing Model Families	June 14, 1983	Do	Do
Safety of Electrically Powered Products: Letter To Medical Device and Electronic Product Manufacturers From Lillian Gill & BHB correction memo	September 18, 1996	Do	Do
Shielded Trocars and Needles used for Abdominal Access during Laparoscopy	August 23, 1996	Do	Do
Suggested State Regulations for Control of Radiation—Volume II Nonionizing Radiation—Lasers (FDA Pub No. 83–8220)	January 1, 1982	Do	Do
Unsafe Patient Lead Wires and Cables	September 3, 1993	Do	Do
Imports: Radiation-Producing Electronic Products (FDA 89–8008)	November 1, 1988	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance for Industry on the Likelihood of Facilities Inspections When Modifying Devices Subject to Premarket Approval	August 5, 1999	Office of Compliance (OC)/ Division of Program Operations (DOP)	Do
Letter to Medical Device Manufacturer on Pentium Processors	February 14, 1995	Office of Compliance (OC)/ Office of the Center Director (OCD)	Do
Sec. 300.600 Commercial Distribution with Regard to Premarket Notification [510(k)] [CPG 7124.19]	September 24, 1987	Do	Do
Letter to Industry, Powered Wheelchair/ Scooter or Accessory/ Component Manufacturer from Susan Alpert, Ph.D.,M.D.	May 26, 1994	Office of the Center Director (OCD)/Office of Device Evaluation (ODE)	Do
General/Specific Intended Use; Guidance for Industry; Final	November 4, 1998	Do	Do
ODE Executive Secretary Guidance Manual	August 7, 1987	Do	Do
Preamendments Class III Strategy; SXAlpert	April 19, 1994	Do	Do
Early Collaboration Meetings Under the FDA Modernization Act (FDAMA), Guidance for Industry and CDRH Staff [FDAMA]	February 19, 1998	Do	Do
''Real-Time'' Review Program for Premarket Approval Application (PMA) Supplements	April 22, 1997	Office of Device Evaluation (ODE)	Do
30-Day Notices and 135-Day PMA Supplements for Manufacturing Method or Process Changes, Guidance for Industry and CDRH [FDAMA]; Final	February 19, 1998	Do	Do
510(k) Quality Review Program (Blue Book Memo)	March 29, 1996	Do	Do
Convenience Kits Interim Regulatory Guidance (include 874)	May 20, 1997	Do	Do
Determination of Intended Use for 510(k) Devices Guidance for Industry and CDRH Staff [FDAMA]; Final	January 30, 1998	Do	Do
Distribution and Public Availability of Premarket Approval Application Summary of Safety and Effectiveness Data Packages [Blue Book Memo #P98–1]; Final	October 10, 1997	Do	Do
Document Review by the Office of the Chief Counsel (Blue Book Memo G96–1))	June 6, 1996	Do	Do
Modifications to Devices Subject to Premarket Approval—The PMA Supplement Decision Making Process; Guidance for Industry, Draft	August 6, 1998	Do	Do
Contents of Product Development Protocol; Guidance for Industry, Draft	July 27, 1998	Do	Do
Frequently Asked Questions on The New 510(k) Paradigm; Guidance for Industry; Final	October 22, 1998	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Evidence Models for the Least Burdensome Means to Market; Guidance for Industry and FDA Reviewers; Draft	September 1, 1999	Do	Do
Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review [FDAMA]; Guidance for Industry; Final	May 20, 1998	Do	Do
New Model Medical Device Development Process; Guidance for Industry; Final	July 21, 1998	Do	Do
Guidance for Off-the-Shelf Software Use in Medical Devices; Final	September 9, 1999	Do	Do
Guidance for Submitting Reclassification Petition	June 1, 1989	Do	Do
Guidance on Amended Procedures for Advisory Panel Meetings [FDAMA]; Final	January 26, 1999	Do	Do
Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies—For Use by CDRH & Industry [FDAMA]; Final	February 19, 1998	Do	Do
Guidance on the Use of Standards in Substantial Equivalence Determinations; Final	March 12, 2000	Do	Do
PMA Shell Development and Modular Review; Guidances for the Medical Device Industry; Final	November 6, 1998	Do	Do
New Section 513(f)(2)—Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff [FDAMA]; Final	February 19, 1998	Do	Do
Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff [FDAMA]; Final	February 19, 1998	Do	Do
SMDA Changes-Premarket Notification; Regulatory Requirements for Medical Devices [510(k)] Manual Insert	April 17, 1992	Do	Do
The New 510(k) Paradigm-Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final	March 20, 1998	Do	Do
4-of-A–Kind PMA's	October 1, 1991	Do	Do
Application of the Device Good Manufacturing Practice (GMP) Regulation to the Manufacture of Sterile Devices	December 1, 1983	Do	Do
CDRH Submissions Coversheet [PMA/PDP/510k/IDE]	May 8, 1998	Do	Do
CDRH's 510(k)/IDE/PMA Refuse to Accept/Accept/File Policies	June 30, 1993	Do	Do
Classified Convenience Kits	April 30, 1993	Do	Do
Color Additive Petitions (p. II–19 of PMA Manual)	June 1, 1987	Do	Do
Color Additive Status List (Inspection Operations Manual)	February 1, 1989	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Color Additives for Medical Devices (Snesko)	November 15, 1995	Do	Do
Deciding When to Submit a 510(k) for a Change to an Existing Device	January 10, 1997	Do	Do
Device Specific Guidance Documents (List)	May 11, 1993	Do	Do
FDA Guide for Validation of Biological Indicator Incubation Time	January 1, 1986	Do	Do
FDA Policy For The Regulation Of Computer Products (DRAFT)	November 13, 1989	Do	Do
Format for IDE Progress Reports	June 1996	Do	Do
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Guidance for FDA and Reviewers and Industry; Final	May 29, 1998	Do	Do
Guidance for Preparation of PMA Manufacturing Information	August 1, 1992	Do	Do
Guide for Establishing and Maintaining a Calibration Constancy Intercomparison System for Microwave Oven Compliance Survey Instruments (FDA 88–8264)	March 1, 1988	Do	Do
Guideline for the Monitoring of Clinical Investigations	January 1, 1988	Do	Do
Guideline on General Principles of Process Validation	May 1, 1987	Do	Do
Guideline on Sterile Drug Products Produced by Aseptic Processing	June 1, 1987	Do	Do
Guideline on Validation of the Limulus Amebocyte Lysate (LAL) Test as an End-Product Endotoxin Test	December 1, 1987	Do	Do
Indications for Use Statement	January 2, 1996	Do	Do
Industry Representatives on Scientific Panels	March 27, 1987	Do	Do
Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance	April 1, 1996	Do	Do
Limulus Amebocyte Lysate; Reduction of Samples for Testing	October 23, 1987	Do	Do
Master Files Part III; Guidance on Scientific and Technical Information	June 1, 1987	Do	Do
Electromagnetic Compatibility for Medical Devices: Issues and Solutions; Memorandum	June 13, 1995	Do	Do
Methods for Conducting Recall Effectiveness Checks	June 16, 1978	Do	Do
Necessary Information for Diagnostic Ultrasound 510(k) (Draft)	November 24, 1987	Do	Do
PMA Review Schedule [P87–1]	March 31, 1988	Do	Do
Points to Consider in the Characterization of Cell Lines Used to Produce Biological Products (from John C. Petricciani, M.D.)	June 1, 1984	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Preamendment Class III Devices	March 11, 1992	Do	Do
Premarket Notification [510(k)] Status Request Form, revised	March 14, 1997	Do	Do
Preproduction Quality Assurance Planning: Recommendations for Medical Device Manufacturers (FDA 90–4236)	September 1, 1989	Do	Do
Proposal for Establishing Mechanisms for Setting Review Priorities Using Risk Assessment and Allocating Review Resources and T93–28 dated June 25, 1993 Device ''Fast Track'' Plan Announcement (include with 926 930)	June 30, 1993	Do	Do
Questions and Answers for the FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities	September 3, 1996	Do	Do
Shelf Life of Medical Devices	March 1, 1991	Do	Do
Substantial Equivalence (SE) Decision Making Documentation ATTACHED: ''SE'' Decision Making Process (Detailed), i.e., the decision making tree	January 1, 1990	Do	Do
Suggested Content for Original IDE Application Cover Letter—Version 4	February 27, 1996	Do	Do
Suggestions for Submitting a Premarket Approval (PMA) Application	April 1, 1993	Do	Do
Threshold Assessment of the Impact of Requirements for Submission of PMA's for 31 Medical Devices Marketed Prior to May 28, 1976	January 1, 1990	Do	Do
Interagency Agreement between FDA & HCFA; #D95–2, Attachment A	September 15, 1995	Office of Device Evaluation (ODE)/BlueBook	Do
Criteria for Categorization of Investigational Devices (HCFA); #D95–2, Attachment B	September 15, 1995	Do	Do
Deciding When to Submit a 510(k) for a Change to an Exisiting Device; Blue Book Memo #K97–1	January 10, 1997	Do	Do
510(k) Additional Information Procedures #K93–1 (Blue Book Memo)	July 23, 1993	Do	Do
510(k) Refuse to Accept Procedures #K94–1 (Blue Book Memo)	May 20, 1994	Do	Do
510(k) Sign-Off Procedures #K94–2 (Blue Book Memo)	June 3, 1994	Do	Do
510(k) Sterility Review Guidance and Revision of November18/1994 #K90–1 (Blue Book Memo)	February 12, 1990	Do	Do
Announcement: Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices, Att. A Interagency Agreement, Att. B Criteria for Categorization of Investigational Devices #D95–2 (Blue Book Memo)	September 15, 1995	Do	Do
Assignment of Review Documents #I90–2 (Blue Book Memo)	August 24, 1990	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Center for Devices and Radiological Health's Investigational Device Exemption (IDE) Refuse to Accept Policy	June 30, 1993	Do	Do
Center for Devices and Radiological Health's Premarket Notification [510(k)] Refuse to Accept Policy—(updated Checklist March 14, 1995)	June 30, 1993	Do	Do
Clinical Utility and Premarket Approval #P91–1 (Blue Book Memo)	May 3, 1991	Do	Do
Consolidated Review of Submissions for Diagnostic Ultrasound Equipment, Accessories and Related Measurement Devices #G90–2 (Blue Book Memo)	October 19, 1990	Do	Do
Consolidated Review of Submissions for Lasers and Accessories #G90–1 (Blue Book Memo)	October 19, 1990	Do	Do
Continued Access to Investigational Devices During PMA Preparation and Review (Blue Book Memo)	July 15, 1996	Do	Do
Cover Letter: 510(k) Requirements During Firm-Initiated Recalls; Attachment A: Guidance on Recall and Premarket Notification Review Procedures During Firm-Initiated Recalls of Legally Marketed Devices (Blue Book Memo #K95–1)	November 21, 1995	Do	Do
Criteria for Panel Review of PMA Supplements #P86–3 (Blue Book Memo)	January 30, 1986	Do	Do
Delegation of IDE Actions #D88–1 (Blue Book Memo)	April 26, 1988	Do	Do
Device Labeling Guidance #G91–1 (Blue Book Memo)	March 8, 1991	Do	Do
Document Review Processing #I91–1 (Blue Book Memo)	February 12, 1992	Do	Do
Documentation and Resolution of Differences of Opinion on Product Evaluations #G93–1 (Blue Book Memo)	December 23, 1993	Do	Do
Executive Secretaries Guidance Manual #G87–3	August 7, 1987	Do	Do
Goals and Initiatives for the IDE Program #D95–1 (Blue Book Memo)	July 12, 1995	Do	Do
Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program #K86–3 (Blue Book Memo)	June 30, 1986	Do	Do
HCFA Reimbursement Categorization Determinations for FDA-approved IDEs	October 31, 1995	Do	Do
IDE Refuse to Accept Procedures #D94–1 (Blue Book Memo)	May 20, 1994	Do	Do
Integrity of Data and Information Submitted to ODE #I91–2 (Blue Book Memo)	May 29, 1991	Do	Do
Meetings with the Regulated Industry #I89–3 (Blue Book Memo)	November 20, 1989	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Memorandum of Understanding Regarding Patient Labeling Review (Blue Book Memo #G96–3))	August 9, 1996	Do	Do
Nondisclosure of Financially Sensitive Information #I92–1 (Blue Book Memo)	March 5, 1992	Do	Do
ODE Regulatory Information for the Office of Compliance—Information Sharing Procedures #G87–2 (Blue Book Memo)	May 15, 1987	Do	Do
Overdue IDE Annual Progress Report Procedures #D93–1 (Blue Book Memo)	July 23, 1993	Do	Do
Panel Report and Recommendations on PMA Approvals #P86–5 (Blue Book Memo)	April 18, 1986	Do	Do
Panel Review of ''Me-Too'' Devices #P86–6 (Blue Book Memo)	July 1, 1986	Do	Do
Panel Review of Premarket Approval Applications #P91–2 (Blue Book Memo)	May 3, 1991	Do	Do
PMA Compliance Program #P91–3 (Blue Book Memo)	May 3, 1991	Do	Do
PMA Filing Decisions #P90–2 (Blue Book Memo)	May 18, 1990	Do	Do
PMA Refuse to File Procedures #P94–1 (Blue Book Memo)	May 20, 1994	Do	Do
PMA Supplements: ODE letter to manufacturers; identifies situations which may require the submission of a PMA supplement (When PMA Supplements are Required) #P90–1 (Blue Book Memo)	April 24, 1990	Do	Do
PMA/510(k) Triage Review Procedures #G94–1 (Blue Book Memo)	May 20, 1994	Do	Do
PMA's—Early Review and Preparation of Summaries of Safety and Effectiveness #P86–1 (Blue Book Memo)	January 27, 1986	Do	Do
Policy Development and Review Procedures #I90–1 (Blue Book Memo)	February 15, 1990	Do	Do
Premarket Approval Application (PMA) Closure #P94–1 (Blue Book Memo)	July 8, 1994	Do	Do
Premarket Notification—Consistency of Reviews #K89–1 (Blue Book Memo)	February 28, 1989	Do	Do
Review and Approval of PMA's of Licensees #P86–4 (Blue Book Memo)	October 22, 1990	Do	Do
Review of 510(k)s for Computer Controlled Medical Devices #K91–1 (Blue Book Memo)	August 29, 1991	Do	Do
Review of Final Draft Medical Device Labeling #P91–4 (Blue Book Memo)	August 29, 1991	Do	Do
Review of IDEs for Feasibility Studies #D89–1 (Blue Book Memo)	May 17, 1989	Do	Do
Review of Laser Submissions #G88–1 (Blue Book Memo)	April 15, 1988	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Telephone Communications Between ODE Staff and Manufacturers #I93–1 (Blue Book Memo)	January 29, 1993	Do	Do
Toxicology Risk Assessment Committee #G89–1 (Blue Book Memo)	August 9, 1989	Do	Do
Use of International Standard ISO–10993, ''Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'' (Replaces #G87–1 #8294) (Blue Book Memo)	May 1, 1995	Do	Do
Points to Consider for Portable Blood Glucose Monitoring Devices Intended for Bedside Use in the Neonate Nursery	February 20, 1996	Office of Device Evaluation (ODE)/Division of Clinical Laboratory Devices (DCLD)	Do
Letter to IVD Manufacturers on Streamlined PMA; Final	December 22, 1997		
Assessing the Safety/Effectiveness of Home-use In Vitro Diagnostic Devices (IVD's): Points to Consider Regarding Labeling and Premarket Submissions; Draft	October 1, 1988	Do	Do
Data for Commercialization of Original Equipment Manufacturer, Secondary and Generic Reagents for Automated Analyzers	June 10, 1996	Do	Do
Criteria for Assessment of In Vitro Diagnostic Devices for Drugs of Abuse Assays Using Various Methodologies; Draft	August 31, 1995	Do	Do
Guidance Document for 510(k) Submission of Fecal Occult Blood Tests; Draft	July 29, 1992	Do	Do
Guidance Document for 510(k) Submission of Glycohemoglobin (Glycated or Glycosylated) Hemoglobin for IVDs; Draft	September 30, 1991	Do	Do
Guidance Document for 510(k) Submission of Immunoglobulins A, G, M, D and E Immunoglobulin System In Vitro Devices; Draft	September 1, 1992	Do	Do
Guidance for 510(k) Submission of Lymphocyte Immunophenotyping IVDs using Monoclonal Antibodies; Draft	September 26, 1991	Do	Do
Premarket Approval Applications for Assays Pertaining to Hepatitis C Viruses (HCV) that are Indicated for Diagnosis or Monitoring of HCV Infection or Associated Disease; Draft	October 8, 1999	Do	Do
Review Criteria for Nucleic Acid Amplification Based In Vitro Diagnostic Devices for Direct Detection of Infectious Microorganisms; Draft	June 14, 1993	Do	Do
Premarketing Approval Review Criteria for Premarket Approval of Estrogen (ER) or Progesterone (PGR) Receptors In Vitro Diagnostic Devices Using Steroid Hormone Binding (SBA) with Dextran-Coated Charcoal (DCC) Separation, Histochemical Receptor Bi; Draft	September 10, 1992	Do	Do
Guidance Criteria for Cyclosporine PMA's	January 24, 1992	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance Document for the Submission of Tumor Associated Antigen Premarket Notification [510(k)] to FDA	September 19, 1996	Do	Do
Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory, and Home Use	July 14, 1995	Do	Do
Guidance for Industry—Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final	February 22, 1999	Do	Do
Document for Special Controls for Erythropoietin Assay Premarket Notifications [510(k)s] Guidance for Industry; Final	April 28, 1999	Do	Do
Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse to Be Used By The Consumer; Guidance for Industry; Draft	December 30, 1998	Do	Do
Guidance on Labeling for Laboratory Tests; Guidance for Industry; Draft	June 24, 1999	Do	Do
In Vitro Diagnostic Bicarbonate/Carbon Dioxide Test System; Guidance for Industry; Final	July 6, 1998	Do	Do
In Vitro Diagnostic Chloride Test System; Guidance for Industry; Final	July 6, 1998	Do	Do
In Vitro Diagnostic C–Reactive Protein Immunological Test System; Guidance for Industry; Final	July 20, 1998	Do	Do
In Vitro Diagnostic Creatinine Test System; Guidance for Industry; Final	July 2, 1998	Do	Do
In Vitro Diagnostic Glucose Test System; Guidance for Industry ; Final	July 6, 1998	Do	Do
Guidance for Industry—In Vitro Diagnostic Potassium Test System; Final	July 6, 1998	Do	Do
In Vitro Diagnostic Sodium Test System; Guidance for Industry; Final	July 6, 1998	Do	Do
In Vitro Diagnostic Urea Nitrogen Test System; Guidance for Industry; Final	July 6, 1998	Do	Do
Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material; Guidance for Industry;	February 3, 1999	Do	Do
In Vitro Diagnostic Fibrin Monomer Paracoagulation Test; Guidance for Industry and FDA Reviewers/Staff; Final	April 27, 1999	Do	Do
Guidance for Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing; Draft	December 21, 1999	Do	Do
Guidance for Submission of Immunohistochemistry Applications to the FDA	June 3, 1998	Do	Do
Points to Consider for Cervical Cytology Devices	July 25, 1994	Do	Do
Points to Consider for Collection of Data in Support of In-Vitro Device Submissions for 510(k) Clearance	September 26, 1994	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Points to Consider for Hematology Quality Control Materials	September 30, 1997	Do	Do
Points to Consider for Review of Calibration and Quality Control Labeling for In Vitro Diagnostic Devices/Cover Letter dated March 14/1996	February 1, 1996	Do	Do
Review Criteria for Assessment of Alpha-Fetoprotein (AFP) in vitro Diagnostic Devices for Fetal Open Neural Tube Defects Using Immunological Test Methodologies	July 15, 1994	Do	Do
Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices; Draft	March 8, 2000	Do	Do
Review Criteria for Assessment of Antimicrobial Susceptibility Test Discs	October 30, 1996	Do	Do
Review Criteria for Assessment of Cytogenetic Analysis Using Automated and Semi-Automated Chromosome Analyzers	July 15, 1991	Do	Do
Review Criteria for Assessment of Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs)	September 27, 1995	Do	Do
Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Mycobacterium Spp. Tuberculosis [(TB)]	July 6, 1993	Do	Do
Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Chlamydiae in Clinical Specimens	January 1, 1992	Do	Do
Review Criteria for Assessment of Laboratory Tests for the Detection of Antibodies to Helicobacter pylori	September 17, 1992	Do	Do
Review Criteria for Assessment of Portable Blood Glucose In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase, or Hexokinase Methodology	February 14, 1996	Do	Do
Review Criteria for Assessment of Rheumatoid Factor(RF) In Vitro Diagnostic Devices Using Enzyme-Linked Immunoassay (EIA), Enzyme Linked Immunosorbent Assay (ELISA), Particle Agglutination Tests, and Laser and Rate Nephelometry	February 21, 1997	Do	Do
Review Criteria for Blood Culture Systems	August 12, 1991	Do	Do
Review Criteria for Devices Assisting in the Diagnosis of C. Difficile Associated Diseases	May 31, 1990	Do	Do
Review Criteria for Devices Intended for the Detection of Hepatitis B ''e'' Antigen and Antibody to Hbe	December 30, 1991	Do	Do
Review Criteria for In Vitro Diagnostic Devices for Detection of IGM Antibodies to Viral Agents	August 1, 1992	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Review Criteria for In Vitro Diagnostic Devices for the Assessment of Thyroid Autoantibodies using Indirect Immunofluorescence Assay (IFA), Indirect Hemagglutination Assay (IHA), Radioimmunoasay (RIA), and Enzyme Linked Immunosorbent Assay (ELISA).	February 1, 1994	Do	Do
Review Criteria for In Vitro Diagnostic Devices that Utilize Cytogenetic In Situ Hybridization Technology for the Detection of Human Genetic Mutations (Germ Line and Somatic)	February 15, 1996	Do	Do
Review Criteria For Premarket Approval of In Vitro Diagnostic Devices for Detection of Antibodies to Parvovirus B19	May 15, 1992	Do	Do
Review Criteria for the Assessment of Allergen-Specific Immunoglobulin E (IGE) In-Vitro Diagnostic Devices Using Immunological Test Methodologies	March 2, 1993	Do	Do
Review Criteria for the Assessment of Antinuclear Antibodies (ANA) In-Vitro Diagnostic Devices Using Indirect Immunofluorescence Assay (IFA), Immunodiffusion (IMD) and Enzyme Linked Immunosorbant Assay (ELISA).	September 1, 1992	Do	Do
Guidance for Industry and FDA; Guidance for Indwelling Blood Gas Analyzer 510(k) Submissions	February 21, 2000	Office of Device Evaluation (ODE)/Division of Cardiovascular, Respiratory & Neurological Devices (DCRND)	Do
Balloon Valvuloplasty Guidance For The Submission Of an IDE Application and a PMA Application	January 1, 1989	Do	Do
Battery Guidance	July 12, 1993	Do	Do
Carotid Stent—Suggestions for Content of Submissions to the Food and Drug Administration in Support of Investigational Devices Exemption (IDE) Applications	October 26, 1996	Do	Do
Coronary and Cerebrovascular Guidewire Guidance	January 1, 1995	Do	Do
510(K) Submission Requirements for Peak Flow Meters; Draft	January 13, 1994	Do	Do
Emergency Resuscitator Guidance; Draft	April 14, 1993	Do	Do
Guidance for Implantable Cardioverter-Defibrillators; Draft	June 24, 1996	Do	Do
Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses; Draft	August 1, 1993	Do	Do
Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices: PTCA Catheters, Atherectomy Catheters, Lasers, Intravascular Stents; Draft	May 1, 1995	Do	Do
Guidance: Human Heart Valve Allografts; Draft	June 21, 1991	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Intravascular Brachytherapy—Guidance for Data to be Submitted to the Food and Drug Administration in Support of Investigational Device Exemption (IDE) Applications; Draft	May 24, 1996	Do	Do
Percutaneous Transluminal Coronary Angioplasty Package Insert Template; Draft	February 7, 1995	Do	Do
Replacement Heart Valve Guidance; Draft	October 14, 1994	Do	Do
Reviewer Guidance for Ventilators; Draft	July 1, 1995	Do	Do
Reviewer Guidance on Face Masks and Shield for CPR; Draft	March 16, 1994	Do	Do
Cardiac Ablation Preliminary Guidance (Data to be Submitted to the FDA in Support Investigation Device Exemption Application; Draft	March 1, 1995	Do	Do
Electrode Recording Catheter Preliminary Guidance (Data to be Submitted to the FDA in Support of Premarket Notifications [510(k)s]) ; Draft	March 1, 1995	Do	Do
Excerpts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch/EMC Standard for Medical Devices (to be used with EMI Standard)	November 1, 1993	Do	Do
General Guidance Document: Non-Invasive Pulse Oximeter	September 7, 1992	Do	Do
Guidance Document: Electrocardiograph (ECG) Surface Electrode Tester—Version 1.0	February 11, 1997	Do	Do
Guidance Document for Premarket Notification Submission for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer; Final	January 24, 2000	Do	Do
Guidance Document for Vascular Prostheses 510(k) Submission; Final	November 26, 1999	Do	Do
Guidance for Annuloplasty Rings 510(k) Submissions; Final	November 26, 1999	Do	Do
Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions; Final	February 21, 2000	Do	Do
Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final	January 17, 2000	Do	Do
Guidance for Cardiovascular Intravascular Filter 510(k) Submission; Final	November 26, 1999	Do	Do
Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions; Final	February 16, 2000	Do	Do
Cardiac Monitor Guidance (including Cardiotachometer and Rate Alarm); Guidance for Industry; Final	November 5, 1998	Do	Do
Diagnostic ECG Guidance (Including Non-Alarming ST Segment Measurement); Guidance for Industry; Final	November 5, 1998	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Recommended Clinical Study Design for Ventricular Tachycardia Ablation; Guidance for Industry and for FDA Reviewers	May 7, 1999	Do	Do
Guidance for Oxygen Conserving Device 510(k) Review 73 BZD 868.5905 Noncontinuous Ventilator Class II	February 1, 1989	Do	Do
Guidance for Peak Flow Meters for Over-the-Counter Sale	June 23, 1992	Do	Do
Guidance for the Preparation of the Annual Report to the PMA Approved Heart Valve Prostheses	April 1, 1990	Do	Do
Guidance for the Submission of 510(k) Premarket Notifications for Electrocardiograph (ECG) Electrode Version 1.0	February 11, 1997	Do	Do
Guidance for the Submission of 510(k) Premarket Notifications for Electrocardiograph (ECG) Lead Switching Adapter Version 1.0	February 11, 1997	Do	Do
Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions; Final	January 14, 2000	Do	Do
Heated Humidifier Review Guidance	August 30, 1991	Do	Do
Implantable Pacemaker Testing Guidance	January 12, 1990	Do	Do
Vascular Graft Manufacturer, Developer, or Representative; Letter/Guidance	May 11, 1990	Do	Do
Medical Device Labeling—Suggested Format and Content; Draft Document	April 25, 1997	Do	Do
Non-Invasive Blood Pressure (NIBP) Monitor Guidance	March 10, 1997	Do	Do
Policy for Expiration Dating (DCRND RB92–G)	October 30, 1992	Do	Do
Review Guidelines for Oxygen Generators and Oxygen Equipment; Draft Document	April 14, 1993	Do	Do
Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators	October 1, 1993	Do	Do
Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators	November 9, 1990	Do	Do
Reviewer's Guidance for Oxygen Concentrator	August 30, 1991	Do	Do
Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves; Draft	November 16, 1999	Office of Device Evaluation (ODE)/Division of Dental, Infection Control and General Hospital Devices (DDIGD)	Do
Devices for the Treatment and/or Diagnosis of Temporomandibular Joint Dysfunction and/or Orofacial Pain; Final	June 10, 1998	Do	Do
Guidance on the Content and Format of Premarket Notification [510(k)] Submission of Washers and Washer-Disinfectors; Draft	November 5, 1998	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance Document for Washers and Washer-Disinfectors Intended for Processing Reusable Medical Devices	June 2, 1998	Do	Do
Overview of Information Necessary for Premarket Notification Submissions for Endoseous Implants; Final	April 21, 1999	Do	Do
Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme; Draft	February 8, 2000	Do	Do
Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities; Addendum	September 19, 1995	Do	Do
Guidance Document for the Preparation of Premarket Notification [510(k)'S] for Dental Alloys; Draft	March 3, 1997	Do	Do
Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for Medical Devices with Sharps Injury Prevention Features (Antistick); Draft	March 1, 1995	Do	Do
Guidance and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants; Final	January 3, 2000	Do	Do
Guidance Document on Dental Handpieces	July 1, 1995	Do	Do
Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization to Chemicals in Natural Latex Products; Guidance for Industry and FDA Reviewers/Staff; Final	January 13, 1999	Do	Do
Testing for Sensitizing Chemicals in Natural Rubber Latex Medical Devices; (Addendum to Premarket Notification [510(k) Submissions for Testing for Skin Sensitization to Chemicals in Natural Latex Products; Guidance for Industry and FDA Reviewers/Staff; Final)	July 27, 1997		
Neonatal and Neonatal Transport Incubators-Premarket Notifications; Guidance for Industry and FDA Reviewers; Final	September 18, 1998	Do	Do
Dental Cements Premarket Notification; Final	August 18, 1998	Do	Do
Guidance For The Arrangement and Content of a Premarket Approval (PMA) Application For An Endosseous Implant For Prosthetic Attachment	May 16, 1989	Do	Do
Guidance for the Preparation of a Premarket Notification [510(k)] for Direct Filling Dental Composites	November 27, 1998	Do	Do
Guidance for the Preparation of Premarket Notification [510(k)] for Resorbable Periodontal Barriers	April 1991	Do	Do
Guidance on 510(k) Submissions for Implanted Infusion Ports	October 1, 1990	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities	August 1, 1993	Do	Do
Guidance on Premarket Notification [510(K)] Submissions for Short-Term and Long-Term Intravascular Catheters	March 16, 1995	Do	Do
Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities	March 1, 1993	Do	Do
Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes	August 1, 1993	Do	Do
Guidance on the Content and Format of Premarket Notification [510(k)] for Testing for Skin Sensitization to Chemicals in Latex Products [Draize Testing]	February 13, 1998	Do	Do
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Sharps Containers	October 1, 1993	Do	Do
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for General Purpose Disinfectants (includes Addendum of March 9, 1994)	October 1, 1993	Do	Do
Guidance on the Content and Format of Premarket Notification 510(k) Submissions for Liquid Chemical Germicides	December 6, 1996	Do	Do
Guidance on the Content of Premarket Notification [510(k)] Submissions for Protective Restraints	December 1, 1995	Do	Do
Guidance on the Content of Premarket Notification [510(K)] Submissions for Hypodermic Single Lumen Needles	April 1, 1993	Do	Do
Guidance on the Content of Premarket Notification [510(K)] Submissions for Piston Syringes	April 1, 1993	Do	Do
Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers	March 1, 1993	Do	Do
Guidance on the Content of Premarket Notification [510(k)] Submissions for External Infusion Pumps	March 1, 1993	Do	Do
Dental Impression Materials Premarket Notification; Final	August 17, 1998	Do	Do
OTC Denture Cushions, Pads, Reliners, Repair Kits and Partially Fabricated Denture Kits; Final	August 18, 1998	Do	Do
Information Necessary for Premarket Notification Submissions For Screw-Type Endossesous Implants	December 9, 1996	Do	Do
510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants	February 20, 1997	Office of Device Evaluation (ODE)/Division of General & Restorative Devices (DGRD)	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Alternate Suture Labeling Resulting From the January 11, 1993 Meeting with HIMA (Reformatted December 17, 1997)	January 11, 1993	Do	Do
Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants	February 21, 1997	Do	Do
Copy of October 9, 1992 Letter and Original Suture Labeling Guidance (Reformatted December 17, 1997)	October 9, 1992	Do	Do
510(k) Guideline for General Surgical Electrosurgical Devices; Draft	May 10, 1995	Do	Do
Data Requirements for Ultrahigh Molecular Weight Polyethylene (Uhmupe) Used in Orthopedic Devices; Draft	March 28, 1995	Do	Do
Guidance Document for Femoral Stem Prostheses; Draft	August 1, 1995	Do	Do
Guidance Document for Testing Acetabular Cup Prostheses; Draft	May 1, 1995	Do	Do
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Orthopedic Devices-The Basic Elements; Draft	July 16, 1997	Do	Do
Guidance for Arthroscopes and Accessory 510(k)s; Draft	May 1, 1994	Do	Do
Guidance for Testing MR Interaction with Aneurysm Clips; Draft	May 22, 1996	Do	Do
Guidance for the Preparation of a Premarket Notification for a Non-Interactive Wound and Burn Dressing [510(k)] ; Draft	May 31, 1995	Do	Do
Guidance for the Preparation of a Premarket Notification for Extended Laparoscopy Devices (ELD); Draft	August 30, 1994	Do	Do
Guidance for the Preparation of an IDE Submission for a Interactive Wound and Burn Dressing; Draft	April 4, 1995	Do	Do
Guidance for the Preparation of Premarket Notifications [510(k)] s for Cemented, Semi-Constrained Total Knee Prostheses; Draft	April 1, 1993	Do	Do
Outline for a Guidance Document for Testing Orthopedic Bone Cement, request for comments by December 10, 1993; Draft	November 1, 1993	Do	Do
Premarket Notification Review Guidance for Evoked Response Somatosensory Stimulators; Draft	June 1, 1994	Do	Do
Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part-3 Implant Model; Draft	September 12, 1994	Do	Do
Biofeedback Devices—Guidance for 510(k) Content; Draft	August 1, 1994	Do	Do
Cranial Perforator Guidance; Draft	July 13, 1994	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance for Clinical Data to be Submitted for Premarket Approval Application for Cranial Electrotherapy Stimulators; Draft	August 20, 1992	Do	Do
Guide for Cortical Electrode 510(k) Content; Draft	August 10, 1992	Do	Do
Neuro Endoscope Guidance; Draft	July 7, 1994	Do	Do
Electroencephalograph Devices Guidance for 510(k) Content; Draft	November 3, 1997	Do	Do
Galvanic Skin Response Measurement Devices-Draft Guidance for 510(k) Content	August 1, 1994	Do	Do
Guidance Document for the Preparation of IDEs for Spinal Systems; Final	January 13, 2000	Do	Do
Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices; Guidance Document for Industry and CDRH Staff; Draft	March 18, 1998	Do	Do
Guidance Document for Surgical Lamp 510Ks; Final	July 13, 1998	Do	Do
Guidance Document for Testing Biodegradable Polymer Implant Devices; Draft	April 20, 1996	Do	Do
Guidance Document for Testing Bone Anchor Devices; Draft	April 20, 1996	Do	Do
Guidance Document for Testing Non-Articulating, ''Mechanically Locked'', Modular Implant Components; Draft	May 1, 1995	Do	Do
Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement (replaces 8623 and 8093)	April 28, 1994	Do	Do
Guidance Document for the Preparation of IDE and PMA Applications for Intra-Articular Prosthetic Knee Ligament Devices	February 18, 1993	Do	Do
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Submerged (Underwater) Exercise Equipment	July 26, 1995	Do	Do
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Electromyograph Needle Electrodes	July 26, 1995	Do	Do
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Exercise Equipment	July 26, 1995	Do	Do
Guidance Document for the Preparation of Premarket Notification [510k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles	July 26, 1995	Do	Do
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Beds	July 26, 1995	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Immersion Hydrobaths	July 26, 1995	Do	Do
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Powered Tables and Multifunctional Physical Therapy Tables	July 26, 1995	Do	Do
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Communications Systems (Powered and Non-Powered) and Powered Environmental Control Systems	July 26, 1995	Do	Do
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Therapeutic Massagers and Vibrators	July 26, 1995	Do	Do
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices	July 26, 1995	Do	Do
Guidance Document For The Preparation of Premarket Notification For Ceramic Ball Hip Systems	January 10, 1995	Do	Do
Guidance Document for Dura Substitute Devices; Final	August 13, 1999	Do	Do
Guidance Document for Neurological Embolization Devices; Guidance for Industry; Final	August 13, 1999	Do	Do
Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater; Guidance for Industry; Final	August 30, 1999	Do	Do
Guidance for Dermabrasion Devices; Final	March 2, 1999	Do	Do
Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses; Guidance for Industry; Draft	October 5, 1999	Do	Do
Guidance for Spinal System 510(k)s; Final	May 7, 1999	Do	Do
Guidance Document for Powered Suction Pump 510(k)s; Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance; Final	October 30, 1998	Do	Do
Guidance Document for Powered Muscle Stimulator 510(k)s; Guidance for Industry, FDA Reviewers/Staff and Compliance; Final	June 9, 1999	Do	Do
Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prostheses; Guidance for Industry; Final	April 28, 1998	Do	Do
Guidance for Studies for Pain Therapy Devices—General Considerations in the Design of Clinical Studies for Pain-Alleviating Devices	May 12, 1988	Do	Do
Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh; Final	March 2, 1999	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance on the Content and Organization of a Premarket Notification for a Medical Laser	June 1, 1995	Do	Do
Guide for TENS 510(k) Content; Draft	August 1, 1994	Do	Do
Guidelines for Reviewing Premarket Notifications that Claim Substantial Equivalence to Evoked Response Stimulators	February 1997	Do	Do
Core Study for Silicone Breast Implants; Letter	January 11, 1996	Do	Do
ORDB 510(k) Sterility Review Guidance	July 3, 1997	Do	Do
Protocol for Dermal Toxicity Testing for Devices in Contact with Skin; Draft	January 1985	Do	Do
Reviewers Guidance Checklist for Intramedullary Rods	February 21, 1997	Do	Do
Reviewers Guidance Checklist for Orthopedic External Fixation Devices	February 21, 1997	Do	Do
Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses; Amendment 1; Draft	June 28, 1994	Office of Device Evaluation (ODE)/Division of Ophthalmic Devices (DOD)	Do
Guidance for Premarket Submission of Orthokeratology Rigid Gas Permeable Contact Lenses; Final	April 10, 2000	Do	Do
An FDA Survey of U.S. Contact Lens Wearers (Carol L. Herman) Reprinted from Contact Lens Spectrum	July 1, 1987	Do	Do
Announcement by Dr. Alpert at July 26, 1996 Ophthalmic Panel Meeting concerning Manufacturers & Users of Lasers for Refractive Surgery [Excimer]	August 26, 1996	Do	Do
Announcement: Information for Manufacturers & Users of Lasers for Refractive Surgery [Excimer]	September 22, 1997	Do	Do
Checklist of Information Usually Submitted in an Investigational Device Exemptions (IDE) Application for Refractive Surgery Lasers [Excimer]	October 10, 1996	Do	Do
Contact Lenses: The Better the Care the Safer the Wear; Publication No. FDA 91–4220	April 1, 1991	Do	Do
Discussion Points for Expansion of the ''Checklist of Information Usually Submitted in an Investigational Device Exemption (IDE) Application for Refractive Surgery Lasers''; Draft	September 5, 1997	Do	Do
Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses and June 28, 1994 corrections to pages 18 & 20; Draft	May 12, 1994	Do	Do
Premarket Notification 510(k) Guidance for Contact Lens Care Products; Draft	May 1, 1997	Do	Do
Facts for Consumers from the Federal Trade Commission-Eyeglasses	April 1, 1986	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
FDA Guidelines for Multifocal Intraocular Lens IDE Studies and PMA's	May 29, 1997	Do	Do
Ophthalmoscope Guidance (Direct and Indirect); Guidance for Industry	July 8, 1998	Do	Do
Guidance Document for Nonprescription Sunglasses; Final	October 9, 1998	Do	Do
Retinoscope Guidance; Final	July 8, 1998	Do	Do
Slit Lamp Guidance; Final	July 13, 1998	Do	Do
Revised Procedures for Adding Lens Finishing Laboratories to Approved Premarket Approval (PMA) Applications for Class III Rigid Gas Permeable Contact Lenses for Extended Wear; Guidance for Industry and FDA Staff; Final	August 11, 1998	Do	Do
Accountability Analysis for Clinical Studies for Ophthalmic Devices; Draft	August 4, 1999	Do	Do
Aqueous Shunts—510(k) Submissions; Final	November 16, 1998	Do	Do
Guidance on 510(k) Submissions for Keratoprostheses; Final	March 3, 1999	Do	Do
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Surgical Mask; Draft	January 16, 1998	Do	Do
Important Information About Rophae Intraocular Lenses	August 20, 1992	Do	Do
Intraocular Lens (IOL) Guidance Document; Draft	October 14, 1999	Do	Do
New FDA Recommendations & Results of Contact Lens Study (7 Day Letter)	May 30, 1989	Do	Do
Owners Certification of Lasers as PMA Approved Devices Excimer]	September 26, 1996	Do	Do
Third Party Review Guidance for Vitreous Aspiration and Cutting Device Premarket Notification [510(k)]	January 31, 1997	Do	Do
Update on Excimer Lasers for Nearsightedness	May 20, 1996	Do	Do
Guidance for Manufacturers Seeking Marketing Clearance of Ear, Nose, and Throat Endoscope Sheaths Used as Protective Barriers; Final	March 12, 2000	Do	Do
510(k) Checklist for Sterile Lubricating Jelly Used With Transurethral Surgical Instruments	September 19, 1994	Office of Device Evaluation (ODE)/Division of Reproductive, Abdominal, ENT & Radiological Devices (DRAERD)	Do
Guidance for Hemodialyzer Reuse Labeling; Draft	November 6, 1995	Do	Do
Content of Premarket Notification for Hemodialysis Delivery Systems; Guidance for Industry and CDRH Reviewers; Final	August 7, 1998	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi	February 8, 1999	Do	
CDRH Interim Regulatory Policy for External Penile Rigidity Devices	September 10, 1997	Do	Do
Checklist for Mechanical Lithotripters and Stone Dislodgers used in Gastroenterology and Urology	November 1, 1994	Do	Do
510(k) Checklist for Conditioned Response Enuresis Alarms; Draft	November 23, 1994	Do	Do
510(k) Checklist for Condom Catheters; Draft	February 23, 1995	Do	Do
510(k) Checklist for Endoscopic Electrosurgical Unit (ESU) and Accessories Used in Gastroenterology and Urology; Draft	August 16, 1995	Do	Do
510(k) Checklist for Endoscopic Light Sources Used in Gastroenterology and Urology; Draft	June 22, 1995	Do	Do
510(k) Checklist for Non-Implanted Electrical Stimulators Used for the Treatment of Urinary Incontinence; Draft	June 6, 1995	Do	Do
510(k) Checklist for Urological Irrigation System and Tubing Set; Draft	August 1, 1995	Do	Do
Guidance for Clinical Investigations of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH); Draft	November 11, 1994	Do	Do
Guidance for Information on Clinical Safety and Effectiveness Data for Extracorporeal Shock Wave Lithotripsy of Upper Urinary Tract (Renal Pelvis, Renal Calyx and Upper Ureteral) Calculi; Draft	February 5, 1992	Do	Do
Guidance for Preclinical and Clinical Investigations of Urethral Bulking Agents Used in the Treatment of Urinary Incontinence; Draft	November 29, 1995	Do	Do
Guidance for Preparation of PMA Applications for Penile Inflatable Implants; Draft	March 16, 1993	Do	Do
Guidance for Preparation of PMA Applications for Testicular Prostheses; Draft	March 16, 1993	Do	Do
Guidance for Preparation of PMA Applications for the Implanted Mechanical/Hydraulic Urinary Continence Device (Artificial Urinary Sphincter); Draft	May 1, 1995	Do	Do
Guidance for Review of Bone Densitometer 510(k) Submissions; Draft	November 9, 1992	Do	Do
Guidance for the Clinical Investigation of Urethral Stents; Draft	November 2, 1995	Do	Do
Guidance for the Content of Premarket Notifications for Endoscopes used in Gastroenterology and Urology; Draft	March 17, 1995	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance for the Content of Premarket Notifications for Loop and Rollerball Electrodes for GYN Electrosurgical Excisions; Draft	July 29, 1991	Do	Do
Guidance for the Content of Premarket Notifications for Menstrual Tampons; Draft	May 25, 1995	Do	Do
Guidance for the Content of Premarket Notifications for Urological Balloon Dilatation Catheters; Draft	January 24, 1992	Do	Do
Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis; Draft	May 30, 1997	Do	Do
Guidance Outline-Points to Consider for Clinical Studies for Vasovasostomy Devices; Draft	November 30, 1993	Do	Do
Guidance to Firms on Biliary Lithotripsy Studies; Draft	August 2, 1990	Do	Do
Suggested Information for Reporting Extracorporeal Shock Wave Lithotripsy Device Shock Wave Measurements; Draft	January 18, 1991	Do	Do
Thermal Endometrial Ablation Devices (Submission Guidance for an IDE); Draft	March 14, 1996	Do	Do
Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures: Submission Guidance for a 510(k); Draft Availability	September 10, 1998	Do	Do
Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters; Guidance for Industry; Final	November 30, 1998	Do	Do
Guidance (''Guidelines'') for Evaluation of Fetal Clip Electrode	March 8, 1977	Do	Do
Guidance (''Guidelines'') for Evaluation of Hysteroscopic Sterilization Devices	May 10, 1978	Do	Do
Guidance (''Guidelines'') for Evaluation of Laparoscopic Bipolar and Thermal Coagulators (and Accessories)	May 1978	Do	Do
Guidance (''Guidelines'') for Evaluation of Tubal Occlusion Devices	November 22, 1977	Do	Do
Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems; Guidance for Industry; Final	December 3, 1998	Do	Do
Guidance for the Submission of Premarket Notifications for Radionuclide Dose Calibrators; Guidance for Industry; Final	November 20, 1998	Do	Do
Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices; Guidance for Industry; Final	November 14, 1998	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Harmonic Imaging With/Without Contrast Premarket Notification; Guidance for Industry; Final	November 16, 1998	Do	Do
Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance; Version 1; Guidance for Industry; Final	November 19, 1998	Do	Do
Uniform Contraceptive Labeling; Guidance for Industry; Final	July 23, 1998	Do	Do
Guidance for the Content of Premarket Notifications for Penile Rigidity Implants; Final	January 16, 2000	Do	Do
Electro-optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA; Guidance for Industry; Draft	August 25, 1999	Do	Do
Noise Claims in Hearing Aid Labeling; Final	October 21, 1998	Do	Do
Guidance for Magnetic Resonance Diagnostic Devices—Criteria for Significant Risk Investigations	September 29, 1997	Do	Do
Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery; Draft	December 16, 1999	Do	Do
Guidance for the Arrangement and Content of a Premarket Approval (PMA) Application for a Cochlear Implant in Children Ages 2 through 17 Years	May 1, 1990	Do	Do
Guidance for the Comment and Review of 510(k) Notifications for Picture Archiving and Communications Systems (PACS) and Related Devices	August 1, 1993	Do	Do
Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology	February 10, 1993	Do	Do
Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters	September 12, 1994	Do	Do
Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents; Final	February 5, 1998	Do	Do
Guidance for the Content of Premarket Notifications for Urethral Stents	February 10, 1993	Do	Do
Guidance for the Content of Premarket Notifications for Urine Drainage Bags	June 7, 1994	Do	Do
Guidance for the Content of Premarket Notifications for Urodynamic/Uroflowmetry Systems	July 29, 1994	Do	Do
Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices; Final	August 6, 1999	Do	Do
Guidance for the Technical Content of a Premarket Approval (PMA) Application for an Endolymphatic Shunt Tube with Valve	April 1, 1990	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance for the Content of Premarket Notifications for Conventional and Permeability Hemodialyzers; Guidance to Industry and CDRH Reviewers; Final	August 7, 1998	Do	Do
Guideline for the Arrangement and Content of a Premarket Approval (PMA) Application for a Cochlear Implant in Adults at Least 18 Years of Age	May 1, 1990	Do	Do
Guidelines for Evaluation of Non-Drug IUD's	September 28, 1976	Do	Do
Home Uterine Activity Monitors: Guidance for the Submission of 510(k) Premarket Notifications; Draft	July 30, 1999	Do	Do
Hysteroscopes and Gynecology Laparoscopes—Submission Guidance for a 510(k) includes 00192	March 27, 1996	Do	Do
Hysteroscopic and Laparoscopic Insufflators: Submission Guidance for a 510(k)	August 1, 1995	Do	Do
Information for a Latex Condom 510(k) Submission for Obstetrics-Gynecology Devices Branch; Draft	July 1, 1997	Do	Do
Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers; Draft	September 30, 1997	Do	Do
Intrapartum Continuous Monitors for Fetal Oxygen Saturation and Fetal pH; Submission Guidance for a PMA; Draft	June 14, 1997	Do	Do
Latex Condoms for Men-Information for 510(k) Premarket Notifications: Use of Consensus Standards for Abbreviated Submissions	July 23, 1998	Do	Do
Notice to Manufacturers of Bone Mineral Densitometers; Letter	September 25, 1997	Do	Do
Premarket Testing Guidelines for Falloposcopes	November 20, 1992	Do	Do
Premarket Testing Guidelines for Female Barrier Contraceptive Devices Also Intended to Prevent Sexually Transmitted Diseases	April 4, 1990	Do	Do
Reviewer Guidance for Automatic X-Ray Film Processor 510(k)	February 1, 1990	Do	Do
Simplified 510(k) Procedures For Certain Radiology Devices (December 21, 1993 letter from L Yin, ODE/DRAERD, to NEMA)	December 21, 1993	Do	Do
Information for Manufacturers Seeking Marketing Clearance of Digital Mammography Systems; Status Update	June 19, 1996	Do	Do
Testing Guidance for Male Condoms Made from New Material (Non-Latex)	June 29, 1995	Do	Do
Tympanostomy Tubes Submission Guidance for a 510(k) Premarket Notification; Final	January 14, 1998	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance on Amended Procedures for Advisory Panel Meetings [FDAMA] Final	March 20, 1998	ODE/Program Operations Staff (POS)	Do
PMA/510(k) Expedited Review-Guidance for Industry and CDRH Staff [FDAMA] Final	March 20, 1998	Do	Do
PMA/510(k) Expedited Review #G98–4 (Blue Book Memo)	March 20, 1998	Do	Do
Guidance on IDE Policies and Procedures [FDAMA]; Final	January 20, 1998	Do	Do
FDA Modernization Act of 1997 Guidance for the Device Industry on Implementation of Highest Priority Provisions [FDAMA]; Final	February 6, 1998	Office of Health and Industry Programs (OHIP)	Do
Overview of FDA Modernization Act of 1997 Medical Device Provisions [FDAMA]; Final	June 5, 1998	Do	Do
Guidance: The Mammography Quality Standards Act Final Regulations Document #1; Final	March 4, 1999	Office of Health and Industry Programs (OHIP)/Division of Mammography Quality and Radiation Programs (DMQRP)	Do
Guidance: The Mammography Quality Standards Act Final Regulations Document #2; Final	February 25, 2000	Do	Do
Guidance: The Mammography Quality Standards Act Final Regulations Document #3; Draft	December 8, 1999	Do	Do
Guidance The Mammography Quality Standards Act Final Regulations—Mammography Facility Survey and Medical Physicist Qualification Requirements Under MQSA; Final	May 5, 1999	Do	Do
Guidance The Mammography Quality Standards Act Final Regulations—Preparing for MQSA Inspections; Final	May 5, 1999	Do	Do
Guidance for Request and Issuance of Interim Notice Letters for Mammography Facilities Under the Mammography Quality Standards Act, 42 U.S.C. Section 263(b); Final	May 4, 1999	Do	Do
Guidance for Review of Cases of Possible Suspension or Revocation of Mammography Facility Certificates Under the Mammography Quality Standards Act, 42 U.S.C. 263(b); Final	March 26, 1998	Do	Do
Guidance for Review of Requests for Reconsideration of Adverse Decisions on Accreditation of Mammography Facilities Under the Mammography Quality Standards Act, 42 U.S. C. 263(b); Final	March 26, 1998	Do	Do
Guidance for Submission of Request for Reconsideration of Adverse Decisions on Accreditation of Mammography Facilities Under the Mammography Quality Standards Acts, 42 U.S.C. 263(b); Final	March 26, 1998	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies; Final	August 13, 1998	Do	Do
Guidance for Policy and Standard Operating Procedures When Mammography Facilities in States that Have Accreditation Bodies Intend to Change Accreditation Bodies; Final	April 15, 1998	Do	Do
Guidance: The Mammography Quality Standards Act Final Regulations Preparing for MQSA Inspections; Final	May 5, 1999	Do	Do
Guidance: The Mammography Quality Standards Act Final Regulations Motion of Tube-Image Receptor Assembly; Final	March 23, 1999	Do	Do
Guidance: The Mammography Quality Standards Act Final Regulations: Quality Assurance Documentation; Final	December 7, 1999	Do	Do
Premarket Notification: 510(k)-Regulatory Requirements for Medical Devices (FDA 95–4158) [available on disk]	August 1, 1995	Office of Health and Industry Programs (OHIP)/Division of Small Manufacturers Assistance (DSMA)	Do
Labeling-Regulatory Requirements for Medical Devices (FDA 89–4203)	September 1, 1989	Do	Do
Classification Names for Medical Devices and In Vitro Diagnostic Products (FDA Pub No. 95–4246)	March 1, 1995	Do	Do
An Introduction to Medical Device Regulations (FDA 92–4222)	January 1, 1992	Do	Do
Comparison Chart: 1996 Quality System Reg vs. 1978 Good Manufacturing Practices Reg vs. ANSI/ISO/ASQC Q9001 and ISO/DI 13485:1996	November 11, 1996	Do	Do
Medical Glove Guidance Manual; FDA 99–4257; Draft	August 30, 1999	Do	Do
In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions (FDA 97–4224) [available on disk]	January 1, 1997	Do	Do
Instructions for Completion of Medical Device Registration and Listing Forms FDA 2891, 2891a and 2892	July 1, 1997	Do	Do
Investigational Device Exemptions [IDE] Manual (FDA 96–4159) [available on disk]	June 1, 1996	Do	Do
Medical Device Appeals and Complaints: A Guidance on Dispute Resolution; Final	February 19, 1998	Do	Do
Medical Device Reporting for Manufacturers [available on disk]	March 1, 1997	Do	Do
Premarket Approval (PMA) Manual; Final	January 1, 1998	Do	Do
Regulatory Requirements for Devices for the Handicapped (FDA 87–4221)	August 1, 1987	Do	Do
Small Business Guide to FDA (FDA 96–1092)	January 1, 1996	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
The FDA Export Reform and Enhancement Act of 1996/Export Certification Package including ''Instructions for Requests for Certificate to Foreign Governments''; Final	February 7, 2000	Do	Do
U.S.-FDA-Regulation of Medical Devices; Background Information for International Officials (entire document available on disk); Final	April 14, 1999	Do	Do
510(k) Manual-Premarket Notification: 510(k)-Regulatory Requirements for Medical Devices	August 1, 1995	Do	Do
Export—Foreign Liaison (part of ''Exporting Medical Devices,'' February 25, 1999)	December 2, 1998	Do	Do
Exporting Medical Devices; Final	February 25, 1999	Do	Do
Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA); Guidance for Staff, Industry, and Third Parties; Final	January 6, 1999	Do	Do
Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Guidance for Staff, Industry, and Third Parties; Final	October 30, 1998	Do	Do
Medical Device Quality Systems Manual: A Small Entity Compliance Guide	December 1, 1996	Do	Do
Do It By Design—An Introduction to Human Factors in Medical Devices	December 1, 1996	Office of Health and Industry Programs (OHIP)/Division of Device User Programs and Systems Analysis (DUPSA)	Do
Guidance on Medical Device Patient Labeling; Guidance for Industry; Draft	March 3, 2000	Do DUPSA	Do
Device Use Safety: Incorporating Human Factors in Risk Management; Guidance For Industry and FDA Premarket and Postmarket Review Staff; Draft	August 3, 1999	Do DUPSA	Do
Human Factors Points to Consider for IDE Devices; Draft	January 17, 1997	Do DUPSA	Do
Human Factors Principles for Medical Device Labeling	September 1, 1993	Do DUPSA	Do
Medical Device Reporting for User Facilities	April 1, 1996	Do DUPSA	Do
Write it Right; Recommendations for Developing User Instruction Manuals for medical Devices Used in Home Health Care	August 1, 1993	Do	Do
Perspectives on Clinical Studies for Medical Device Submissions (Statistical)	Unknown Pre-1997	Office of Surveillance and Biometrics (OSB)/	Do
PMA Review Statistical Checklist	Unknown Pre-1997	Do	Do
Statistical Aspects of Submissions to FDA: A Medical Device Perspective (also includes an Appendix the article ''Observed Uses and Abuses of Statistical Procedures in Medical Device Submissions''	June 1, 1984	Office of Surveillance and Biometrics (OSB)/Division of Biostatistics (DB)	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Amendment to Guidance on Discretionary Postmarket Surveillance on Pacemaker Leads; Final	March 30, 1994	Office of Surveillance and Biometrics (OSB)/Issues Management Staff (IMS)	Do
Guidance on Procedures for Review of Postmarket Surveillance Submissions [FDAMA]; Final	February 19, 1998	Do	Do
Guidance on Procedures to Determine Application of Postmarket Surveillance Strategies [FDAMA]; Final	February 19, 1998	Do	Do
SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance Protocols [FDAMA]; Guidance for Industry and FDA Staff; Final	November 2, 1998	Do	Do
Guidance to Sponsors on the Development of a Discretionary Postmarket Surveillance Study for Permanent Implantable Cardiac Pacemaker Electrodes (Leads); Final	June 9, 1993	Do	Do
Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements; Guidance for Industry; Final	February 2, 2000	Office of Surveillance and Biometrics (OSB)/Division of Postmarket Surveillance (DPS)	Do
Common Problems: Baseline Reports and Medwatch Form 3500A	January 1997	Office of Surveillance and Biometrics (OSB)/Division of Surveillance Systems (DSS)	Do
Instructions for Completing FDA Form 3500A with Coding Manual for Form 3500A (MEDWATCH) (MDR)	December 15, 1995	Do	Do
MDR Documents Access Information for National Technical Information Service (NTIS)	May 10, 1996	Do	Do
MDR Internet List Server (listserv) Instruction sheet	August 29, 1996	Do	Do
MEDWATCH FDA Form 3500A For Use By User Facilities, Distributors and Manufacturers for Mandatory Reporting (MDR)	June 1, 1993	Do	Do
MDR Reporting Guidance For Breast Implants—E1996002	August 7, 1996	Do	Do
Addendum to the Instructions for Completing FDA Form 3500A with Coding Manual (MEDWATCH) (MDR)	June 9, 1999	Do	Do
Instructions for Completing Form 3417: Medical Device Reporting Baseline Report MDR]	March 31, 1997	Do	Do
Summary Reporting Approval for Adverse Events; Letter to Manufacturers; Final	July 31, 1997	Do	Do
MDR Guidance Document No. 1—IOL—E1996004	August 7, 1996	Do	Do
MDR Guidance Document No. 3-Needlestick & Blood Exposure—E1996003	August 9, 1996	Do	Do
MDR Guidance Document: Remedial Action Exemption—E1996001	July 30, 1996	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
MDR Reporting Guidance for Date-Related Problems Including Y2K	April 16, 1999	Do	Do
Medical Device Reporting: An Overview; Final	April 1, 1996	Do	Do
Variance from Manufacturer Report Number Format [MDR letter]; Final	July 16, 1996	Do	Do
A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems; Draft	February 7, 1997	Office of Science and Technology (OST)	Do
Frequently Asked Questions on Recognition of Consensus Standards [FDAMA]; Final	December 21, 1998	Do	Do
Viable Bacteriophage in CO2 Laser Plume: Aerodynamic Size Distribution	Unknown pre-1997	Do	Do
Guidance on the Recognition and Use of Consensus Standards/Appendix A [FDAMA]; Final	February 19, 1998	Do	Do
CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standard for Recognition; Final	August 6, 1999	Do	Do
Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices), Guidance for FDA Reviewers and Industry; Final	November 16, 1998	Do	Do
Guidance on FDA's Expectations of Medical Device Manufacturers Concerning the Year 2000 Date Problems; Final	May 15, 1998	Do	Do
Guidance on Immunotoxicity Testing; Final	May 6, 1999	Office of Science and Technology (OST)/Division of Life Sciences (DLS)	Do

V. Guidance Documents Issued by the Center for Food Safety and Applied Nutrition (CFSAN)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How To Obtain A Hard Copy of The Document (Name and Address, Phone, Fax, E–Mail or Internet)
Compliance Policy Guides Manual	1998	FDA Regulated Industries	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, PB96–920500
Compliance Programs Guidance Manual	1995	FDA Regulated Industries	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, PB95–915499
FDA Recall Policy	1995	FDA Regulated Industries	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204
Investigators' Operations Manual	May 1996	FDA Regulated Industries	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, PB–95–913399

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How To Obtain A Hard Copy of The Document (Name and Address, Phone, Fax, E–Mail or Internet)
Regulatory Procedures Manual	August 1995	FDA Regulated Industries	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, PB95–265534
Requirements of Laws and Regulations Enforced by the U.S. Food and Drug Administration ''Blue Book''	1997	FDA Regulated Industries	Superintendent of Documents, Government Printing Office, Washington, DC 20402
Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed	1995	Food and Animal Feed Industries	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, PB96–920500
Pesticides Analytical Manual	1994	Food Industry	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, PB94–911899
FDA Advisory for Deoxynivanol (DON) in Finished Wheat Products Intended for Human Consumption and in Grain and Grain By-Products for Animal Feed	September 16, 1993	Food and Animal Feed Industries	Office of Plant & Dairy Foods & Beverages, Food and Drug Administration (HFS–306), 200 C St. SW., Washington, DC 20204, 202–205–4681
FDA's Cosmetic Labeling Manual	October 1991	Cosmetic Industry	Food and Drug Administration, Office of Colors and Cosmetics (HFS–105), 200 C St. SW., Washington, DC 20204, 202–205–4493
Statement of Policy: Foods Derived from New Plant Varieties: Notice	May 29, 1992 (57 FR 22984)	Developers of New Plant Food Varieties	Office of Premarket Approval, Food and Drug Administration (HFS–200), 200 C St. SW., Washington, DC 20204, 202–418–3100
A Food Labeling Guide	May 1997	Food Industry	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–5251
Appendix I—Model Small Business Food Labeling Exemption Notice	June 1996	Food Industry	Do
Food Labeling: Questions and Answers	August 1994	Food Industry	Do
Food Labeling: Questions and Answers: Volume II	February 1996	Food Industry	Superintendent of Documents, Government Printing Office, Washington, DC 20420, 202–512–1800
Fair Packaging and Labeling Act Manual	June 1978	Food Industry	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, 703–487–4650, PB–83–222117
Bacteriological Analytical Manual 7th Edition	1992	FDA Regulated Industries	AOAC International, 481 N. Frederick Ave., Suite 500, Gaithersburg, MD, 20877–2417, 301–924–7077
FDA Food Importer's Guide for Low-Acid Canned and Acidified Foods	1985	Food Industry	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–5251

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How To Obtain A Hard Copy of The Document (Name and Address, Phone, Fax, E–Mail or Internet)
Fabrication of Single Service Containers and Closures for Milk and Milk Products	1995	States	Milk Safety Branch (HFS–626), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20202, 202–205–9175
Evaluation of Milk Laboratories	1995	States	Do
Methods of Making Sanitation Ratings Of Milk Supplies	1995	States	Do
Dry Milk Ordinance	1995	States	Do
Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program for Certification of Interstate Milk Shippers	1995	Dairy Industry	Do
Frozen Dessert Processing Guidelines	1989	Dairy Industry	Office of Plant and Dairy Foods and Beverages (HFS–302), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204, 202–205–9175
Pasteurized Milk Ordinance	1995	States	Milk Safety Branch (HFS–626), Center for Food Safety and Applied Nutrition 200 C St. SW., Washington, DC 20204, 202–205–9175
FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases	1993	Food Industry	Office of Nutritional Products, Labeling, and Dietary Supplements, Food and Drug Administration (HFS–800), 200 C St. SW., Washington, DC 20204, 202–205–4561
Guidelines for Determining Metric Equivalents of Household Measures	October 1, 1993	Food Industry	Do
List of Food Defect Action Levels (DALS)	1995	Food and Animal Feed Industries	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–5251
Action Levels for Poisonous or Deleterious Substances in Human Food and Feed (Also Found in CPG's)	1995	Food and Animal	Do
1997 FDA Food Code	1997	States	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, 703–487–4650
Seafood List	1993	Seafood Industry	Superintendent of Documents, Government Printing Office, Washington, DC 20402, 202–512–1800
Manual of Operations National Shellfish Sanitation	1992	States	Office of Seafood, Office of Seafood (HFS–407), Shellfish Sanitation Branch, 200 C St. SW., Washington, DC 20204, 202–418–3150
Fish and Fisheries Products Hazards and Controls Guide	1996	Seafood Industry	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How To Obtain A Hard Copy of The Document (Name and Address, Phone, Fax, E–Mail or Internet)
Guidance for Submitting Requests under 21 CFR 170.39, Threshold of Regulation for Substances Used in Food Articles	1996	Food Packaging Industry,	Office of Premarket Approval, Food and Drug Administration (HFS–200), 200 C St. SW., Washington, DC 20204, 202–418–3100
Guidelines for the Preparation of Petition Submissions	1996	Food Ingredient or Packaging Industry	Do
Guidelines for Approval of Color Additives in Contact Lenses Intended as Colors	1996	Color or Contact Lens Industry	Do
FDA Recommendations for Submission of Chemical and Technological Data on Color Additives for Food, Drugs or Cosmetics Use	February 1993	Color Additives Industry	Do
Points to Consider for the Use of Recycled Plastics in Food Packaging: Chemistry Considerations	December 1992	Food Packaging Industry	Do
Recommendations for Submission of Chemical and Technological Data for Direct Food Additive and GRAS Food Ingredient Petitions	May 1993	Food Packaging Industry	Do
Recommendations for Chemistry Data for Indirect Food Additive Petitions	June 1995	Food Packaging Industry	Do
Enzyme Preparations: Chemistry Recommendations for Food Additive and GRAS Affirmation Petitions	January 1993	Food Enzyme Industry	Do
Estimating Exposure to Direct Food Additive and Chemical Contaminants in the Diet	September 1995	Food and Food Ingredient Industry	Do
Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food (also known as Redbook I)	1982	Petitioners for Food or Color Additives	Do
Environmental Assessment Technical Handbook	March 1987	Petitioners for Food or Color Additives	National Technical Inion Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, Pub. No. PB87175345–AS, Ab–01
Color Additive Petitions Information and Guidance	1996	Petitioners for Color Additives	Office of Premarket Approval, Food and Drug Administration (HFS–200), 200 C St. SW., Washington, DC 20204, 202–418–3100
Toxological Testing of Food Additives	1983	Petitioners for Food or Color Additives	Office of Premarket Approval, Food and Drug Administration (HFS–200), 200 C St. SW., Washington, DC 20204, 202–418–3100
List of Products for Each Product Category	October 8, 1992	Food Industry	Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–800), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4561
Label Declaration of Allergenic Substances in Foods; Notice to Manufacturers	June 10, 1996	Food Industry	Do
Guidance on Labeling of Foods that Need Refrigeration by Consumers	February 24, 1997 (62 FR 8248)	Food Industry	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How To Obtain A Hard Copy of The Document (Name and Address, Phone, Fax, E–Mail or Internet)
Guidelines Concerning Notification and Testing of Infant Formula	1985	Infant Formula Manufacturers	Do
Clinical Testing of Infant Formulas with Respect to Nutritional Suitability for Term Infants	1988	Infant Formula Manufacturers	Do
Guidelines for the Evaluation of the Safety and Suitability of New Infant Formulas for Feeding Infants with Allergic Diseases	1988	Infant Formula Manufacturers	Do
Guidelines for the Evaluation of the Safety and Suitability of Infant Formulas for Feeding Infants with Allergic Diseases	1990	Infant Formula Manufacturers	Do
Guidelines for the Clinical Evaluation of New Products Used in the Dietary Management of Infants, Children and Pregnant Women with Metabolic Disorders	1987	Infant Formula Manufacturers	Do
Guidance Document for Arsenic (Trace Elements in Seafood)	January 1993	States	Office of Seafood, Food and Drug Administration (HFS–400), 200 C St. SW., Washington, DC 20204, 202–418–3150, Internet: FDA Home Page Http://vm.cfsan.fda.gov/list.html
Guidance Document for Cadmium (Trace Elements in Seafood)	January 1993	States	Do
Guidance Document for Chromium (Trace Elements in Seafood)	January 1993	States	Do
Guidance Document for Lead (Trace Elements in Seafood)	August 1993	States	Do
Guidance Document for Nickel (Trace Elements in Seafood)	January 1993	States	Do
FDA's Policy for Foods Developed by Biotechnology	1995	Food Industry	Do
Bovine Spongiform Encephalopathy (BSE) In Products for Human Use	1997	Food Industry	Office of Plant and Dairy Foods and Beverages (HFS–302), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204, 202–205–9175, Internet: FDA Home Page Http://www.fda.gov/opacom/morechoices/industry/guidance/gelguide.htm
Interim Guidance on the Voluntary Labeling of Milk and Milk Products that have not been treated with Recombinant Bovine Somatropin	February 1994	Regulated Industry	Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–800), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4168
Shellfish Sanitation Model Ordinance	1995	States	Shellfish Program Implementation Branch, Division of Cooperative Programs Office of Field Programs (HFS–628), 200 C St. SW., Washington, DC 20204, 202–205–8137
Guide to Minimize Microbial Hazards for Fresh Fruits and Vegetables	1998	Farmers and Food Packers	Lou Carson, Food Safety Initiative (HFS–3), FDA–CFSAN, 200 C St. SW., Washington, DC 20204 or jsaltsman@bangate.fda.gov

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How To Obtain A Hard Copy of The Document (Name and Address, Phone, Fax, E–Mail or Internet)
Iron-Containing Supplements and Drugs: Label Warning and Unit Dose Packaging; Small Entity Compliance Guide	1997	Dietary Supplement Manufacturers: Small Entities	Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–450), FDA–CFSAN, 200 C. St. SW., Washington, DC 20204
Partial List of Enzyme Preparations That are Used in Foods	1998	FDA Regulated Industry	Do
Partial List of Microorganisms and Microbial-Derived Ingredients That Are Used in Food	1998	FDA Regulated Industry	Office of Premarket Approval (HFS–200), FDA–CFSAN, 200 C St. SW., Washington, DC 20204
Fish and Fishery Products Hazards and Controls Guide, 2nd Edition	January 1998	FDA Regulated Industry	Office of Seafood (HFS–400), FDA–CFSAN, 200 C St. SW., Washington DC 20204
HACCP Regulations for Fish and Fishery Products: Questions and Answers	1998	FDA Regulated Industry	Do
Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body	1998	FDA Regulated Industry	Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–150), 200 C St. SW., Washington, DC 20204
Small Business Juice Labeling: Questions and Answers	1998	Small Business	Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–150), 200 C St. SW., Washington, DC 20204, Geraldine June, 202–205–5099
FDA Nutrition Labeling Manual, A Guide for Developing and Using Data Bases	March 1998	FDA Regulated Industry	Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–150), 200 C St. SW., Washington, DC 20204
HACCP Regulation for Fish and Fishery Products: Questions and Answers, Issue Three, Revised January 1999	January 1999	Seafood Processors	Office of Seafood, CFSAN/FDA (HFS–400), 200 C St. SW., Washington, DC 20204, Ellen Nesheim, 202–418–3150
Foods—Adulteration Involving Hard or Sharp Foreign Objects (CPG)	February 1999	FDA Field Offices	Office of Plant and Dairy Foods and Beverages (HFS–300), 200 C. St. SW., Washington, DC 20204
Food Additive Petition Expedited Review	January 1999	Guidance for Industry and Center for Food Safety and Applied Nutrition Staff	Robert L. Martin (HFS–215), OPA/CFSAN/FDA, 200 C St. SW., Washington, DC 20204, 202–418–3074, premarkt@cfsan.fda.gov OR http://vm.cfsan.fda.gov/~dms/opa-expe.html
Use of Antibiotic Resistance Marker Genes in Transgenic Plants	September 1998	Guidance for Industry	Nega Beru (HFS–206), OPA/CFSAN/FDA, 200 C. St. SW., Washington, DC 20204, 202–418–3097, premarkt@cfsan.fda.gov OR http://vm.cfsan.fda.gov//dms/opa-armg.html
Draft Guidance: Channels of Trade Policy for Commodities with Methyl Parathion Residues	June 2000	Regulated Industry	Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition (HFS–300), FDA, 200 C St. SW., Washington, DC 20204, http://vm.cfsan.fda.gov/dms

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How To Obtain A Hard Copy of The Document (Name and Address, Phone, Fax, E–Mail or Internet)
Draft Guidance: Fumonisin Levels in Human Foods and Animal Feeds	June 2000	Regulated Industry	Do
Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements Small Entity Compliance Guide	January 1999	Small Business Entities	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–5251
Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements (December 1999)	December 1999	Regulated Industry,	Office of Nutritional Products, Labeling, and Dietary Supplements, Center For Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–4561
Antimicrobial Food Additives	July 1999	Regulated Industry	Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–418–3100
Preparation of Premarket Notifications for Food Contact Substances: Chemistry Recommendations	November 1999	Regulated Industry	Do
Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations	November 1999	Regulated Industry	Do
Guidance for Small Businesses: Submission of Comments for CFSAN Rulemaking	October 1999	Small Business Entities	Division of Market Studies (HFS–726), Center for Food Safety and Applied Nutrition, Food and Drug Administration, Washington, DC 20204, 202–401–4590
Warning and Notice Statement: Labeling of Juice Products Small Entity Compliance Guide	September 1998	Regulated Industry	Office of Nutritional Products, Labeling, and Dietary Supplements, Center For Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–4561
Reducing Microbial Food Safety Hazards for Sprouted Seeds	October 1999	Regulated Industry	Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–4064
Seafood HACCP Transition Policy	December 1999	Regulated Industry	Office of Seafood (HFS–400), 200 C St. SW., Washington DC 20204, 202–205–3150

VI. Guidance Documents Issued by the Center for Veterinary Medicine (CVM)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guideline 3—General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals	July 1994	Animal Drug Industry	Internet via: http://www.fda.gov/cvm or Communications Staff (HFV–12), FDA/CVM, 7500 Standish Pl., Rockville, MD 20855, 301–594–1755, FAX 301–594–1831
Guideline 4—Guidelines for Efficacy Studies for Systemic Sustained Release Sulfonamide Boluses for Cattle		Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guideline 5—Stability Guidelines	December 1990	Do	Do
Guideline 6—Guidelines for Submitting NADA's for Generic Drugs Reviewed by NAS/NRC		Do	Do
Guideline 9—Preclearance Guidelines for Production Drugs	October 1975	Do	Do
Guideline 10—Amendment of Section II (G)(1)(b)(4) of the Preclearance Guidelines	October 1975	Do	Do
Guideline 13—Guidelines for Evaluation of Effectiveness of New Animal Drugs for Use in Free-Choice Feeds	January 1985	Do	Do
Guideline 14—Guideline and Format for Reporting the Details of Clinical Trials Using An Investigational New Animal Drug in FOOD Producing Animals		Do	Do
Guideline 15—Guideline and Format for Reporting the Details of Clinical Trials Using An Investigational New Animal Drug in Non-Food Producing Animals	February 1977	Do	Do
Guideline 16—FOI Summary Guideline	May 1985	Do	Do
Guideline 18—Antibacterial Drugs in Animal Feeds: Human Health Safety Criteria		Do	Do
Guideline 19—Antibacterial Drugs in Animal Feeds: Animal Health Safety Criteria		Do	Do
Guideline 20—Antibacterial Drugs in Animal Feeds: Antibacterial Effectiveness Criteria		Do	Do
Guideline 22—Guideline Labeling of Arecoline Base Drugs Intended for Animal Use		Do	Do
Guideline 23—Medicated Free Choice Feeds—Manufacturing Control	July 1985	Do	Do
Guideline 24—Guidelines for Drug Combinations for Use in Animals	October 1983	Do	Do
Guideline 25—Guidelines for the Efficacy Evaluation of Equine Anthelmintics	January 1979	Do	Do
Guideline 29—Guidelines for the Effectiveness Evaluation of Swine Anthelmintics	September 1980	Do	Do
Guideline 31— Guidelines for the Evaluation of Bovine Anthelmintics	July 1981	Do	Do
Guideline 33—Target Animal Safety Guidelines for New Animal Drugs	June 1989	Do	Do
Guideline 35—Bioequivalence Guideline—Final	1996	Do	Do
Guideline 36—Guidelines for Efficacy Evaluation of Canine/Feline Anthelmintics	July 1985	Do	Do
Guideline 37—Guidelines for Evaluation of Effectiveness of New Animal Drugs for Use in Poultry Feed for Pigmentation	March 1984	Do	Do
Guideline 38—Guideline for Effectiveness Evaluation of Topical/Otic Animal Drugs	August 1984	Do	Do
Guideline 40—Draft Guideline for the Evaluation of the Efficacy of Anticoccidial Drugs and Anticoccidial Drug Combinations in Poultry	April 1992	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guideline 41—Draft Guideline: Formatting, Assembling, and Submitting New Animal Drug Applications	June 1992	Do	Do
Guideline 42—Animal Drug Manufacturing Guidelines, 1994	1994	Do	Do
Guideline 43—Guidance on Generic Animal Drug Products Containing Fermentation-Derived Drug Substances	October 1995	Do	Do
Guideline 45—Guideline for Uniform Labeling of Drugs for Dairy and Beef Cattle	August 1993	Do	Do
Guideline 48—Guidance for Industry for the Submission of Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products	November 1994	Do	Do
Guideline 49—Guidance Document for Target Animal Safety and Drug Effectiveness Studies for Anti-Microbial Bovine Mastitis Products	April 1996	Do	Do
Guideline 50—Draft Guideline for Target Animal and Human Food Safety, Drug Efficacy, Environmental and Manufacturing Studies for Teat Antiseptic Products	February 1993	Do	Do
Guideline 52—Guidance—Microbiological Testing of Antimicrobial Drug Residues in Food	January 1996	Do	Do
Guideline 53—Guideline for the Evaluation of the Utility of Food Additives in Diets Fed to Aquatic Animals	May 1994	Do	Do
Guideline 54—Draft Guideline for Utility Studies for Anti-Salmonella Chemical Food Additives in Animal Feeds	June 1994	Do	Do
Guideline 55—Supportive Data for Cat Food Labels Bearing ''Reduces Urinary pH Claims: Guideline in Protocol Development''	June 1994	Do	Do
Guideline 56—Protocol Development Guideline for Clinical Effectiveness and Target Animal Safety Trials	November 1994	Do	Do
Guideline 57—Master Files—Guidance for Industry for the Preparation and Submission of Veterinary Master Files	July 1995	Do	Do
Guideline 58—Guidance for Industry for Good Target Animal Study Practices: Clinical Investigators and Monitors	May 1997	Do	Do
Guideline 59—Guidance for Industry: Submitting a Notice of Claimed Investigational Exemption in Electronic Format to CVM via E–Mail	January 1999	Do	Do
Guidance 61—Guidance for Industry—FDA Approval of Animal Drugs for Minor Uses and for Minor Species	January 1999	Do	Do
Guideline 62—Guidance for Industry—Consumer-Directed Broadcast Advertisements	August 1997	Do	Do
Guideline 63—Guidance for Industry—Validation of Analytical Procedures: Definition and Terminology—Draft Guidance	December 1997	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guideline 64—Guidance for Industry—Validation of Analytical Procedures: Methodology—Draft Guidance	December 1997	Do	Do
Guideline 65—Guidance for Industry—Industry-Supported Scientific and Educational Activities	November 1997	Do	Do
Guideline 66—Guidance for Industry— Professional Flexible Labeling of Antimicrobial Drugs—Draft Guidance	January 1998	Do	Do
Guideline 67—Guidance for Industry—Small Entities Compliance Guide for Renderers	February 1998	Do	Do
Guideline 68—Guidance for Industry—Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers, and Distributors	February 1998	Do	Do
Guideline 69—Guidance for Industry—Small Entities Compliance Guide for Feeders of Ruminant Animals With On-Farm Feed Mixing Operations	February 1998	Do	Do
Guideline 70—Guidance for Industry—Small Entities Compliance Guide for Feeders of Ruminant Animals Without On-Farm Feed Mixing Operations	February 1998	Do	Do
Guideline 71—Guidance for Industry—Use of Human Chorionic Gonadotropic (HCG) as a Spawning Aid for Fish	April 1998	Do	Do
Guideline 72—Guidance for Industry—GMP's for Medicated Feed Manufacturers Not Required to Register and Be Licensed With FDA	May 1998	Do	Do
Guideline 73—Draft Guidance for Industry—Stability Testing of New Animal Drug Substances and Products	July 1998	Do	Do
Guideline 74—Draft Guidance for Industry—Stability Testing for New Dosage Forms of New Animal Drugs	July 1998	Do	Do
Guideline 75—Guidance for Industry—Stability Testing: Photostability Testing of New Animal Drug Substances and Products: Draft Guidance	July 1998	Do	Do
Guideline 76—Guidance for Industry—Questions and Answers—BSE Feed Regulation	September 1998	Do	Do
Guideline 77—Guidance for Industry—Interpretation of On-Farm Feed Manufacturing and Mixing Operations—Draft Guidance	September 1998	Do	Do
Guideline 78—Guidance for Industry—Evaluation of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals	December 1999	Do	Do
Guidance for Industry: Chemistry, Manufacturing and Controls Changes to an Approved NADA or ANADA: Draft Guidance	June 1999	Do	Do
Draft Guidance for Industry: Good Clinical Practices	July 1999	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance for Industry: Efficacy of Anthelmintics: General Recommendations: Draft Guidance	July 1999	Do	Do
Guidance for Industry: Stability Testing for Medicated Premixes Draft Guidance	July 1999	Do	Do
Guidance for Industry: Impurities in New Veterinary Drug Substances Draft Guidance	July 1999	Do	Do
Guidance for Industry: Impurities in New Veterinary Medical Products Draft Guidance	July 1999	Do	Do
Guidance for Industry: Efficacy of Anthelmintics: Specific Recommendations for Bovines: Draft Guidance	July 1999	Do	Do
Guidance for Industry: Efficacy of Anthelmintics: Specific Recommendations for Ovines: Draft Guidance	July 1999	Do	Do
Guidance for Industry—Validation of Analytical Procedures: Definition and Terminology	July 1999	Do	Do
Guidance for Industry—Validation of Analytical Procedures: Methodology: Final Guidance	July 1999	Do	Do
Guidance for Industry: Efficacy of Anthelmintics: Specific Recommendations for Caprines: Draft Guidance	July 1999	Do	Do
Guidance for Industry: Manufacture and Distribution of Unapproved Piperazine Products	August 1999	Do	Do
Guidance for Industry: Possible Dioxin/PCB Contamination of Drug and Biological Products	August 1999	Do	Do
Guidance for Industry—Consumer-Directed Broadcast Advertisements: Final Guidance	August 1999	Do	Do
Guidance for Industry: Stability Testing of New Veterinary Dosage Forms VICH GL4: Final Guidance	September 1999	Do	Do
Guidance for Industry: Stability Testing of New Veterinary Drug Substances and Medicinal Products VICH GL3: Final Guidance	September 1999	Do	Do
Guidance for Industry: Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's)—Phase I: Draft Guidance	September 1999	Do	Do
Guidance for Industry: Quality of Biotechnological Products in the Veterinary Field: Stability Testing of Biotechnological/Biological Products VICH GL 17: Draft Guidance	September 1999	Do	Do
Guidance for Industry: Impurities: Residual Solvents VICH GL 18: Draft Guidance	September 1999	Do	Do
Guidance for Industry—Content and Format of Effectiveness and Target Animal Safety Technical Sections and Final Study Reports for Submission to the Division of Therapeutic Drugs for Non-Food Animals	September 1999	Do	Do
Guidance for Industry: Stability Testing: Photostability Testing of New Veterinary Drug Substances and Medicinal Products: Final Guidance	September 1999	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Computerized Systems Used in Clinical Trials	October 1999	Do	Do
Dioxin in Anti-Caking Agents Used in Animal Feed and Feed Ingredients	October 1999	Do	Do
Guidance for Industry—Evaluation of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals	December 1999	Do	Do
Guidance for Industry: Development of Supplemental Applications for Approved New Animal Drugs—Draft Guidance	January 2000	Do	Do
Guidance for Industry: Stability Testing for Medicated Premixes Guidance	March 2000	Do	Do
Guidance for Industry: The Use of Published Literature in Support of New Animal Drug Approval—Draft Guidance	April 11, 2000	Do	Do
Guidance for Industry: Dioxin In Anti-Caking Agents Used In Animal Feed And Feed Ingredients	Revised April 12, 2000	Do	Do
Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds—Draft Guidance	June 6, 2000	Do	Do

VII. Guidance Documents Issued by the Office of Policy (OP)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How To Obtain A Hard Copy of The Document (Name and Address, Phone, FAX, E-mail, or Internet)
FDA's Development, Issuance, and Use of Guidance Documents	February 27, 1997	FDA Personnel and Regulated Industry	Internet via www.fda.gov/opacom/morechoices/moreindu.html or Office of Policy (301–827–3360)
Draft Guidance for Industry; Exports and Imports under the FDA Export Reform and Enhancement Act of 1996	June 12, 1998	Regulated Industry	Internet via www.fda.gov/opacom/fedregister/frexport.html
Direct Final Rule Guidance	November 21, 1997	FDA Personnel	Internet via www.fda.gov/opacom/morechoices/industry/guidedc.htm or Carol Kimbrough (301–827–3480)
Industry Supported Scientific and Educational Activities	December 3, 1997	Regulated Industry	Internet via www.fda.gov/cder/guidance/index.htm or Office of Policy (301–827–3360)
Draft Guidance of Broadcast Advertisements	February 1997	Do	Do
Small Entities Compliance Guide On: Regulations to Restrict the Sale and Distribution of Cigarettes and Smokeless Tobacco in Order to Protect Children and Adolescents (21 CFR Part 897)	February 1997	Do	Internet via www.fda.gov/opacom/campaigns/tobacco/tobret.htm or 1–888–FDA–4KIDS
Children & Tobacco—Frequently Asked Questions about the new regulations (DRAFT)	July 1997	Do	Do
Children & Tobacco—A Retailer's Guide to the New Federal Regulations	October 1997	Do	Do
Children & Tobacco—A Guide to the New Federal Regulations	October 1997	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How To Obtain A Hard Copy of The Document (Name and Address, Phone, FAX, E-mail, or Internet)
FDA's Standards Policy	October 1995	FDA Personnel and Regulated Industry	60 FR 53078, October 11, 1995 or Office of Policy (301–827–3360)

VIII. Guidance Documents Issued by the Office of Regulatory Affairs (ORA)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How To Obtain A Hard Copy of The Document (Name and Address, Phone, FAX, E–mail, or Internet)
Compliance Policy Guides Manual	August 1996	FDA Staff Personnel	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161 (Order No. PB96–915499) or via Internet www.fda.gov/ora/compliance__ref/cpg/cpgtc.html
Compliance Policy Guide-DRAFT Commercialization of In Vitro Diagnostic Devices (IVD's) Labeled for Research Use Only or Investigational Use Only	January 5, 1998	Do	Do—Internet at www.fda.gov/cdrh/comp/ivddrfg.html
Compliance Policy Guide 675.400 (CPG 7126.24) REVISION Rendered Animal Feed Ingredients	November 13, 1998	Do	Do—Internet at www.fda.gov/ora/compliance__ref/cpg/cpgvet/cpg675.400.html
Compliance Policy Guide DRAFT Distributor Medical Device Reporting	August 28, 1997	FDA Staff Personnel and Regulated Industry	Do—Internet at www.fda.gov/ora/compliance__ref/cpg__mdr3.txt
Compliance Policy Guide, Chapter 5, Sec. 555.425, NEW: Foods Adulteration Involving Hard or Sharp Foreign Objects	March 23, 1999	FDA Staff Personnel	Do—Internet at http://www.fda.gov/ora/compliance__ref/cpg/cpgfod/cpg555–425.htm
Compliance Policy Guide, Chapter 1, Sec.160.800, NEW:Year 2000 (Y2K) Computer Compliance	April 26, 1999	Do	Do—Internet at http://www.fda.gov/ora/compliance__ref/cpg/cpggenl/cpt160.800.html
Compliance Policy Guide, Chapter 1, Sec. 140.100, REVISION/DRAFT: Regulatory Policy on the Disposition of Publications That Constitute Labeling (CPG 7153.13)	April 26, 1999	Do	Do—Internet at http://www.fda.gov/ora/compliance__ref/cpg/cpgfod/draftrev-cpg715313.htm
Compliance Policy Guide, Chapter 1, Sec. 160.850: NEW, Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures (CPG 7153.17)	May 13, 1999	Do	Do—Internet at htpp://www.fda.gov/ora/compliance__ref/cpg/cpggenl/cpg160–180.htm
Compliance Policy Guide, Chapter 2, Sec. 230.140, NEW, Evaluation and Processing of Post Donation Information Reports	July 9, 1999	Do	Do—Internet at http://www.fda.gov/ora/compliance__ref/default.htm
Compliance Policy Guide, Chapter 2, Sec. 252.110, NEW: Volume Limits for Automated Collection of Source Plasma	March 6, 2000	Do	Do—Internet at http://www.fda.gov/ora/compliance__ref/cpgbio/cpg252.110.htm
Compliance Policy Guide, Chapter 2, Sec. 257.100, REVISED: Deferral of Source Plasma Donors Due to Red Cell Loss During Collection of Source Plasma by Automated Plasmapheresis	March 22, 2000	Do	Do—Internet at http://www.fda.gov/ora/cmpliance__ref/cpg/cpgbio/cpg257.100.htm
Compliance Policy Guide, Chapter 1, Sec. 110.100: REVISED: Certificates for Export	April 14, 2000	Do	Do—Internet at http://www.fda.gov/ora/compliance__ref/cpg/cpggenl/cpg110–100.html
Medical Device Warning Letter Pilot	March 8, 1999	FDA Staff Personnel and Regulated Industry	Do—Internet at http://www.fda.gov/ohrms/Dockets/98fr/030899e.pdf

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How To Obtain A Hard Copy of The Document (Name and Address, Phone, FAX, E–mail, or Internet)
Draft Guidance Policy Statement: Draft Civil Money Penalty Reduction Policy for Small Entities	May 18, 1999	Do	Do—Internet at http://www.fda.gov/ohrms/Dockets/98fr/051899.txt
Glossary of Computerized System and Software Development Terminology	August 1995	Do	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161 (Order No. PB96–127352) or via Internet www.fda.gov/ora/inspect__ref/igs/iglist.html
Guidelines for Entry Review of Radiation-Emitting Electronic Devices	March 12, 1999	FDA Staff Personnel	Division of Import Operations and Policy (HFC–170), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1218
Import Alerts	Continuous	Do	FDA/Freedom of Information Staff (HFI–35), 5600 Fishers Lane, Rockville, MD 20857 or via Internetwww.fda.gov/ora/fiars/ora__import__alerts.html
Investigations Operations Manual	March 2000	Do	Division of Emergency and Investigational Operations (HFC–130), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301–443–3276 2000 Edition is not yet available on Internet. 1999 Edition is available on Internet at http:// www.fda.gov/ora/inspect__ref/iom/iomtc.html
Investigations Operations Manual, REVISION: Chapter 4, Sampling	July 1998	Do	Do
Investigations Operations Manual, REVISION: Chapter 5, Establishment Inspections	July 1998	Do	Do
Memorandum: ORA Investigational Strategy on Gamma-Butyrolactone (GBL) and Related Products	May 15, 2000	Do	Do—Not available on Internet
Laboratory Procedures Manual	June 1994	Do	Division of Field Science (HFC–141), Food and Drug Administration, 5600 Fishers Lane, rm. 12–41, Rockville, MD 20857, ATTN: Donna Porter or via Internet www.fda.gov/ora/science__ref/lpm/lpmtc.html
Laboratory Procedures Manual, Chapter X, NEW: Method Validation Samples	May 1999	Do	Do—Not available on Internet
Regulatory Procedures Manual	August 1997	Do	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161 (Order No. PB97–196182) or via Internet www.fda.gov/ora/compliance__ref/rpm/rpmtc.html
Regulatory Procedures Manual: UPDATE/New Subchapter/Application Integrity Policy	March 1998	Do	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420 or via Internet www.fda.gov/ora/compliance__ref/rpm/rpmtc.html
Regulatory Procedures Manual: UPDATE Subchapter/Warning Letters	March 1998	Do	Do
Regulatory Procedures Manual: UPDATE/REVISION Subchapter/Import Procedures	April 1998	Do	Do
Regulatory Procedures Manual; UPDATE/REVISION Subchapter/Priority Enforcement Strategy for Problem Importers	April 1998	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How To Obtain A Hard Copy of The Document (Name and Address, Phone, FAX, E–mail, or Internet)
Regulatory Procedures Manual: UPDATE/ REVISION Subchapter/Import Procedures	April 1998	Do	Do
Regulatory Procedures Manual: UPDATE/ REVISION Subchapter/Notice of Sampling	April 1998	Do	Do
Regulatory Procedures Manual: UPDATE/ NEW Subchapter/Granting and Denying Transportation and Exportation (T&E) Entries	May 1998	Do	Do
Regulatory Procedures Manual: UPDATE/ REVISION Subchapter/Seizure	June 1998	Do	Do—Internet at www.fda.gov/ora/compliance__ref/ rpm__new2/ch6.html
Regulatory Procedures Manual: UPDATE/ REVISION Subchapter/Supervisory Charges	June 1998	Do	Do—Internet at www.fda.gov/ora/compliance__ref/ rpm__new2/ch9chgs.html
Regulatory Procedures Manual: NEW Subchapter/Civil Penalties—Electronic Product Radiation Control	July 1998	Do	Do—Internet at www.fda.gov/ora/compliance__ref/ ch6civpen.html
Regulatory Procedures Manual, UPDATE/ REVISION: Chapter 4, Subchapter/Warning Letters	March 21, 2000	Do	Do Internet at http://www.fda.gov/ora/compliance__ref/rpm__new2/ch4.html
Guide to Inspections of Bulk Pharmaceutical Chemicals	May 1994	Do	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161 (Order No. PB96–127154) or via Internet www.fda.gov/ora/inspect__ref/igs/iglist.html
Guide to Inspections of Pharmaceutical Quality Control Laboratories	July 1993	Do	Do—(NTIS Order No. PB96–127279)
Guide to Inspections of Microbiological Pharmaceutical Quality Control Laboratories	July 1993	Do	Do—(NTIS Order No. PB96–127287)
Guide to Inspections of Validation of Cleaning Processes	July 1993	Do	Do—(NTIS Order No. PB96–127246)
Guide to Inspections of Lyophilization of Parenterals	July 1993	Do	Do—(NTIS Order No. PB96–127253)
Guide to Inspections of High Purity Water Systems	July 1993	Do	Do—(NTIS Order No. PB96–127261)
Guide to Inspections of Dosage Form Drug Manufacturers-CGMPs	October 1993	Do	Do—(NTIS Order No. PB96–127212)
Guide to Inspections of Oral Solid Dosage Forms Pre/Post Approval Issues for Development and Validation	January 1994	Do	Do—(NTIS Order No. PB96–127345)
Guide to Inspections of Topical Drug Products	July 1994	Do	Do—(NTIS Order No. PB96–127394)
Guide to Inspections of Sterile Drug Substance Manufacturers	July 1994	Do	Do—(NTIS Order No. PB96–127295)
Guide to Inspections of Oral Solutions and Suspensions	August 1994	Do	Do—(NTIS Order No. PB96–127147)
Guide to Inspections of Nutritional Labeling and Education Act (NLEA) Requirements	February 1995	Do	Do—(NTIS Order No. PB96–127378)
Guide to Inspections of Interstate Carriers and Support Facilities	April 1995	Do	Do—(NTIS Order No. PB96–127386)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How To Obtain A Hard Copy of The Document (Name and Address, Phone, FAX, E–mail, or Internet)
Guide to Inspections of Dairy Product Manufacturers	April 1995	Do	Do—(NTIS Order No. PB96–127329)
Guide to Inspections of Miscellaneous Foods Vol. I	May 1995	Do	Do—(NTIS Order No. PB96–127220)
Guide to Inspections of Miscellaneous Foods Vol. II	September 1996	Do	Do—(NTIS Order No. PB97–196133)
Guide to Inspections of Low Acid Canned Foods Manufacturers, Part 1-Administrative Procedures/Scheduled Processes	November 1996	Do	Do—(NTIS Order No. PB97–196141)
Guide to Inspections of Low Acid Canned Foods Manufacturers, Part 2– Processes/ Procedures	April 1997	Do	Do—(NTIS Order No. PB97–196158)
Guide to Inspections of Cosmetic Product Manufacturers	February 1995	Do	Do—(NTIS Order No. PB96–127238)
Guide to Inspections of Blood Banks	September 1994	Do	Do—(NTIS Order No. PB96–127303)
Guide to Inspections of Source Plasma Establishments	December 1994	Do	Do—(NTIS Order No. PB96–127360)
Guide to Inspections of Infectious Disease Marker Testing Facilities	June 1996	Do	Do—(NTIS Order No. PB96–199476)
Biotechnology Inspections Guide	November 1991	Do	Do—(NTIS Order No. PB96–127402)
Guide to Inspections of Computerized Systems in Drug Processing	February 1983	Do	Do—(NTIS Order No. PB96–127337)
Guide to Inspections of Foreign Medical Device Manufacturers	September 1995	Do	Do—(NTIS Order No. PB96–127311)
Guide to Inspections of Foreign Pharmaceutical Manufacturers	May 1996	Do	Do—(NTIS Order No. PB96–199468)
Mammography Quality Standards Act (MQSA) Auditors Guide	January 1998	Do	Do—(NTIS Order No. PB98–127178)
Guide to Inspections of Electromagnetic Compatibility Aspects of Medical Device Quality Systems	December 1997	Do	Do—(NTIS Order No. PB98–127152)
Guide to Inspections of Grain Product Manufacturers	March 1998	Do	Division of Emergency and Investigational Operations (HFC–130), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301–443–3276
Guide to Bioresearch Monitoring Inspections of In Vitro Devices	February 1998	Do	Do
Guide to Inspections of Viral Clearance Processes for Plasma Derivatives	March 1998	Do	Do
Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations	August 1998	Do	Do
Guide to Inspections of Computerized Systems in the Food Processing Industry	August 1998	Do	Do—Internet at www.fda.gov/ora/inspect__ref/igf/iglist.html
Guide to International Inspections and Travel, REVISION (Formerly: FDA/ORA International Inspection Manual and Travel Guide)	July 1999	Do	Do Revision not available on Internet
Guide to Inspections of Quality Systems	August 1999	Do	Do—Internet at http://www.fda.gov/ora/inspect__ref/igs/qsit/QSITGUIDE.PDF

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How To Obtain A Hard Copy of The Document (Name and Address, Phone, FAX, E–mail, or Internet)
Guideline for the Monitoring of Clinical Investigators	January 1988	FDA Regulated Industry	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420
Computerized Systems Used in Clinical Trials	April 1999	Do	Do—Internet at http://www.fda.gov/ora/compliance__ref/bimo/ffinalcct.htm
Draft Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research	March 30, 2000	Do	Do—Internet at http;//www.fda.gov/ora/compliance__ref/bimo__err-guide.htm
Compliance Program 7348.808: Bioresearch Monitoring; Good Laboratory Practices (Nonclinical)	Revised August 17, 1998	FDA Staff Personnel	Do—Internet http://www.fda.gov/ora/compliance__ref/bimo/default.html
Compliance Program 7348.810: Sponsors, Contract Research Organizations and Monitors	Revised October 30, 1998	Do	Do
Compliance Program 7348.811: Bioresearch Monitoring; Clinical Investigations	Revised September 2, 1998	Do	Do
Food Laboratory Practice Program (Nonclinical Laboratories) 7348.808A; EPA Data Audit Inspections	October 1, 1991	Do	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420
Compliance Program 7348.809; Bioresearch Monitoring; Institutional Review Board	August 18, 1994	Do	Do
Good Laboratory Practice Regulations Management Briefings	August 1979	Do	Do—Internet at www.fda.gov/ora/compliance__ref/bimo/default.html

Dated: July 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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H.R. 4425/P.L. 106–246

Making appropriations for military construction, family housing, and base realignment and closure for the Department of Defense for the fiscal year ending September 30, 2001, and for other purposes. (July 13, 2000; 114 Stat. 511)

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