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

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. APHIS–2006–0114]

RIN 0579–AC07

Citrus Canker; Quarantine of the State of Florida; Technical Amendment

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule; technical amendment.

SUMMARY: In an interim rule published in the **Federal Register** on August 1, 2006, we amended the citrus canker regulations to list the entire State of Florida as a quarantined area for citrus canker and to amend the requirements for the movement of regulated articles from Florida now that the eradication of citrus canker in Florida is no longer being carried out as an objective. We also amended the regulations to allow regulated articles that would not otherwise be eligible for interstate movement to be moved to a port for immediate export. In this amendment, we are clarifying that, if citrus canker is found in any grove during the preharvest inspection or afterward, fruit from that grove will be ineligible to move interstate for that entire shipping season.

DATES: *Effective Date:* January 12, 2007.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Poe, Senior Operations Officer, EDP, PPQ, APHIS, 4700 River Road Unit 137, Riverdale, MD 20737–1231; (301) 734–4387.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 7 CFR 301.75–1 through 301.75–14 (referred to below as the regulations) prohibit or restrict the interstate movement of regulated articles from and through areas quarantined because of citrus canker and provide conditions under which regulated fruit may be moved into, through, and from quarantined areas for packing. These regulations are promulgated pursuant to the Plant Protection Act (7 U.S.C. 7701 *et seq.*).

In an interim rule published in the **Federal Register** on August 1, 2006 (71 FR 43345–43352, Docket No. APHIS–2006–0114), we amended the regulations to list the entire State of Florida as a quarantined area for citrus canker and to amend the requirements for the movement of regulated articles from Florida now that the eradication of citrus canker in Florida is no longer being carried out as an objective. We also amended the regulations to allow regulated articles that would not otherwise be eligible for interstate movement to be moved to a port for immediate export.

Following publication of the interim rule, it came to our attention that one of the provisions in the rule did not make clear our intention. As established by the interim rule, § 301.75–7 spells out the requirements that must be met in order for regulated fruit to be moved from a quarantined area. Paragraph (a)(2) of that section provides that, no more than 30 days before the beginning of harvest, every tree must be inspected by an inspector and the grove must be found free of citrus canker. Further, in groves producing limes, every tree must be inspected by an inspector and the grove must be found free of citrus canker every 120 days or less thereafter for as long as harvest continued. Some regulated entities have interpreted these provisions as allowing for the interstate movement of fruit from groves with trees showing signs of citrus canker, provided that the affected trees are removed and the grove is then reinspected prior to harvest and found free of citrus canker. This interpretation is not consistent with the intent of these provisions. Rather, these provisions are intended to only allow the interstate movement of fruit from groves where citrus canker has not been found during the preharvest inspection and afterward. Therefore, in order to avoid confusion, we are revising § 301.75–7(a)(2) to explicitly state that, if citrus canker is found in a grove when the preharvest inspection is conducted, or at any other time beginning August 1 of the year in which the fruit is to be harvested and extending through the harvest season (including into the next calendar year), fruit from the grove will not be eligible for interstate movement for the remainder of the harvest season.

List of Subjects in 7 CFR Part 301

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

■ Accordingly, we are amending 7 CFR part 301 as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

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

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75–15 issued under Sec. 204, Title II, Public Law 106–113, 113 Stat. 1501A–293; sections 301.75–15 and 301.75–16 issued under Sec. 203, Title II, Public Law 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

■ 2. In § 301.75–7, paragraph (a)(2) is revised to read as follows:

§ 301.75–7 Interstate movement of regulated fruit from a quarantined area.

(a) * * *

(2) No more than 30 days before the beginning of harvest, every tree was inspected by an inspector and the grove was found free of citrus canker. Further, in groves producing limes, every tree was inspected by an inspector and the grove was found free of citrus canker every 120 days or less thereafter for as long as harvest continued. If citrus canker is found in a grove when the preharvest inspection is conducted, or at any other time beginning August 1 of the year in which the fruit is to be harvested and extending through the harvest season (including into the next calendar year), fruit from that grove will not be eligible for interstate movement for the remainder of the harvest season.

* * * * *

Done in Washington, DC, this 8th day of January 2007.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E7–370 Filed 1–11–07; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 145 and 147

[Docket No. APHIS–2006–0008]

RIN 0579–AC27

National Poultry Improvement Plan and Auxiliary Provisions

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the National Poultry Improvement Plan (the Plan) and its auxiliary provisions by providing new or modified sampling and testing procedures for Plan participants and participating flocks. The changes were voted on and approved by the voting delegates at the Plan's 2004 National Plan Conference. These changes will keep the provisions of the Plan current with changes in the poultry industry and provide for the use of new sampling and testing procedures.

EFFECTIVE DATE: February 12, 2007.

FOR FURTHER INFORMATION CONTACT: Mr. Andrew R. Rhorer, Senior Coordinator, Poultry Improvement Staff, National Poultry Improvement Plan, Veterinary Services, APHIS, USDA, 1498 Klondike Road, Suite 101, Conyers, GA 30094–5104; (770) 922–3496.

SUPPLEMENTARY INFORMATION:

Background

The National Poultry Improvement Plan (NPIP, also referred to below as ''the Plan'') is a cooperative Federal-State-industry mechanism for controlling certain poultry diseases. The Plan consists of a variety of programs intended to prevent and control egg-transmitted, hatchery-disseminated poultry diseases. Participation in all Plan programs is voluntary, but flocks, hatcheries, and dealers must first qualify as ''U.S. Pullorum-Typhoid Clean'' as a condition for participating in the other Plan programs.

The Plan identifies States, flocks, hatcheries, and dealers that meet certain disease control standards specified in the Plan's various programs. As a result, customers can buy poultry that has tested clean of certain diseases or that has been produced under disease-prevention conditions.

The regulations in 9 CFR parts 145 and 147 (referred to below as the regulations) contain the provisions of the Plan. The Animal and Plant Health Inspection Service (APHIS, also referred to as ''the Service'') of the U.S. Department of Agriculture (USDA, also referred to as ''the Department'') amends these provisions from time to time to incorporate new scientific information and technologies within the Plan.

On June 19, 2006, we published in the **Federal Register** (71 FR 35203–35220, Docket No. APHIS–2006–0008) a proposal [1] to amend the Plan by providing new or modified sampling and testing procedures; adding a procedure for the approval of diagnostic test kits; reorganizing the egg-type and meat-type breeding chicken regulations to separate the regulations concerning primary breeding flocks from those concerning multiplier breeding flocks; and making other changes to update and clarify the regulations.

We solicited comments concerning our proposal for 60 days ending August 18, 2006. We received one comment by that date, from a private citizen. The commenter raised concerns about the welfare of poultry in an agricultural setting.

APHIS does not have statutory authority to promulgate regulations regarding the welfare of poultry in an agricultural setting. The NPIP is designed to control the incidence of disease in breeding and commercial poultry.

The commenter also stated that the Plan should have provisions for ensuring that Authorized Agents are not corrupt.

The Official State Agencies that work with APHIS to administer the provisions of the Plan designate Authorized Agents to perform sampling on flocks that participate in the Plan. Each Official State Agency has provisions for determining whether persons are qualified to serve as Authorized Agents and for ensuring the integrity of Authorized Agents that it designates to perform tasks in the administration of the Plan.

We are not making any changes in response to this commenter's comments.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, without change.

Executive Order 12866 and Regulatory Flexibility Act

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

We are amending the Plan and its auxiliary provisions by providing new or modified sampling and testing procedures for Plan participants and participating flocks. The proposed changes were voted on and approved by the voting delegates at the Plan's 2004 National Plan Conference. These changes will keep the provisions of the Plan current with changes in the poultry industry and provide for the use of new sampling and testing procedures.

The poultry industry plays an important role in the U.S. economy, directly employing approximately 240,000 workers.[2] The poultry industry is primarily composed of two types of companies: Primary breeding companies and highly integrated companies that combine multiplier breeding, hatching, and growing functions. The primary breeder companies are responsible for the development of genetic lines of poultry for commercial companies that market the product to final consumers. They maintain and expand pure designated blood lines and supply breeding stock to commercial poultry companies all over the globe. Improved genetic poultry are multiplied through the hatchery system. The hatcheries, in turn, supply these more efficient birds to producers and growers in nearby States. Hatcheries incubate and hatch eggs and sell chicks to the commercial producer when they are 1 day old. The commercial producers grow the chicks either for meat production or as egg-laying varieties. The genetic lines of both egg-laying varieties and meat-producing poultry are carefully controlled by primary breeding companies.

Almost all birds are produced on a contractual basis between a highly integrated company and individual contract growers who raise the birds, *i.e.*, growers. In such arrangements, the grower normally supplies the poultry house, land, labor, litter, equipment, taxes, utilities, and insurance, while the company provides the chicks, feed, necessary medications, and supervision. Labor and equipment for catching and hauling the birds to market are also provided by the company. The company retains title to the birds, and in return growers are paid according to the amount produced (pounds of birds or dozens of eggs).

Currently, there are three major firms that produce primary breeding stock of

[1] To view the proposed rule and the comment we received, go to *http://www.regulations.gov,* click on the ''Advanced Search'' tab, and select ''Docket Search.'' In the Docket ID field, enter APHIS–2006–0008, then click on ''Submit.'' Clicking on the Docket ID link in the search results page will produce a list of all documents in the docket.

[2] USDA/FAS, Export Promotion Increase Employment in U.S. Poultry Industry, FASONLINE (*http://www.fas.usda.gov/dlp/poultry/success.html*), May 6, 2002.

egg-type chickens, three breeders of meat-type chickens, two breeders of turkey, and one firm producing both egg-type and meat-type chickens. All of these are large facilities headquartered in the United States, and all of them operate in domestic and international markets. Other multinational organizations headquartered in Europe, Israel, and Japan produce several varieties of breeding stock offered to commercial facilities around the globe.

U.S. broiler production totaled 8.5 billion birds in 2003. Ten States accounted for over 79 percent of broilers produced in the United States (table 1). U.S. turkey production in 2003 totaled 274 million birds. The top 10 turkey-producing States accounted for 82 percent of total production. A total of 87.2 billion eggs were produced in 2003. Ten States accounted for 62 percent of total egg production. Approximately 85 percent of egg production was for human consumption (the table-egg market), while the remainder of production was for the hatching market.

TABLE 1.—BROILERS, EGG-LAYING CHICKENS, AND TURKEYS: VALUE BY MAJOR STATES, 2003

Broilers		Egg-laying chickens		Turkeys	
State	Value (million $)	State	Value (million $)	State	Value (million $)
Georgia	2,143	Iowa	460	Minnesota	425
Arkansas	1,987	Georgia	396	North Carolina	398
Alabama	1,838	Ohio	374	Missouri	286
North Carolina	1,512	Pennsylvania	371	Virginia	177
Mississippi	1,424	Arkansas	344	Arkansas	176
Texas	1,032	Texas	310	South Carolina	172
Delaware	543	Indiana	308	California	151
Kentucky	507	Alabama	296	Indiana	139
Maryland	495	California	282	Pennsylvania	101
Virginia	442	North Carolina	242	Iowa	96
Other States	3,292	Other States	1,932	Other States	599
U.S. total	15,215	U.S. total	5,315	U.S. total	2,720

Source: USDA/NASS, Poultry-Production and Value: 2003 Summary, April 2004.

Cash receipts from sales of poultry and eggs (broilers, farm chickens, eggs, turkey, ducks, and other poultry) were about $23.9 billion in 2003.[3] Of this total, 64 percent was from broilers, 22 percent from eggs, 11 percent from turkeys, and 3 percent from other poultry. In terms of tonnage, poultry production and trade exceeds that of beef or pork. For instance, in 2003, the United States produced 38.4 billion pounds of poultry meat, compared with 26.2 billion pounds of beef and 19.9 billion pounds of pork. Poultry meat per capita consumption (98.9 pounds) exceeded that of both beef (64.9 pounds) and pork (51.8). Furthermore, the United States exported more poultry meat (5,404 million pounds) than beef and veal (2,518 million pounds) or pork (1,717 million pounds) during the same period.[4]

The United States is a major exporter of poultry and poultry products. It exported poultry and poultry products valued at $2,287 million in 2003.[5] The major importers, accounting for $1,720 million worth of exports of U.S. poultry, are Russia ($384 million), Canada ($346 million), Mexico ($293 million), Hong Kong ($236 million), China ($117 million), Japan ($83 million), South Korea ($56 million), European Union ($126 million), Turkey ($42 million), and Taiwan ($37 million). U.S. imports of poultry and poultry products totaled $307 million. Of this total, $135 million was from Canada, $113 million from China, $19 million from Taiwan, and $16 million from France.

Impact on Small Entities

The Regulatory Flexibility Act requires that agencies consider the economic impact of their rules on small entities. The Small Business Administration has established guidelines for determining which types of firms are to be considered small under the Regulatory Flexibility Act. The main entities that will be affected by this rule are those engaged in production of poultry breeding stock. Currently there are three major firms that produce primary breeding stock of egg-type chickens, three breeders of meat-type chickens, two breeders of turkeys, and one firm producing both egg-type and meat-type chickens. All of these are large facilities headquartered in the United States and operating in domestic and international markets. Additionally, broiler operations (North American Industry Classification System [NAICS] 112320), turkey operations (NAICS 112330), hatcheries (NAICS 112340) and other poultry operations (NAICS 112390) will be positively, at least qualitatively, affected, as they will benefit from the supply of improved and healthy breeding stock. There were a total of 79,600 commercial growers with sales in 2002.[6] Nearly 100 percent of broiler operations, 70 percent of turkey operations, and about 43 percent of layer operations produce poultry through production contracts. All of these commercial grower farms are considered to be small if they have annual sales of $750,000 or less. About 93 percent of these farms are small, while the rest are large. Commercial egg producers (NAICS 112310) are considered small if they have annual sales of less than $10.5 million.

This rule will introduce a series of minor changes to the NPIP and will not involve significant changes in program operations. Most of the changes involve clarifications, rearrangements of procedures, and definitions of terms. These changes are in line with the industry's best practices and will likely involve no additional costs in order to meet these requirements. Additionally, the NPIP is a voluntary program established between the industry and State and Federal governments. Any person producing or dealing in products may participate in the NPIP when he or she has demonstrated that his or her facilities, personnel, and practices are

[3] USDA/ERS, Cash receipts by commodity groups and selected commodities, United States, 1997–2003, August 2004.

[4] USDA/ERS, Livestock, Dairy and Poultry Outlook/LDP–M–122, August 2004.

[5] USDA/ERS, Foreign Agricultural Trade of the United States, September 2004.

[6] USDA/NASS, 2002 Census of Agriculture-State Data (Table 13), page 356.

adequate for carrying out the applicable provisions of the NPIP. Since most countries will not accept hatching eggs or live birds from a producer unless it can be shown to be a NPIP participant, being a member of the NPIP allows greater ease in exporting hatching eggs or live birds to other countries. The poultry industry plays a very important role in the U.S. economy, and the final rule will help to ensure the safety of the industry and benefit the economy.

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 final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict 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

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

List of Subjects in 9 CFR Parts 145 and 147

Animal diseases, Poultry and poultry products, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR parts 145 and 147 as follows:

PART 145—NATIONAL POULTRY IMPROVEMENT PLAN

■ 1. The authority citation for part 145 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 145.1 is amended as follows:

■ a. By revising the definition of *Authorized Agent* to read as set forth below.

■ b. By adding, in alphabetical order, a new definition of *Authorized Testing Agent* to read as set forth below.

§ 145.1 Definitions.

* * * * *

Authorized Agent. Any person designated under § 145.11(a) to collect official samples for submission to an authorized laboratory as described in §§ 147.1(a) and 147.12 of this subchapter.

* * * * *

Authorized Testing Agent. Any person designated under § 145.11(a) to collect official samples for submission to an authorized laboratory as described in §§ 147.1(a) and 147.12 of this subchapter and to perform the stained antigen, rapid whole blood test for pullorum typhoid.

* * * * *

■ 3. In § 145.11, paragraphs (a) and (b) are revised to read as follows:

§ 145.11 Supervision.

(a) The Official State Agency may designate qualified persons as Authorized Agents to do the sample collecting provided for in § 145.14 and may designate qualified persons as Authorized Testing Agents to do the sample collecting and blood testing provided for in § 145.14.

(b) The Official State Agency shall employ or authorize qualified persons as State Inspectors to perform the qualification testing of participating flocks, and to perform the official inspections necessary to verify compliance with the requirements of the Plan.

* * * * *

§ 145.12 [Amended]

■ 4. In § 145.12, paragraph (a), the word ''inspected'' is removed and the words ''audited at least one time annually or'' are added in its place.

■ 5. In § 145.14, in the introductory text of the section, the second, third, and fifth sentences are revised to read as follows:

§ 145.14 Blood testing.

* * * Blood samples for official tests shall be drawn by an Authorized Agent, Authorized Testing Agent, or State Inspector and tested by an authorized laboratory, except that the stained antigen, rapid whole-blood test for pullorum-typhoid may be conducted by an Authorized Testing Agent or State Inspector. For Plan programs in which a representative sample may be tested in lieu of an entire flock, except the ostrich, emu, rhea, and cassowary program in § 145.63(a), the minimum number tested shall be 30 birds per house, with at least 1 bird taken from each pen and unit in the house. * * * In houses containing fewer than 30 birds other than ostriches, emus, rheas, and cassowaries, all birds in the house must be tested.

* * * * *

■ 6. A new § 145.15 is added to Subpart A to read as follows:

§ 145.15 Approved tests.

(a) The procedures for the bacteriological examination of poultry and poultry environments described in part 147 of this subchapter are approved tests for use in the NPIP. In addition, all tests that use veterinary biologics (*e.g.,* antiserum and other products of biological origin) that are licensed or produced by the Service and used as described in part 147 of this subchapter are approved for use in the NPIP.

(b) Diagnostic test kits that are not licensed by the Service (*e.g.,* bacteriological culturing kits) may be approved through the following procedure:

(1) The sensitivity of the kit will be estimated in at least three authorized laboratories selected by the Service by testing known positive samples, as determined by the official NPIP procedures found in part 147 of this subchapter. If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and significance of the effect(s) can be evaluated.

(2) The specificity of the kit will be estimated in at least three authorized laboratories selected by the Service by testing known negative samples, as determined by the official NPIP procedures found in part 147 of this subchapter. If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and significance of the effect(s) can be evaluated.

(3) The kit will be provided to the cooperating laboratories in its final form and include the instructions for use. The cooperating laboratories must perform the assay exactly as stated in the supplied instructions. Each laboratory must test a panel of at least 25 known positive clinical samples supplied by the manufacturer of the test kit. In addition, each laboratory will be asked to test 50 known negative clinical samples obtained from several sources, to provide a representative sampling of the general population. The identity of the samples must be coded so that the cooperating laboratories are blinded to identity and classification. Each sample must be provided in duplicate or triplicate, so that error and repeatability data may be generated.

(4) Cooperating laboratories will submit to the kit manufacturer all raw data regarding the assay response. Each sample tested will be reported as positive or negative and the official NPIP procedure used to classify the sample must be submitted in addition to the assay response value.

(5) The findings of the cooperating laboratories will be evaluated by the NPIP technical committee, and the technical committee will make a recommendation regarding whether to approve the test kit to the General Conference Committee. If the technical committee recommends approval, the final approval will be granted in accordance with the procedures described in §§ 147.46 and 147.47 of this subchapter.

■ 7. In subpart B, the subpart heading is revised to read as follows:

Subpart B—Special Provisions for Multiplier Egg-Type Chicken Breeding Flocks and Products

§ 145.22 [Amended]

■ 8. Section 145.22 is amended as follows:

■ a. In the introductory text, by adding the word ''multiplier'' before the words ''egg type''.

■ b. In paragraph (b), by removing the word ''primary'' and adding the word ''multiplier'' in its place.

§ 145.23 [Amended]

■ 9. Section 145.23 is amended as follows:

■ a. In paragraph (b)(2), in the introductory text, by removing the words ''or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks,''.

■ b. In paragraph (b)(2)(iii), by adding the word ''Testing'' after the word ''Authorized''.

■ c. By removing paragraph (b)(5).

■ d. By removing and reserving paragraph (c)(1)(i).

■ e. In paragraph (c)(2), by removing the words '': *Provided,* That U.S. M. Gallisepticum Clean chicks from primary breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (c)(1)(i) of this section are set''.

■ f. By removing and reserving paragraph (e)(1)(i).

■ g. In paragraph (e)(2), by removing the words '': *Provided,* That U.S. M. Synoviae Clean chicks from primary breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (e)(1)(i) or (ii) of this section are set''.

■ h. By removing and reserving paragraph (h)(1).

■ i. In paragraph (h)(2)(i), by adding the words '': *Provided:* That multiplier spent fowl must be tested within 30 days prior to movement to disposal'' after the words ''180 days''.

§ 145.24 [Amended]

■ 10. Section 145.24 is amended as follows:

■ a. In paragraph (a)(1)(i), by removing the word ''and'' and by adding the words '', § 145.73(b)(2)(i), and § 145.83(b)(2)(i)'' immediately before the period.

■ b. By adding and reserving paragraph (b).

■ 11. In subpart C, the subpart heading is revised to read as follows:

Subpart C—Special Provisions for Multiplier Meat-Type Chicken Breeding Flocks and Products

§ 145.32 [Amended]

■ 12. Section 145.32 is amended as follows:

■ a. In the introductory text, by adding the word ''multiplier'' before the words ''meat type''.

■ b. In paragraph (b), by removing the word ''primary'' and adding the word ''multiplier'' in its place.

§ 145.33 [Amended]

■ 13. Section 145.33 is amended as follows:

■ a. In paragraph (b)(2), in the introductory text, by removing the words ''or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks,''.

■ b. In paragraph (b)(2)(iii), by adding the word ''Testing'' after the word ''Authorized''.

■ c. By removing paragraph (b)(5).

■ d. By removing and reserving paragraph (c)(1)(i).

■ e. In paragraph (c)(2), by removing the words '': *Provided,* That U.S. M. Gallisepticum Clean chicks from primary breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (c)(1)(i) of this section are set''.

■ f. By removing and reserving paragraph (e)(1)(i).

■ g. In paragraph (e)(2), by removing the words '': *Provided,* That U.S. M. Synoviae Clean chicks from primary breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (e)(1)(i) or (ii) of this section are set''.

■ h. By removing and reserving paragraphs (h) and (i).

■ i. By removing and reserving paragraph (l)(1).

■ j. In paragraph (l)(2), in the introductory text, by adding the words ''and prior to the onset of egg production'' after the word ''age.''

■ k. In paragraph (l)(2)(i), by adding the words '': *Provided:* That multiplier spent fowl must be tested within 30 days prior to movement to slaughter'' after the words ''180 days.''

§ 145.34 [Amended]

■ 14. Section 145.34 is amended as follows:

■ a. In paragraph (a)(1)(i), by removing the word ''and'' and by adding the words '', § 145.73(b)(2)(i), and § 145.83(b)(2)(i)'' immediately before the period.

■ b. In paragraph (b)(1)(ii), by adding the words ''in accordance with §§ 145.33(c) and 145.83(c)'' after the word ''Clean''.

■ 15. Section 145.43 is amended as follows:

■ a. In paragraph (b)(2)(iii), by adding the word ''Testing'' after the word ''Authorized''.

■ b. By revising paragraphs (f)(1), (f)(2), (f)(7), (g)(1) introductory text, (g)(1)(i), (g)(2) introductory text, and (g)(2)(i) to read as set forth below.

§ 145.43 Terminology and classification; flocks and products.

* * * * *

(f) * * *

(1) Hatchery debris (dead germ hatching eggs, fluff, and meconium collected by sexors), swabs collected from hatch debris in hatcher trays, a sample of all the poults that died within 10 days after hatching up to 10 poults, or a combination of 2 or all 3 of the above, from each hatch or a candidate breeding flock produced by a primary breeder, are examined bacteriologically at an authorized laboratory for *Salmonella.*

(2) The poults for the candidate breeding flock are placed in a building that has been cleaned and disinfected. An Authorized Agent must collect environmental samples from the building and submit them to an authorized laboratory for a bacteriological examination for the presence of *Salmonella,* as described in § 147.12 of this subchapter.

* * * * *

(7) Hatchery debris (dead germ hatching eggs, fluff, and meconium collected by sexors), swabs collected from hatch debris in hatcher trays, a

sample of all the poults that died within 10 days after hatching up to 10 poults, or a combination of 2 or all 3 of the above, shall be cultured as a means of evaluating the effectiveness of the control procedures.

(g) * * *

(1) It is a primary breeding flock in which a minimum of 30 birds has been tested negative for antibodies to type A avian influenza virus by the agar gel immunodiffusion test specified in § 147.9 of this subchapter. Positive samples shall be further tested by an authorized laboratory using the hemagglutination inhibition test to detect antibodies to the hemagglutinin subtypes H5 and H7 when more than 4 months of age and prior to the onset of egg production. To retain this classification:

(i) A sample of at least 30 birds must be tested negative at intervals of 90 days; *Provided,* that primary spent fowl be tested within 30 days prior to movement to disposal; or

* * * * *

(2) It is a multiplier breeding flock in which a minimum of 30 birds has been tested negative for antibodies to type A avian influenza virus by the agar gel immunodiffusion test specified in § 147.9 of this subchapter. Positive samples shall be further tested by an authorized laboratory using the hemagglutination inhibition test to detect antibodies to the hemagglutinin subtypes H5 and H7 when more than 4 months of age and prior to the onset of egg production. To retain this classification:

(i) A sample of at least 30 birds must be tested negative at intervals of 180 days; *Provided,* that multiplier spent fowl be tested within 30 days prior to movement to disposal; or

* * * * *

§ 145.53 [Amended]

■ 16. Section 145.53 is amended as follows:

■ a. In paragraph (b)(2)(iii), by adding the word ''Testing'' after the word ''Authorized''.

■ b. In paragraph (e), in the paragraph heading, by adding the words ''*H5/H7*'' before the words ''*Avian Influenza*''.

■ c. In the introductory text of paragraphs (e), (e)(1), and (e)(2), by adding the words ''the H5 and H7 subtypes of'' before the words ''avian influenza'' each time they occur.

■ 17. In § 145.63, paragraph (a)(2) is revised to read as follows:

§ 145.63 Terminology and classification; flocks and products.

* * * * *

(a) * * *

(2) It is a breeding flock that meets one of the following criteria:

(i)(A) It is a multiplier or primary breeding flock of fewer than 300 birds in which a sample of 10 percent of the birds in a flock or at least 1 bird from each pen, whichever is more, has been officially tested for pullorum-typhoid within the past 12 months with no reactors; or

(B) It is a multiplier or primary breeding flock of 300 birds or more in which a sample of a minimum of 30 birds has been officially tested for pullorum-typhoid within the past 12 months with no reactors.

(ii) It is a flock that has already been designated U.S. Pullorum-Typhoid Clean and uses a subsequent bacteriological examination monitoring program of hatcher debris or eggs for ostriches, emus, rheas, or cassowaries acceptable to the Official State Agency and approved by the Service in lieu of annual blood testing.

(iii) It is a multiplier breeding flock located in a State that has been deemed to be a U.S. Pullorum-Typhoid Clean State for the past 3 years, and during which time no isolation of pullorum or typhoid has been made that can be traced to a source in that State, that uses a bacteriological examination monitoring program of hatcher debris or eggs or a serological examination monitoring program acceptable to the Official State Agency and approved by the Service in lieu of annual blood testing.

* * * * *

■ 18. A new Subpart G is added to read as follows:

Subpart G—Special Provisions for Primary Egg-Type Chicken Breeding Flocks and Products

Sec.
145.71 Definitions.
145.72 Participation.
145.73 Terminology and classification; flocks and products.

Subpart G—Special Provisions for Primary Egg-Type Chicken Breeding Flocks and Products

§ 145.71 Definitions.

Except where the context otherwise requires, for the purposes of this subpart the following terms shall be construed, respectively, to mean:

Chicks. Newly hatched chickens.

Primary egg-type chicken breeding flocks. Foundation flocks that are composed of pedigree, great-grandparent, and grandparent stock that has been developed for egg production and are maintained for the principal purpose of producing multiplier breeding chicks used to produce table egg layers.

Started chickens. Young chickens (chicks, pullets, cockerels, capons) which have been fed and watered and are less than 6 months of age.

§ 145.72 Participation.

Participating flocks of primary egg-type chickens, and the eggs and chicks produced from them, shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart G.

(a) Started chickens shall lose their identity under Plan terminology when not maintained by Plan participants under the conditions prescribed in § 145.5(a).

(b) Hatching eggs produced by primary breeding flocks shall be fumigated (see § 147.25 of this subchapter) or otherwise sanitized.

(c) Any nutritive material provided to chicks must be free of the avian pathogens that are officially represented in the Plan disease classifications listed in § 145.10.

§ 145.73 Terminology and classification; flocks and products.

Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section, may be designated by the following terms and the corresponding designs illustrated in § 145.10:

(a) [Reserved]

(b) *U.S. Pullorum-Typhoid Clean.* A flock in which freedom from pullorum and typhoid has been demonstrated to the Official State Agency under the criteria in paragraph (b)(1) or (b)(2) of this section: *Provided,* That a flock qualifying by means of a blood test shall be tested within the past 12 months, except that the retesting of a participating flock which is retained for more than 12 months shall be conducted a minimum of 4 weeks after the induction of molt. (See § 145.14 relating to the official blood test where applicable.)

(1) It has been officially blood tested with no reactors.

(2) It is a primary breeding flock that meets the following criteria:

(i) The primary breeding flock is located in a State in which pullorum disease or fowl typhoid is not known to exist nor to have existed in hatchery supply flocks during the preceding 12 months and in which it has been determined by the Service that:

(A) All hatcheries within the State are qualified as ''National Plan Hatcheries'' or have met equivalent requirements for pullorum-typhoid control under official supervision;

(B) All hatchery supply flocks within the State are qualified as U.S. Pullorum-Typhoid Clean or have met equivalent requirements for pullorum-typhoid control under official supervision: *Provided,* That if other domesticated fowl, except waterfowl, are maintained on the same premises as the participating flock, freedom from pullorum-typhoid infection shall be demonstrated by an official blood test of each of these fowl;

(C) All shipments of products other than U.S. Pullorum-Typhoid Clean, or equivalent, into the State are prohibited;

(D) All persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which *S. pullorum* or *S. gallinarum* is isolated;

(E) All reports of any disease outbreak involving a disease covered under the Plan are promptly followed by an investigation by the Official State Agency to determine the origin of the infection; *Provided,* That if the origin of the infection involves another State, or if there is exposure to poultry in another State from the infected flock, then officials administering the National Poultry Improvement Plan will conduct an investigation;

(F) All flocks found to be infected with pullorum or typhoid are quarantined until marketed or destroyed under the supervision of the Official State Agency, or until subsequently blood tested following the procedure for reacting flocks as contained in § 145.14(a)(5), and all birds fail to demonstrate pullorum or typhoid infection;

(G) All poultry, including exhibition, exotic, and game birds, but excluding waterfowl, going to public exhibition shall come from U.S. Pullorum-Typhoid Clean or equivalent flocks, or have had a negative pullorum-typhoid test within 90 days of going to public exhibition; and

(H) Discontinuation of any of the conditions or procedures described in paragraphs (b)(2)(i)(A) through (b)(2)(i)(G) of this section, or the occurrence of repeated outbreaks of pullorum or typhoid in poultry breeding flocks within or originating within the State shall be grounds for the Service to revoke its determination that such conditions and procedures have been met or complied with. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity to present its views; and

(ii) In the primary breeding flock, a sample of 300 birds from flocks of more than 300, and each bird in flocks of 300 or less, has been officially tested for pullorum-typhoid with no reactors: *Provided,* That a bacteriological examination monitoring program acceptable to the Official State Agency and approved by the Service may be used in lieu of blood testing.

(c) *U.S. M. Gallisepticum Clean.* (1) A flock maintained in compliance with the provisions of § 147.26 of this subchapter and in which freedom from *M. gallisepticum* has been demonstrated under the criteria specified in paragraph (c)(1)(i) of this section.

(i) It is a flock in which all birds or a sample of at least 300 birds has been tested for *M. gallisepticum* as provided in § 145.14(b) when more than 4 months of age: *Provided,* That to retain this classification, a minimum of 150 birds shall be tested at intervals of not more than 90 days: *And provided further,* That a sample comprised of fewer than 150 birds may be tested at any one time, if all pens are equally represented and a total of 150 birds is tested within each 90-day period.

(ii) [Reserved]

(2) A participant handling U.S. M. Gallisepticum Clean products shall handle only products of equivalent status.

(3) U.S. M. Gallisepticum Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected as described in § 147.24(a) of this subchapter.

(d) *U.S. S. Enteritidis Clean.* This classification is intended for primary egg-type breeders wishing to assure their customers that the hatching eggs and multiplier chicks produced are certified free of *Salmonella enteritidis.*

(1) A flock and the hatching eggs and chicks produced from it which have met the following requirements as determined by the Official State Agency:

(i) The flock originated from a U.S. S. Enteritidis Clean flock, or meconium from the chick boxes and a sample of chicks that died within 7 days after hatching are examined bacteriologically for salmonella at an authorized laboratory. Cultures from positive samples shall be serotyped.

(ii) All feed fed to the flock shall meet the following requirements:

(A) Pelletized feed shall contain either no animal protein or only animal protein products produced under the Animal Protein Products Industry (APPI) *Salmonella* Education/Reduction Program. The protein products must have a minimum moisture content of 14.5 percent and must have been heated throughout to a minimum temperature of 190 °F, or above, or to a minimum temperature of 165 °F for at least 20 minutes, or to a minimum temperature of 184 °F under 70 lbs. pressure during the manufacturing process.

(B) Mash feed may contain no animal protein other than an APPI animal protein product supplement manufactured in pellet form and crumbled: *Provided,* That mash feed may contain nonpelleted APPI animal protein product supplements if the finished feed is treated with a salmonella control product approved by the U.S. Food and Drug Administration.

(iii) Feed shall be stored and transported in such a manner as to prevent possible contamination;

(iv) The flock is maintained in compliance with §§ 147.21, 147.24(a), and 147.26 of this subchapter. Rodents and other pests should be effectively controlled;

(v) Environmental samples shall be collected from the flock by an Authorized Agent, as described in § 147.12 of this subchapter, when the flock is 2 to 4 weeks of age. The samples shall be examined bacteriologically for group D salmonella at an authorized laboratory. Cultures from positive samples shall be serotyped. The Authorized Agent shall also collect samples every 30 days after the first sample has been collected.

(vi) If a *Salmonella* vaccine is used that causes positive reactions with pullorum-typhoid antigen, one of the following options must be utilized.

(A) Administer the vaccine after the pullorum-typhoid testing is done as described in paragraph (d)(1)(vii) of this section.

(B) If an injectable bacterin or live vaccine that does not spread is used, keep a sample of 350 birds unvaccinated and banded for identification until the flock reaches at least 4 months of age. Following negative serological and bacteriological examinations as described in paragraph (d)(1)(vii) of this section, vaccinate the banded, non-vaccinated birds.

(vii) Blood samples from 300 non-vaccinated birds as described in paragraph (d)(1)(vi) of this section shall be tested with either pullorum antigen or by a federally licensed *Salmonella enteritidis* enzyme-linked immunosorbent assay (ELISA) test when the flock is more than 4 months of age. All birds with positive or inconclusive reactions, up to a maximum of 25 birds, shall be submitted to an authorized laboratory and examined for the presence of group D salmonella, as described in § 147.11 of this subchapter. Cultures from positive samples shall be serotyped.

(viii) Hatching eggs are collected as quickly as possible and are handled as described in § 147.22 of this subchapter and are sanitized or fumigated (see § 147.25 of this subchapter).

(ix) Hatching eggs produced by the flock are incubated in a hatchery that is in compliance with the recommendations in §§ 147.23 and 147.24(b) of this subchapter, and sanitized either by a procedure approved by the Official State Agency or fumigated (see § 147.25 of this subchapter).

(2) A flock shall not be eligible for this classification if *Salmonella enteritidis* serotype *enteritidis* (SE) is isolated from a specimen taken from a bird in the flock. Isolation of SE from an environmental or other specimen, as described in paragraph (d)(1)(v) of this section, will require bacteriological examination for SE in an authorized laboratory, as described in § 147.11(a) of this subchapter, of a random sample of 60 live birds from a flock of 5,000 birds or more, or 30 live birds from a flock with fewer than 5,000 birds. If only one specimen is found positive for SE, the participant may request bacteriological examination of a second sample, equal in size to the first sample, from the flock. If no SE is recovered from any of the specimens in the second sample, the flock will be eligible for the classification.

(3) A non-vaccinated flock shall be eligible for this classification if SE is isolated from an environmental sample collected from the flock in accordance with paragraph (d)(1)(v) of this section: *Provided,* That testing is conducted in accordance with paragraph (d)(1)(vii) of this section each 30 days and no positive samples are found.

(4) In order for a hatchery to sell products of this classification, all products handled shall meet the requirements of the classification.

(5) This classification may be revoked by the Official State Agency if the participant fails to follow recommended corrective measures. The Official State Agency shall not revoke the participant's classification until the participant has been given an opportunity for a hearing in accordance with rules of practice adopted by the Official State Agency.

(e) *U.S. M. Synoviae Clean.* (1) A flock maintained in compliance with the provisions of § 147.26 of this subchapter and in which freedom from *M. synoviae* has been demonstrated under the criteria specified in paragraph (e)(1)(i) of this section.

(i) It is a flock in which a minimum of 300 birds has been tested for *M. synoviae* as provided in § 145.14(b) when more than 4 months of age: *Provided,* That to retain this classification, a sample of at least 150 birds shall be tested at intervals of not more than 90 days: *And provided further,* That a sample comprised of fewer than 150 birds may be tested at any one time if all pens are equally represented and a total of 150 birds is tested within each 90-day period.

(ii) [Reserved]

(2) A participant handling U.S. M. Synoviae Clean products shall handle only products of equivalent status.

(3) U.S. M. Synoviae Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected as described in § 147.24(a) of this subchapter.

(f) *U.S. Avian Influenza Clean.* This program is intended to be the basis from which the breeding-hatchery industry may conduct a program for the prevention and control of avian influenza. It is intended to determine the presence of avian influenza in primary breeding chickens through routine serological surveillance of each participating breeding flock. A flock and the hatching eggs and chicks produced from it will qualify for this classification when the Official State Agency determines that they have met the following requirements:

(1) It is a primary breeding flock in which a minimum of 30 birds have been tested negative for antibodies to avian influenza when more than 4 months of age. To retain this classification:

(i) A sample of at least 30 birds must be tested negative at intervals of 90 days: *Provided,* That primary spent fowl must be tested within 30 days prior to movement to disposal; or

(ii) A sample of fewer than 30 birds may be tested, and found to be negative, at any one time if all pens are equally represented and a total of 30 birds is tested within each 90-day period.

(2) [Reserved]

■ 19. A new subpart H is added to read as follows:

Subpart H—Special Provisions for Primary Meat-Type Chicken Breeding Flocks and Products

Sec.
145.81 Definitions.
145.82 Participation.
145.83 Terminology and classification; flocks and products.

Subpart H—Special Provisions for Primary Meat-Type Chicken Breeding Flocks and Products

§ 145.81 Definitions.

Except where the context otherwise requires, for the purposes of this subpart the following terms shall be construed, respectively, to mean:

Chicks. Newly hatched chickens.

Primary meat-type chicken breeding flocks. Foundation flocks that are composed of pedigree, great-grandparent, and grandparent stock that has been developed for meat production and are maintained for the principal purpose of producing multiplier breeding chicks used to produce commercial broilers.

Started chickens. Young chickens (chicks, pullets, cockerels, capons) which have been fed and watered and are less than 6 months of age.

§ 145.82 Participation.

Participating flocks of primary meat-type chickens, and the eggs and chicks produced from them, shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart H.

(a) Started chickens shall lose their identity under Plan terminology when not maintained by Plan participants under the conditions prescribed in § 145.5(a).

(b) Hatching eggs produced by primary breeding flocks shall be fumigated (see § 147.25 of this subchapter) or otherwise sanitized.

(c) Any nutritive material provided to chicks must be free of the avian pathogens that are officially represented in the Plan disease classifications listed in § 145.10.

§ 145.83 Terminology and classification; flocks and products.

Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section, may be designated by the following terms and the corresponding designs illustrated in § 145.10:

(a) [Reserved]

(b) *U.S. Pullorum-Typhoid Clean.* A flock in which freedom from pullorum and typhoid has been demonstrated to the Official State Agency under the criteria in paragraph (b)(1) or (b)(2) of this section: *Provided,* That a flock qualifying by means of a blood test shall be tested within the past 12 months, except that the retesting of a participating flock which is retained for more than 12 months shall be conducted a minimum of 4 weeks after the induction of molt. (See § 145.14 relating to the official blood test where applicable.)

(1) It has been officially blood tested with no reactors.

(2) It is a primary breeding flock that meets the following criteria:

(i) The primary breeding flock is located in a State in which pullorum

disease or fowl typhoid is not known to exist nor to have existed in hatchery supply flocks within the State during the preceding 12 months and in which it has been determined by the Service that:

(A) All hatcheries within the State are qualified as ''National Plan Hatcheries'' or have met equivalent requirements for pullorum-typhoid control under official supervision;

(B) All hatchery supply flocks within the State are qualified as U.S. Pullorum-Typhoid Clean or have met equivalent requirements for pullorum-typhoid control under official supervision: *Provided,* That if other domesticated fowl, except waterfowl, are maintained on the same premises as the participating flock, freedom from pullorum-typhoid infection shall be demonstrated by an official blood test of each of these fowl;

(C) All shipments of products other than U.S. Pullorum-Typhoid Clean, or equivalent, into the State are prohibited;

(D) All persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which *S. pullorum* or *S. gallinarum* is isolated;

(E) All reports of any disease outbreak involving a disease covered under the Plan are promptly followed by an investigation by the Official State Agency to determine the origin of the infection; *Provided,* That if the origin of the infection involves another State, or if there is exposure to poultry in another State from the infected flock, then officials administering the National Poultry Improvement Plan will conduct an investigation;

(F) All flocks found to be infected with pullorum or typhoid are quarantined until marketed or destroyed under the supervision of the Official State Agency, or until subsequently blood tested following the procedure for reacting flocks as contained in § 145.14(a)(5) of this subchapter, and all birds fail to demonstrate pullorum or typhoid infection;

(G) All poultry, including exhibition, exotic, and game birds, but excluding waterfowl, going to public exhibition shall come from U.S. Pullorum-Typhoid Clean or equivalent flocks, or have had a negative pullorum-typhoid test within 90 days of going to public exhibition; and

(H) Discontinuation of any of the conditions or procedures described in paragraphs (b)(2)(i)(A) through (b)(2)(i)(G) of this section, or the occurrence of repeated outbreaks of pullorum or typhoid in poultry breeding flocks within or originating within the State shall be grounds for the Service to revoke its determination that such conditions and procedures have been met or complied with. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity to present its views; and

(ii) In the primary breeding flock, a sample of 300 birds from flocks of more than 300, and each bird in flocks of 300 or less, has been officially tested for pullorum-typhoid with no reactors: *Provided,* That a bacteriological examination monitoring program acceptable to the Official State Agency and approved by the Service may be used in lieu of blood testing.

(c) *U.S. M. Gallisepticum Clean.* (1) A flock maintained in compliance with the provisions of § 147.26 of this subchapter and in which freedom from *M. gallisepticum* has been demonstrated under the criteria specified in paragraph (c)(1)(i) of this section.

(i) It is a flock in which all birds or a sample of at least 300 birds has been tested for *M. gallisepticum* as provided in § 145.14(b) of this subchapter when more than 4 months of age: *Provided,* That to retain this classification, a minimum of 40 birds shall be tested at intervals of not more than 28 days, and a total of at least 150 birds shall be tested within each 90-day period.

(ii) [Reserved]

(2) A participant handling U.S. M. Gallisepticum Clean products must handle only products of equivalent status.

(3) U.S. M. Gallisepticum Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected as described in § 147.24(a) of this subchapter.

(d) *U.S. M. Synoviae Clean.* (1) A flock maintained in compliance with the provisions of § 147.26 of this subchapter and in which freedom from *M. synoviae* has been demonstrated under the criteria specified in paragraph (d)(1)(i) of this section.

(i) It is a flock in which all birds or a sample of at least 300 birds has been tested for *M. synoviae* as provided in § 145.14(b) of this subchapter when more than 4 months of age: *Provided,* That to retain this classification, a sample of at least 40 birds shall be tested at intervals of not more than 28 days, and a total of at least 150 birds shall be tested within each 90-day period.

(ii) [Reserved]

(2) A participant handling U.S. M. Synoviae Clean products shall handle only products of equivalent status.

(3) U.S. M. Synoviae Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected as described in § 147.24(a) of this subchapter.

(e) *U.S. S. Enteritidis Clean.* This classification is intended for primary meat-type breeders wishing to assure their customers that the chicks produced are certified free of *Salmonella enteritidis.*

(1) A flock and the hatching eggs and chicks produced from it shall be eligible for this classification if they meet the following requirements, as determined by the Official State Agency:

(i) The flock originated from a U.S. S. Enteritidis Clean flock, or one of the following samples has been examined bacteriologically for *S. enteritidis* at an authorized laboratory and any group *D Salmonella* samples have been serotyped:

(A) A 25-gram sample of meconium from the chicks in the flock collected and cultured as described in § 147.12(a)(5) of this subchapter; or

(B) A sample of chick papers collected and cultured as described in § 147.12(c) of this subchapter; or

(C) A sample of 10 chicks that died within 7 days after hatching.

(ii) All feed fed to the flock meets the following requirements:

(A) Pelletized feed must have a minimum moisture content of 14.5 percent and must have been heated throughout to a minimum temperature of 190 °F, or to a minimum temperature of 165 °F for at least 20 minutes, or to a minimum temperature of 184 °F under 70 lbs. pressure during the manufacturing process;

(B) Mash feed may contain animal protein if the finished feed is treated with a salmonella control product approved by the U.S. Food and Drug Administration.

(C) All feed is stored and transported in such a manner as to prevent possible contamination.

(iii) The flock is maintained in compliance with §§ 147.21, 147.24(a), and 147.26 of this subchapter.

(iv) Environmental samples are collected from the flock by or under the supervision of an Authorized Agent, as described in § 147.12 of this subchapter, when the flock reaches 4 months of age and every 30 days thereafter. The environmental samples shall be examined bacteriologically for group D salmonella at an authorized laboratory, and cultures from group D positive samples shall be serotyped.

(v) Blood samples from 300 birds from the flock are officially tested with pullorum antigen when the flock is at least 4 months of age. All birds with

positive or inconclusive reactions, up to a maximum of 25 birds, shall be submitted to an authorized laboratory and examined for the presence of group D salmonella in accordance with §§ 147.10 and 147.11 of this subchapter. Cultures from group D positive samples shall be serotyped.

(vi) Hatching eggs produced by the flock are collected as quickly as possible and are handled as described in § 147.22 of this subchapter.

(vii) Hatching eggs produced by the flock are incubated in a hatchery that is in compliance with the recommendations in §§ 147.23 and 147.24(b) of this subchapter, and the hatchery must have been sanitized either by a procedure approved by the Official State Agency or by fumigation.

(2) If *Salmonella enteritidis* serotype *enteritidis* (SE) is isolated from a specimen taken from a bird in the flock, except as provided in paragraph (e)(3) of this section, the flock shall not be eligible for this classification.

(3) If SE is isolated from an environmental sample collected from the flock in accordance with paragraph (e)(1)(iv) of this section, 25 randomly selected live birds from the flock and/or 500 cloacal swabs collected in accordance with § 147.12(a)(2) of this subchapter must be bacteriologically examined for SE as described in § 147.11 of this subchapter. If only 1 bird from the 25-bird sample is found positive for SE, the participant may request bacteriological examination of a second 25-bird sample from the flock. If no SE is recovered from any of the specimens in the second sample, the flock will be eligible for the classification and will remain eligible for this classification if the flock is tested in accordance with paragraph (e)(1)(v) of this section each 30 days and no positive samples are found.

(4) In order for a hatchery to sell products of this classification, all products handled by the hatchery must meet the requirements of this paragraph.

(5) This classification may be revoked by the Official State Agency if the participant fails to follow recommended corrective measures. The Official State Agency shall not revoke the participant's classification until the participant has been given an opportunity for a hearing in accordance with rules of practice adopted by the Official State Agency.

(6) A pedigree, experimental, or great-grandparent flock that is removed from the U.S. S. Enteritidis Clean program may be reinstated whenever the following conditions are met:

(i) The owner attests that corrective measures have been implemented, which may include one or more of the following:

(A) Test and slaughter infected birds based on blood tests of every bird in the flock, with either pullorum antigen or by a federally licensed *Salmonella enteritidis* enzyme-linked immunosorbent assay (ELISA) test when the flock is more than 4 months of age.

(B) Perform other corrective actions including, but not limited to, vaccination, medication, cleaning and disinfection of houses, rodent control, and movement of uninfected birds to premises that have been determined to be environmentally negative for *S. enteritidis* as described in § 147.12(a) of this subchapter.

(C) One hundred percent of blood samples from the birds moved to the clean premises are tested negative for *Salmonella pullorum* and group D *Salmonella.* All birds with positive or inconclusive reactions, up to a maximum of 25 birds, shall be submitted to an authorized laboratory and examined for the presence of group D *Salmonella,* as described in § 147.11 of this subchapter. Cultures from positive samples shall be serotyped.

(D) Two consecutive environmental drag swabs taken at the clean premises collected as specified in § 147.12(a) of this subchapter 4 weeks apart are negative for *S. enteritidis.*

(E) Other corrective measures at the discretion of the Official State Agency.

(ii) Following reinstatement, a flock will remain eligible for this classification if the flock is tested in accordance with paragraph (e)(1)(v) of this section every 30 days and no positive samples are found and the flock meets the requirements set forth in § 145.83(e).

(f) *U.S. Salmonella Monitored.* This program is intended to be the basis from which the breeding-hatching industry may conduct a program for the prevention and control of salmonellosis. It is intended to reduce the incidence of *Salmonella* organisms in hatching eggs and chicks through an effective and practical sanitation program at the breeder farm and in the hatchery. This will afford other segments of the poultry industry an opportunity to reduce the incidence of *Salmonella* in their products.

(1) A flock and the hatching eggs and chicks produced from it that have met the following requirements, as determined by the Official State Agency.

(i) The flock is maintained in compliance with §§ 147.21, 147.24(a), and 147.26 of this subchapter;

(ii) If feed contains animal protein, the protein products must have a minimum moisture content of 14.5 percent and must have been heated throughout to a minimum temperature of 190 °F or above, or to a minimum temperature of 165 °F for at least 20 minutes, or to a minimum temperature of 184 °F under 70 lbs. pressure during the manufacturing process;

(iii) Feed shall be stored and transported in a manner to prevent possible contamination;

(iv) Chicks shall be hatched in a hatchery meeting the requirements of §§ 147.23 and 147.24(b) of this subchapter and sanitized or fumigated (see § 147.25 of this subchapter).

(v) An Authorized Agent shall take environmental samples from the hatchery every 30 days; i.e., meconium or chick papers. An authorized laboratory for *Salmonella* shall examine the samples bacteriologically;

(vi) An Authorized Agent shall take environmental samples as described in § 147.12 of this subchapter from each flock at 4 months of age and every 30 days thereafter. An authorized laboratory for *Salmonella* shall examine the environmental samples bacteriologically;

(vii) Owners of flocks may vaccinate with a paratyphoid vaccine: *Provided,* That a sample of 350 birds, which will be banded for identification, shall remain unvaccinated until the flock reaches at least 4 months of age.

(2) The Official State Agency may use the procedures described in § 147.14 of this subchapter to monitor the effectiveness of the egg sanitation practices.

(3) In order for a hatchery to sell products of this classification, all products handled shall meet the requirements of the classification.

(4) This classification may be revoked by the Official State Agency if the participant fails to follow recommended corrective measures.

(g) *U.S. Avian Influenza Clean.* This program is intended to be the basis from which the breeding-hatchery industry may conduct a program for the prevention and control of avian influenza. It is intended to determine the presence of avian influenza in primary breeding chickens through routine serological surveillance of each participating breeding flock. A flock and the hatching eggs and chicks produced from it will qualify for this classification when the Official State Agency determines that they have met the following requirements:

(1) It is a primary breeding flock in which a minimum of 30 birds have been tested negative for antibodies to avian influenza when more than 4 months of age and prior to the onset of egg production. To retain this classification:

(i) A sample of at least 30 birds must be tested negative at intervals of 90 days; *Provided,* that primary spent fowl be tested within 30 days prior to movement to slaughter; or

(ii) A sample of fewer than 30 birds may be tested, and found to be negative, at any one time if all pens are equally represented and a total of 30 birds is tested within each 90-day period.

(2) [Reserved]

PART 147—AUXILIARY PROVISIONS ON NATIONAL POULTRY IMPROVEMENT PLAN

■ 20. The authority citation for part 147 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

§ 147.7 [Amended]

■ 21. In § 147.7, paragraph (b)(1)(vii), the citation ''§ 147.6'' is removed and the citation ''§ 147.6(a)'' is added in its place.

■ 22. Section 147.11 is amended as follows:

■ a. In paragraph (a), by revising the introductory text to read as set forth below.

■ b. By removing and reserving paragraph (b).

§ 147.11 Laboratory procedure recommended for the bacteriological examination of salmonella.

(a) *For egg- and meat-type chickens, turkeys, waterfowl, exhibition poultry, and game birds.* All reactors to the pullorum-typhoid tests, up to 25 birds, and birds from *Salmonella enteritidis* (SE) positive environments should be cultured in accordance with both the direct enrichment (paragraph (a)(1)) and selective enrichment (paragraph (a)(2)) procedures described in this section: *Provided,* That in turkeys, if there are more than four reactors to the pullorum-typhoid tests in the flock, a minimum of four reactors as provided for in § 145.14(a)(6)(ii) of this subchapter shall be submitted to the authorized laboratory for bacteriological examination. Careful aseptic technique should be used when collecting all tissue samples.

* * * * *

§ 147.12 [Amended]

■ 23. In § 147.12, paragraph (b)(3) is amended by adding the words ''using a PCR-based assay approved by the NPIP under § 145.15'' after the word ''enrichment''.

■ 24. Section 147.17 is amended as follows:

■ a. By revising the section heading, the introductory text of the section, and paragraphs (a) and (c) to read as set forth below.

■ b. In paragraph (d), by removing the number ''15''.

§ 147.17 Laboratory procedure recommended for the bacteriological examination of cull chicks and poults for salmonella.

The laboratory procedure described in this section is recommended for the bacteriological examination of cull chicks from egg-type and meat-type chicken flocks and waterfowl, exhibition poultry, and game bird flocks and poults from turkey flocks for salmonella.

(a) For cull chicks, from 25 randomly selected 1- to 5-day-old chicks that have not been placed in a brooding house, prepare 5 organ pools, 5 yolk pools, and 5 intestinal tissue pools as follows. For poults, from a sample of 10 poults that died within 10 days after hatching, prepare organ pools, yolk pools, and intestinal pools as follows:

(1) *Organ pool:* From each of five chicks or two poults, composite and mince 1- to 2-gram samples of heart, lung, liver, and spleen tissues. Include the proximal wall of the bursa of Fabricius for chicks only.

(2) *Yolk pool:* From each of five chicks or two poults, composite and mince 1- to 2-gram samples of the unabsorbed yolk sac or, if the yolk sac is essentially absent, the entire yolk stalk remnant.

(3) *Intestinal pool:* From each of five chicks or two poults, composite and mince approximately 0.5 cm^2 sections of the crop wall and 5-mm-long sections of the duodenum, cecum, and ileocecal junction.

* * * * *

(c) For cull chicks, repeat the steps in paragraphs (a) and (b) of this section for each 5-chick group until all 25 chicks have been examined, producing a total of 15 pools (5 organ, 5 yolk, and 5 intestinal). For poults, repeat the steps in paragraphs (a) and (b) of this section for each two-poult group until all the poults in the sample have been examined.

* * * * *

■ 25. A new subpart D is added to read as set forth below.

Subpart D—Molecular Examination Procedures

§ 147.30 Laboratory procedure recommended for the polymerase chain reaction (PCR) test for Mycoplasma gallisepticum and M. synoviae.

(a) *DNA isolation.* Isolate DNA from 1 mL of eluate from tracheal swabs in PBS or 1 mL of broth culture by a non-phenolic procedure. Centrifuge samples at 14,000 x g for 5 to 10 minutes. Decant supernatant and wash the pellet with 1 mL of PBS. Centrifuge as above and re-suspend the pellet in 25–50 µl of 0.1 percent DEP (Diethyl Pyrocarbonate; Sigma) water. Boil at 120 °C for 10 minutes followed by 10 minutes incubation at 4 °C. Centrifuge as above and transfer the supernatant DNA to a nuclease-free tube. Estimate the DNA concentration and purity by spectrophotometric reading at 260 nm and 280 nm.

(b) *Primer selection.* (1) *M. gallisepticum.* The primer for *M. gallisepticum* should consist of the following sequences:

MG-F	5' GAG CTA ATC TGT AAA GTT GGT C
MG-R	5' GCT TCC TTG CGG TTA GCA AC

(2) *M. synoviae.* The primer for *M. synoviae* should consist of the following sequences:

MS–F	5'	GAG	AAG	CAA	AAT	AGT	GAT	ATC	A
MS–R	5'	CAG	TCG	TCT	CCG	AAG	TTA	ACA	A

(c) *Polymerase chain reaction.* (1) Treat each sample (100 to 2000 ng/5 µl) with one of the following 45 µl PCR cocktails:

(i) 5 µl 10x PCR buffer, 1 µl dNTP (10 mM), 1 µl of Reverse primer (50 µM), 1 µl of Forward primer (50 µM), 4 µl $MgCl_2$ (25 mM), 1 µl taq-polymerase (5 U), 32 µl DEP water.

(ii) 18 µl water, 25 µl PCR mix (Promega), 1 µl Reverse primer (50 µM), 1 µl Forward primer (50 µM).

(2) Perform DNA amplification in a Perkin-Elmer 9600 thermocycler or in a Hybaid PCR Express thermocycler.[24] The optimized PCR program is as follows:

Temperature (°C)	Duration	Cycles
94	30 seconds	30–40.
55	30 seconds	30–40.
72	1 minute	30–40.
72	5 minutes	1 (final extension).

(d) *Electrophoresis.* Mix PCR products (5 to 10 µl) with 2 µl loading buffer (Sigma) and electrophorese on a 2 percent agarose gel containing 0.5 µg/mL ethidium bromide in TAE buffer (40 mM tris; 2 mM EDTA; pH 8.0 with glacial acetic acid) for 30 minutes at 80 V. *M. gallisepticum* (185 bp) and *M. synoviae* (214 bp) amplicons can be visualized under an ultraviolet transilluminator along with the PCR marker (50 to 2000 bp; Sigma).

Done in Washington, DC, this 28th day of December 2006.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E6–22635 Filed 1–11–07; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 110

RIN 3150–AI02

Export and Import of Nuclear Material; Exports to Libya Restricted

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its export/import regulations by moving Libya from the list of embargoed destinations to the list of restricted destinations. This amendment is necessary to conform NRC's regulations with U.S. Government foreign policy.

DATES: The final rule is effective January 12, 2007.

ADDRESSES: Publicly available documents related to this rulemaking may be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), Public File Area O1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee. Selected documents, including comments can be viewed and downloaded electronically via the NRC's rulemaking Web site at *http://ruleforum.llnl.gov.*

Publicly available documents created or received at the NRC are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/NRC/reading-rm/adams.html.* From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737 or by e-mail to *PDR@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Jennifer Schwartzman, International Relations Specialist, Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone 301–415–2317, e-mail *jks1@nrc.gov,* or Brooke G. Smith, International Policy Analyst, Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone 301–415–2347, e-mail *bgs@nrc.gov.*

SUPPLEMENTARY INFORMATION: The purpose of this final rule is to revise the NRC's export/import regulations in 10 CFR Part 110, ''Export and Import of Nuclear Equipment and Material,'' with regard to Libya in light of the June 30, 2006 rescission by the Secretary of State of Libya's designation as a State Sponsor of Terrorism. Libya was designated as a State Sponsor of Terrorism in 1979. The Executive Branch has recommended that, in light of the rescission of the designation, 10 CFR Part 110 should be amended by moving Libya from the embargoed destinations list to the restricted destinations list.

This rule moves Libya from the embargoed destinations list for exports in 10 CFR 110.28 to the restricted destinations list in 10 CFR 110.29. This means that exports to Libya of small quantities of certain nuclear materials and byproduct materials may qualify for the NRC general license specified in §§ 110.21 through 110.24.

The NRC staff has determined that moving Libya from the embargoed list to the restricted list is consistent with current U.S. law and policy, and will pose no unreasonable risk to the public health and safety or to the common defense and security of the United States.

Because this rule involves a foreign affairs function of the United States, the notice and comment provisions of the Administrative Procedure Act do not apply (5 U.S.C. 553(a)(1)). This rule will become effective immediately upon publication.

Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) requires that Federal Agencies use technical standards that are developed or adopted by voluntary

[24] Trade names are used in these procedures solely for the purpose of providing specific information. Mention of a trade name does not constitute a guarantee or warranty of the product by the U.S. Department of Agriculture or an endorsement over other products not mentioned.

consensus standards bodies unless using such a standard is inconsistent with applicable law or otherwise impractical. This final rule does not constitute the establishment of a standard for which the use of a voluntary consensus standard would be applicable.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for the rule.

Paperwork Reduction Act Statement

This final rule does not contain new or amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget (OMB), approval number 3150–0036.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

Regulatory Analysis

The NRC currently controls exports to Libya as an embargoed destination in section 110.28. There is no alternative to amending the regulations for the export and import of nuclear equipment and materials. This final rule would not result in any increase or cost to the public.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, (5 U.S.C. 605(b)), the Commission certifies that this final rule will not have a significant economic impact on a substantial number of small entities. This rule affects only companies exporting nuclear equipment and materials to Libya which do not fall within the scope of the definition of ''small entities'' set forth in the Regulatory Flexibility Act (5 U.S.C. 601(3)), or the Size Standards established by the NRC (10 CFR 2.810).

Backfit Analysis

The NRC has determined that a backfit analysis is not required for this rule because these amendments do not include any provisions that would impose backfits as defined in 10 CFR Chapter I.

Congressional Review Act

Under the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects in 10 CFR Part 110

Administrative practice and procedure, Classified information, Criminal penalties, Export, Import, Intergovernmental relations, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Scientific equipment.

■ For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR part 110.

PART 110—EXPORT AND IMPORT OF NUCLEAR EQUIPMENT AND MATERIAL

■ 1. The authority citation for part 110 continues to read as follows:

Authority: Secs. 51, 53, 54, 57, 63, 64, 65, 81, 82, 103, 104, 109, 111, 126, 127, 128, 129, 161, 181, 182, 187, 189, 68 Stat. 929, 930, 931, 932, 933, 936, 937, 948, 953, 954, 955, 956, as amended (42 U.S.C. 2071, 2073, 2074, 2077, 2092–2095, 2111, 2112, 2133, 2134, 2139, 2139a, 2141, 2154–2158, 2201, 2231–2233, 2237, 2239); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841; sec. 5, Pub. L. 101–575, 104 Stat. 2835 (42 U.S.C. 2243); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Sections 110.1(b)(2) and 110.1(b)(3) also issued under Pub. L. 96–92, 93 Stat. 710 (22 U.S.C. 2403). Section 110.11 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152) and secs. 54c and 57d, 88 Stat. 473, 475 (42 U.S.C. 2074). Section 110.27 also issued under sec. 309(a), Pub. L. 99–440. Section 110.50(b)(3) also issued under sec. 123, 92 Stat. 142 (42 U.S.C. 2153). Section 110.51 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 110.52 also issued under sec. 186, 68 Stat. 955 (42 U.S.C. 2236). Sections 110.80–110.113 also issued under 5 U.S.C. 552, 554. Sections 110.30–110.135 also issued under 5 U.S.C. 553. Sections 110.2 and 110.42(a)(9) also issued under sec. 903, Pub. L. 102–496 (42 U.S.C. 2151 *et seq.*).

§ 110.28 [Amended]

■ 2. Section 110.28 is amended by removing ''Libya'' from the list of embargoed destinations.

§ 110.29 [Amended]

■ 3. Section 110.29 is amended by adding ''Libya'' to the list of restricted destinations in alphabetical order.

Dated at Rockville, Maryland, this 29th day of December, 2006.

For the Nuclear Regulatory Commission.

Jacqueline E. Silber,

Acting Executive Director for Operations.

[FR Doc. E7–320 Filed 1–11–07; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–26811; Directorate Identifier 2006–NM–262–AD; Amendment 39–14887; AD 2007–01–15]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747SR, and 747SP Series Airplanes Equipped with General Electric CF6–45 or –50 Series Engines, or Equipped with Pratt & Whitney JT9D–3 or –7 (Excluding –70) Series Engines

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule; request for comments.

SUMMARY: The FAA is superseding an existing airworthiness directive (AD) that applies to certain Boeing Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747SR, and 747SP series airplanes. The existing AD currently requires repetitive inspections to detect cracks and fractures of the strut front spar chord assembly at each strut location, and repair if necessary. This new AD expands the inspection area by requiring repetitive inspections for any cracks or fracture of the strut front spar chord assembly in an area forward of the existing inspection area at each strut location, and repair if necessary. This AD results from a strut front spar chord assembly that was found fractured, forward of the inspection area required by the existing AD. We are issuing this AD to detect and correct cracks and fracture of the nacelle strut front spar chord assembly. Fracture of the front spar chord assembly could lead to loss of the strut upper link load path and consequent fracture of the diagonal brace, which could result in in-flight separation of the strut and engine from the airplane.

DATES: This AD becomes effective January 29, 2007.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of January 29, 2007.

On December 27, 2004 (69 FR 71349, December 9, 2004), the Director of the Federal Register approved the incorporation by reference of Boeing Alert Service Bulletin 747–54A2224, dated September 30, 2004.

We must receive any comments on this AD by March 13, 2007.

ADDRESSES: Use one of the following addresses to submit comments on this AD.

- *DOT Docket Web site:* Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590.
- *Fax:* (202) 493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207, for service information identified in this AD.

You may examine the contents of the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Room PL–401, Washington, DC. This docket number is FAA–2007–26811; the directorate identifier for this docket is 2006–NM–262–AD.

FOR FURTHER INFORMATION CONTACT: Ivan Li, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6437; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Discussion

On November 30, 2004, we issued AD 2004–25–05, amendment 39–13893 (69 FR 71349, December 9, 2004). That AD applies to certain Boeing Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747SR, and 747SP series airplanes. That AD requires repetitive inspections to detect cracks and fractures of the strut front spar chord assembly at each strut location, and repair if necessary. That AD resulted from a report of a fractured front spar chord assembly for strut No. 3, which resulted in the loss of the strut upper link load path. The actions specified in that AD are intended to prevent loss of the strut upper link load path and consequent fracture of the diagonal brace, which could result in in-flight separation of the strut and engine from the airplane.

Actions Since AD Was Issued

Since we issued AD 2004–25–05, we have received a report that the front spar chord assembly for strut No. 3 was found fractured on a Boeing Model 747–200 series airplane equipped with General Electric (GE) CF6–50E series engines. The fracture was located forward of the inspection area required by AD 2004–25–05. The airplane had accumulated about 79,800 total flight hours and 15,100 total flight cycles. (Since strut modification, the airplane had accumulated about 9,800 flight cycles and 48,200 flight hours.) We have determined that the inspection area required by AD 2004–25–05 must be expanded to adequately detect and correct cracks and fracture of the nacelle strut front spar chord assembly. Fracture of the front spar chord assembly could lead to loss of the strut upper link load path and consequent fracture of the diagonal brace, which could result in in-flight separation of the strut and engine from the airplane.

Relevant Service Information

We have reviewed Boeing Alert Service Bulletin 747–54A2224, Revision 1, dated November 16, 2006. The Accomplishment Instructions of the service bulletin are divided into two parts: Part 1—Aft Side Inspection and Part 2—Forward Side Inspection. Part 1 describes procedures for accomplishing detailed and high frequency eddy current (HFEC) inspections for any cracks or fracture of the front spar chord assembly for strut Nos. 1, 2, 3, and 4. For struts carrying Pratt & Whitney JT9D–3 or –7 (excluding –70) series engines and inboard struts carrying GE CF6–45 or –50 series engines, the inspection area is aft of the rear engine mount bulkhead. For outboard struts carrying GE CF6–45 or –50 series engines, the inspection area is aft of the strut station 270 bulkhead. (Part 1 contains the same procedures as those described in the original issue of the service bulletin, dated September 30, 2006, which we referred to as the appropriate source of service information for AD 2004–25–05.) Part 2 describes procedures for accomplishing detailed and HFEC inspections for any cracks or fracture of the front spar chord assembly for strut Nos. 1, 2, 3, and 4, forward of the rear engine mount bulkhead or strut station 270 bulkhead, as applicable. The Part 2 inspections include inspecting in areas adjacent to the frame, around certain fasteners, and on the front spar chord radius. If any crack or fracture is found, Part 1 and Part 2 specify to contact Boeing for additional instructions and repair.

FAA's Determination and Requirements of This AD

The unsafe condition described previously is likely to exist or develop on other airplanes of the same type design. For this reason, we are issuing this AD to supersede AD 2004–25–05. This new AD retains the requirements of the existing AD. This AD also requires repetitive inspections for any cracks or fracture of the strut front spar chord assembly forward of the bulkhead at each strut location, and repair if necessary, except as discussed under ''Difference Between the AD and Service Bulletin.''

Difference Between the AD and Service Bulletin

The service bulletin specifies to contact the manufacturer for instructions on how to repair certain conditions, but this AD requires repairing those conditions in one of the following ways:

- Using a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization whom we have authorized to make those findings.

Change to Existing AD

This AD retains all requirements of AD 2004–25–05. Since AD 2004–25–05 was issued, the AD format has been revised, and certain paragraphs have been rearranged. As a result, the corresponding paragraph identifiers have changed in this AD, as listed in the following table:

REVISED PARAGRAPH IDENTIFIERS

Requirement in AD 2004–25–05	Corresponding requirement in this AD
Paragraph (b)	Paragraph (c).
Paragraph (c)	Paragraph (d).
Paragraph (d)	Paragraph (e).
Paragraph (e)	Paragraph (f).
Paragraph (f)	Paragraph (g).
Paragraph (g)	Paragraph (h).
Paragraph (h)	Paragraph (i).

Explanation of Change Made to This AD

Boeing Commercial Airplanes has received a Delegation Option Authorization (DOA). We have revised paragraph (i) of this AD to delegate the authority to approve an alternative method of compliance for any repair required by this AD to an Authorized Representative for the Boeing Commercial Airplanes DOA, rather than a Designated Engineering Representative (DER).

Clarification of Alternative Method of Compliance (AMOC) Paragraph

We have revised this action to clarify the appropriate procedure for notifying the principal inspector before using any approved AMOC on any airplane to which the AMOC applies.

Interim Action

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

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD; therefore, providing notice and opportunity for public comment before the AD is issued is impracticable, and good cause exists to make this AD effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements that affect flight safety and was not preceded by notice and an opportunity for public comment; however, we invite you to submit any relevant written data, views, or arguments regarding this AD. Send your comments to an address listed in the **ADDRESSES** section. Include ''Docket No. FAA–2007–26811; Directorate Identifier 2006–NM–262–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the AD that might suggest a need to modify it.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *http://dms.dot.gov*.

Examining the Docket

You may examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the Docket Management System receives them.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD 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.

For the reasons discussed above, I certify that the regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA 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. The Federal Aviation Administration (FAA) amends § 39.13 by removing amendment 39–13893 (69 FR 71349, December 9, 2004) and adding the following new airworthiness directive (AD):

2007–01–15 BOEING: Docket No. FAA–2007–26811; Directorate Identifier 2006-NM–262–AD; Amendment 39–14887.

Effective Date

(a) This AD becomes effective January 29, 2007.

Affected ADs

(b) This AD supersedes AD 2004–25–05.

Applicability

(c) This AD applies to Boeing Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747SR, and 747SP series airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin 747–54A2224, Revision 1, dated November 16, 2006.

Unsafe Condition

(d) This AD results from a strut front spar chord assembly that was found fractured, forward of the inspection area required by AD 2004–25–05. We are issuing this AD to detect and correct cracks and fracture of the nacelle strut front spar chord assembly. Fracture of the front spar chord assembly could lead to loss of the strut upper link load path and consequent fracture of the diagonal brace, which could result in in-flight separation of the strut and engine from the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Restatement of Requirements of AD 2004–25–05

Aft Side Detailed and High Frequency Eddy Current (HFEC) Inspections With New Service Information

(f) Within 90 days after December 27, 2004 (the effective date of AD 2004–25–05), perform detailed and HFEC inspections to detect any cracks or fractures of the front spar chord assembly for strut numbers 1 through 4 inclusive, in accordance with Boeing Alert Service Bulletin 747–54A2224, dated September 30, 2004; or in accordance with Part 1—Aft Side Inspection of the Accomplishment Instructions of Boeing Alert Service Bulletin 747–54A2224, Revision 1, dated November 16, 2006. As of the effective date of this AD, only Part 1—Aft Side Inspection of the Accomplishment Instructions of Revision 1 of the service bulletin may be used.

(g) Accomplishment of the detailed and HFEC inspections in accordance with Boeing 747 Fleet Team Digest 747–FTD–54–04002, dated April 15, 2004, May 4, 2004, June 1, 2004, July 12, 2004, or July 28, 2004; or Boeing Message 1–C6ELC (Service Request ID No.: 218724992), dated April 14, 2004; before December 27, 2004, is considered acceptable for compliance with the requirements of paragraph (f) of this AD.

Repetitive Inspections

(h) For airplanes on which no crack or fracture is detected during the inspections required by paragraph (f) of this AD: At the applicable times specified in Table 1—Repetitive Intervals of this AD, repeat the detailed and HFEC inspections required by paragraph (f) of this AD.

TABLE 1.—REPETITIVE INTERVALS

For airplanes identified in Boeing Alert Service Bulletin 747–54A2224, dated September 30, 2004; or Revision 1, dated November 16, 2006; as—	Repeat the inspections at intervals not to exceed—
Group 1	1,000 flight cycles or 18 months, whichever occurs first.
Group 2 and Group 3	1,200 flight cycles or 18 months, whichever occurs first.
Group 4 and Group 6	1,500 flight cycles or 18 months, whichever occurs first.
Group 5	2,000 flight cycles or 18 months, whichever occurs first.

Corrective Action

(i) If any crack or fracture is found during any inspection required by paragraphs (f) and (h) of this AD, and the bulletin specifies contacting Boeing for appropriate action: Before further flight, repair the crack or fracture according to a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or using a method approved in accordance with the procedures specified in paragraph (m) of this AD. For a repair method to be approved, the approval must specifically reference this AD.

New Requirements of This Ad

Forward Side Detailed and HFEC Inspections

(j) Within 90 days after the effective date of this AD, do detailed and HFEC inspections for any cracks or fracture of the front spar chord assembly for strut numbers 1, 2, 3, and 4, in accordance with Part 2—Forward Side Inspection of the Accomplishment Instructions of Boeing Alert Service Bulletin 747–54A2224, Revision 1, dated November 16, 2006. If no crack or fracture is found, repeat the inspections thereafter at the applicable interval specified in Table 1 of this AD.

Corrective Action for Forward Side Inspection

(k) If any crack or fracture is found during any inspection required by paragraph (j) of this AD, and Boeing Alert Service Bulletin 747–54A2224, Revision 1, dated November 16, 2006, specifies to contact Boeing for appropriate action: Before further flight, repair the crack or fracture using a method approved in accordance with the procedures specified in paragraph (m) of this AD.

Credit for Inspections Done According to Boeing 747 Fleet Team Digest

(l) Detailed and HFEC inspections done before the effective date of this AD in accordance with Boeing 747 Fleet Team Digest 747–FTD–54–06002, dated June 29, 2006; or October 16, 2006; are acceptable for compliance with the initial inspection required by paragraph (j) of this AD.

Alternative Methods of Compliance (AMOCs)

(m)(1) The Manager, Seattle ACO, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

Material Incorporated by Reference

(n) You must use Boeing Alert Service Bulletin 747–54A2224, dated September 30, 2004; and Boeing Alert Service Bulletin 747–54A2224, Revision 1, dated November 16, 2006; as applicable; to perform the actions that are required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of Boeing Alert Service Bulletin 747–54A2224, Revision 1, dated November 16, 2006, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) On December 27, 2004 (69 FR 71349, December 9, 2004), the Director of the Federal Register approved the incorporation by reference of Boeing Alert Service Bulletin 747–54A2224, dated September 30, 2004.

(3) Contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207, for a copy of this service information. You may review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Room PL–401, Nassif Building, Washington, DC; on the Internet at *http://dms.dot.gov*; or at the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

Issued in Renton, Washington, on December 26, 2006.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–220 Filed 1–11–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–22559; Directorate Identifier 2005–NM–076–AD; Amendment 39–14879; AD 2007–01–07]

RIN 2120–AA64

Airworthiness Directives; Bombardier Model CL–600–2B19 (Regional Jet Series 100 & 440) Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is superseding an existing airworthiness directive (AD), that applies to certain Bombardier Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes. That AD currently requires repetitive inspections for cracks, sealant damage, and corrosion of the main fittings of the

main landing gear (MLG), and corrective actions if necessary. This new AD reduces the compliance times for inspecting certain low-utilization airplanes, and provides a terminating action for the repetitive inspections. This AD results from a report of a cracked main fitting of the MLG. We are issuing this AD to detect and correct fatigue cracking of the main fitting of the MLG and consequent failure of the main fitting, which could result in the collapse of the MLG.

DATES: This AD becomes effective February 16, 2007.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the AD as of February 16, 2007.

On October 21, 2004 (69 FR 59790, October 6, 2004), the Director of the Federal Register approved the incorporation by reference of Bombardier Alert Service Bulletin A601R–32–099, including Appendices A, B, and D, and excluding Appendix C, dated September 15, 2004.

ADDRESSES: You may examine the AD docket on the Internet at *http://dms.dot.gov* or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC.

Contact Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada, for service information identified in this AD.

FOR FURTHER INFORMATION CONTACT: Richard Beckwith, Aerospace Engineer, Airframe and Propulsion Branch, ANE–171, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, suite 410, Westbury, New York 11590; telephone (516) 228–7302; fax (516) 794–5531.

SUPPLEMENTARY INFORMATION:

Examining the Docket

You may examine the airworthiness directive (AD) docket on the Internet at *http://dms.dot.gov* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the street address stated in the **ADDRESSES** section.

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that supersedes AD 2004–20–09, amendment 39–13814 (69 FR 59790, October 6, 2004). The existing AD applies to certain Bombardier Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes. That NPRM was published in the **Federal Register** on July 12, 2006 (71 FR 39237). That NPRM proposed to continue to require repetitive inspections for cracks, sealant damage, and corrosion of the main fittings of the main landing gear (MLG), and corrective actions if necessary. That NPRM also proposed to reduce the compliance times for inspecting certain low-utilization airplanes, and to provide a terminating action for the repetitive inspections.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comments that have been received on the NPRM.

Request To Change Incorporation of Certain Information

The Modification and Replacement Parts Association (MARPA) states that, typically, airworthiness directives are based on service information originating with the type certificate holder or its suppliers. MARPA adds that manufacturer service documents are privately authored instruments generally having copyright protection against duplication and distribution. MARPA notes that when a service document is incorporated by reference into a public document, such as an airworthiness directive, it loses its private, protected status and becomes a public document. MARPA adds that if a service document is used as a mandatory element of compliance, it should not simply be referenced, but should be incorporated into the regulatory document; by definition, public laws must be public, which means they cannot rely upon private writings. MARPA is concerned that the failure to incorporate essential service information could result in a court decision invalidating the AD.

MARPA adds that incorporated by reference service documents should be made available to the public by publication in the Docket Management System (DMS), keyed to the action that incorporates them. MARPA notes that the stated purpose of the incorporation by reference method is brevity, to keep from expanding the **Federal Register** needlessly by publishing documents already in the hands of the affected individuals; traditionally, ''affected individuals'' means aircraft owners and operators, who are generally provided service information by the manufacturer. MARPA adds that a new class of affected individuals has emerged, since the majority of aircraft maintenance is now performed by specialty shops instead of aircraft owners and operators. MARPA notes that this new class includes maintenance and repair organizations, component servicing and repair shops, parts purveyors and distributors, and organizations manufacturing or servicing alternatively certified parts under section 21.303 (''Parts Manufacturer Approval'') of the Federal Aviation Regulations (14 CFR part 21). MARPA adds that the concept of brevity is now nearly archaic as documents exist more frequently in electronic format than on paper. Therefore, MARPA asks that the service documents deemed essential to the accomplishment of the NPRM be incorporated by reference into the regulatory instrument, and published in the DMS.

We understand MARPA's comment concerning incorporation by reference. The Office of the Federal Register (OFR) requires that documents that are necessary to accomplish the requirements of the AD be incorporated by reference during the final rule phase of rulemaking. This final rule incorporates by reference the documents necessary for the accomplishment of the requirements mandated by this AD. Further, we point out that while documents that are incorporated by reference do become public information, they do not lose their copyright protection. For that reason, we advise the public to contact the manufacturer to obtain copies of the referenced service information.

Additionally, we do not publish service documents in DMS. We are currently reviewing our practice of publishing proprietary service information. Once we have thoroughly examined all aspects of this issue, and have made a final determination, we will consider whether our current practice needs to be revised. However, we consider that to delay this AD action for that reason would be inappropriate, since we have determined that an unsafe condition exists and that the requirements in this AD must be accomplished to ensure continued safety. Therefore, we have not changed the AD in this regard.

Request To Reference Parts Manufacturer Approval (PMA) Parts

MARPA also states that type certificate holders in their service documents typically ignore the possible existence of PMA parts. MARPA states that this is particularly true with foreign manufacturers where the concept may not exist or be implemented in the

country of origin. MARPA points out that the service document upon which an airworthiness directive is based frequently will require removing a certain part-numbered part and installing a different part-numbered part as a corrective action. According to MARPA, this runs afoul of section 21.303, which permits the development, certification, and installation of alternatively certified parts.

MARPA further states that installing a certain part-numbered part to the exclusion of all other parts is not a favored general practice. MARPA states that such an action has the dual effect of preventing, in some cases, the installation of a perfectly good part; while at the same time prohibiting the development of new parts permitted under section 21.303. According to MARPA, such a prohibition runs the risk of taking the AD out of the realm of safety and into the world of economics, since prohibiting the development, sale, and use of a perfectly airworthy part has nothing to do with safety. MARPA states that courts could easily construe such actions as being outside the statutory basis of the AD (safety) and, as such, unenforceable. MARPA adds that courts are reluctant to find portions of a rule unenforceable since they lack the knowledge and authority to re-write requirements, and are thus generally inclined to simply void the entire rule.

In response to the commenter's statement regarding running afoul of section 21.303, under which the FAA issues PMAs, this statement appears to reflect a misunderstanding of the relationship between ADs and the certification procedural regulations of 14 CFR part 21. Those regulations, including section 21.303, are intended to ensure that aeronautical products comply with the applicable airworthiness standards. But ADs are issued when, notwithstanding those procedures, we become aware of unsafe conditions in these products or parts. Therefore, an AD takes precedence over design approvals when we identify an unsafe condition, and mandating installation of a certain part number in an AD is not at variance with section 21.303.

The AD provides a means of compliance for operators to ensure that the identified unsafe condition is addressed appropriately. For an unsafe condition attributable to a part, the AD normally identifies the replacement parts necessary to obtain that compliance. As stated in section 39.7 of the Federal Aviation Regulations (14 CFR 39.7), ''Anyone who operates a product that does not meet the requirements of an applicable airworthiness directive is in violation of this section.'' Unless an operator obtains approval for an alternative method of compliance (AMOC), replacing a part with one not specified by the AD would make the operator subject to an enforcement action and result in a civil penalty. No change to the AD is necessary in this regard.

Request To Stop Using AMOC

MARPA also believes that the practice of requiring an AMOC to install a PMA part should be stopped. MARPA states that this is somehow tantamount to stating, illogically, that all PMA parts are inherently defective and require an additional layer of approval when the original equipment manufacturer (OEM) part is determined to be defective. MARPA suspects that the FAA personnel who labored diligently to certify the PMA part might disagree with such a narrow, OEM-slanted view. MARPA states that if the PMA part is defective, then it must be deemed so in the AD, and not simply implied by a catch-all AMOC requirement. MARPA states that this is why it has repeatedly requested that we adopt language to trap such defective parts, and suggests that the FAA's Transport Airplane Directorate adopt the language used by the Small Airplane Directorate to accomplish this.

We infer that MARPA would like the AD to permit installation of any equivalent PMA parts so that it is not necessary for an operator to request approval of an AMOC in order to install an ''equivalent'' PMA part. Whether an alternative part is ''equivalent'' in adequately resolving the unsafe condition can only be determined on a case-by-case basis based on a complete understanding of the unsafe condition. The Transport Airplane Directorate's policy is that, in order for operators to replace a part with one that is not specified in the AD, they must request an AMOC. This is necessary so that we can make a specific determination that an alternative part is or is not susceptible to the same unsafe condition. No change to the AD is necessary in this regard.

Request for Compliance With FAA Order 8040.2/Agreement on Parts Replacement

MARPA points out that this AD, as written, does not comply with proposed Order 8040.2 (AD Process for Mandatory Continuing Airworthiness Information (MCAI)), which states in the PMA section: ''MCAI that require replacement or installation of certain parts could have replacement parts approved under 14 CFR § 21.303 based on a finding of identicality. We have determined that any parts approved under this regulation and installed should be subject to the actions of our AD and included in the applicability of our AD.'' MARPA points out that the Small Airplane Directorate has developed a blanket statement that resolves this issue. The statement includes words similar to those in the proposed Order 8040.2.

MARPA also points out that the Engine and Rotocraft Directorates avoid the issue by specifying ''airworthy parts'' be installed, leaving the determination of exactly which parts to the discretion of the installer.

MARPA further states that because the NPRM differs markedly in treatment of this issue from that of the other directorates, the mandates contained in Section 1, paragraph (b)(10) of Executive Order 12866 are not being met. This paragraph requires that all agencies act uniformly on a given issue. MARPA therefore requests that we take steps to bring the universe of PMA parts under the appropriate scope of this AD both with respect to possible defective PMA parts and the use of possible present or future approved parts.

The NPRM did not address PMA parts, as provided in draft FAA Order 8040.2, because the Order was only a draft that was out for comment at the time. After issuance of the NPRM, the Order was revised and issued as FAA Order 8040.5 with an effective date of September 29, 2006. FAA Order 8040.5 does not address PMA parts in ADs. We acknowledge the need to ensure that unsafe PMA parts are identified and addressed in MCAI-related ADs. We are currently examining all aspects of this issue, including input from industry. Once we have made a final determination, we will consider how our policy regarding PMA parts in ADs needs to be revised. We consider that to delay this AD action would be inappropriate, since we have determined that an unsafe condition exists and that replacement of certain parts must be accomplished to ensure continued safety. Therefore, no change has been made to the final rule in this regard.

Clarification of Paragraphs (i) and (k) of the Final Rule

We have changed paragraphs (i) and (k) of the final rule to specify more clearly if operators choose to do the terminating action after finding a crack indication, the terminating action must be done before further flight.

Conclusion

We have carefully reviewed the available data, including the comments received, and determined that air safety and the public interest require adopting the AD with the changes described previously. We have determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Costs of Compliance

The following table provides the estimated costs for U.S. operators to comply with this AD. There are approximately 201 U.S.-registered airplanes. The average labor rate is $80 per hour.

ESTIMATED COSTS

Action	Work hours	Parts	Cost per airplane	Fleet cost
Detailed inspection for cracks of the main fitting (required by AD 2004–20–09).	1	N/A	$80, per inspection cycle	$16,080 per inspection cycle.
Detailed inspection for sealant damage of the bushing (required by AD 2004–20–09).	1	N/A	$80, per inspection cycle	$16,080 per inspection cycle.
Ultrasonic inspection for cracks of the main fittings (required by AD 2004–20–09).	1	N/A	$80, per inspection cycle	$16,080, per inspection cycle.
Replacement (new action)	56	$105,732	$110,212	$22,152,612.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD 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.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866;

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The Federal Aviation Administration (FAA) amends § 39.13 by removing amendment 39–13814 (69 FR 59790, October 6, 2004) and by adding the following new airworthiness directive (AD):

2007–01–07 BOMBARDIER, INC. (Formerly Canadair): Amendment 39–14879. Docket No. FAA–2005–22559; Directorate Identifier 2005–NM–076–AD.

Effective Date

(a) This AD becomes effective February 16, 2007.

Affected ADs

(b) This AD supersedes AD 2004–20–09.

Applicability

(c) This AD applies to Bombardier Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes, certificated in any category; serial numbers 7003 through 7067 inclusive, and 7069 through 8999 inclusive; equipped with main landing gear (MLG) main fittings, having part number (P/N) 601R85001–3 or –4 (Messier-Dowty P/N 17064–101, –102, –103, or –104).

Unsafe Condition

(d) This AD results from a report of a cracked main fitting of the MLG. We are issuing this AD to detect and correct fatigue cracking of the main fitting of the MLG and consequent failure of the main fitting, which could result in the collapse of the MLG.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Service Bulletin

(f) Unless otherwise specified in this AD, the term ''service bulletin,'' as used in this AD, means the Accomplishment Instructions of the applicable service bulletin identified in paragraph (f)(1) or (f)(2) of this AD.

(1) For the actions specified in paragraphs (g), (h), (i), (j), and (k) of this AD: Bombardier Alert Service Bulletin A601R–32–099, including Appendices A, B, and D, and excluding Appendix C, dated September 15, 2004; or Bombardier Alert Service Bulletin A601R–32–099, Revision A, including Appendices A, B, and D, and excluding Appendix C, dated December 13, 2004; or Bombardier Alert Service Bulletin A601R–32–099, Revision B, dated June 16, 2005, including Appendices A, B, and D, and excluding Appendix C, Revision A, dated December 13, 2004.

(2) For the actions specified in paragraph (l) of this AD: Bombardier Service Bulletin 601R–32–093, Revision B, dated July 14, 2005.

(3) After the effective date of this AD, only Revision B of Bombardier Alert Service Bulletin A601R–32–099, dated July 16, 2005, may be used for the actions specified in paragraphs (g), (h), (i), (j), and (k) of this AD.

(4) Although the service bulletins identified in paragraph (f)(1) of this AD specify to submit certain information to the airplane manufacturer and to return cracked

main fittings to the supplier, this AD does not include those requirements.

Restatement of the Requirements of AD 2004–20–09

Initial Inspections at New Reduced Compliance Times

(g) Do the actions in Table 1 of this AD.

TABLE 1.—INITIAL INSPECTION THRESHOLDS AT NEW REDUCED COMPLIANCE TIMES

Do the following in Column 1—	At the earlier of the times specified in Column 2 or Column 3—	
Column 1—	Column 2—The latest of—	Column 3—The latest of—
(1) A detailed inspection for cracks of the inboard and outboard sides of the main fitting of the MLG between the pintle pin trunnion and the radius of the shock strut lug, in accordance with Part A of the applicable service bulletin.	(i)(A) Before the accumulation of 8,000 total flight cycles since the main fitting of the MLG was new. (B) Within 8,000 flight cycles since the last overhaul of the MLG done before the effective date of this AD. (C) Within 50 flight cycles after October 21, 2004 (the effective date of AD 2004–20–09).	(ii)(A) Within 48 months since the main fitting of the MLG was new. (B) Within 48 months since the last overhaul of the MLG done before the effective date of this AD. (C) Within 50 flight cycles after the effective date of this AD.
(2) A detailed inspection for sealant damage or corrosion around the forward bushing of the left and right main fittings of the MLG, in accordance with Part B of the applicable service bulletin.	(i)(A) Before the accumulation of 8,000 total flight cycles since the main fitting of the MLG was new. (B) Within 8,000 flight cycles since the last overhaul of the MLG done before the effective date of this AD. (C) Within 500 flight cycles after October 21, 2004.	(ii)(A) Within 48 months since the main fitting of the MLG was new. (B) Within 48 months since the last overhaul of the MLG done before the effective date of this AD. (C) Within 500 flight cycles or 6 months after the effective date of this AD, whichever occurs first.
(3) An ultrasonic inspection for cracks of the left and right main fittings of the MLG, in accordance with Part C of the applicable service bulletin.	(i)(A) Before the accumulation of 8,000 total flight cycles since the main fitting of the MLG was new. (B) Within 8,000 flight cycles, since the last overhaul of the MLG done before the effective date of this AD. (C) Within 500 flight cycles after October 21, 2004.	(ii)(A) Within 48 months since the main fitting of the MLG was new. (B) Within 48 months since the last overhaul of the MLG done before the effective date of this AD. (C) Within 500 flight cycles or 6 months after the effective date of this AD, whichever occurs first.

Note 1: For the purposes of this AD, a detailed inspection is: ''An intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required.''

Repetitive Inspections

(h) Repeat the inspections in paragraph (g) of this AD thereafter at the applicable interval in paragraph (h)(1) or (h)(2) of this AD, until the terminating action required by paragraph (l) of this AD is accomplished.

(1) For airplanes on which the applicable initial inspection in paragraph (g) of this AD has been done before the effective date of this AD, do the next inspection at the applicable interval in Table 2 of this AD.

(2) For airplanes on which the applicable initial inspection in paragraph (g) of this AD has not been done before the effective date of this AD, repeat the inspection at the applicable interval in Table 2 of this AD.

TABLE 2.—REPETITIVE INSPECTIONS AT NEW INTERVALS

For the inspection required by—	Repeat at intervals not to exceed—	Until the action required by—
(3) Paragraph (g)(1) of this AD	5 days	Paragraph (g)(3) of this AD is done, unless required by paragraph (j) of this AD.
(4) Paragraph (g)(2) of this AD	500 flight cycles or 6 months, whichever occurs first.	Paragraph (j)(2) of this AD is done.
(5) Paragraph (g)(3) of this AD	5,000 flight cycles or 30 months, whichever occurs first, except as required by paragraph (j)(2) of this AD.	(None).

Corrective Actions

(i) If there is an indication of a crack during any inspection required by paragraph (g)(1), (h)(3), or (j)(1) of this AD, before further flight, do the actions specified in paragraph (i)(1) or (i)(2) of this AD in accordance with part A of the applicable service bulletin; or do the terminating action required by paragraph (l) of this AD before further flight.

(1) Replace the cracked main fitting of the MLG with a new or serviceable main fitting.

(2) Do an eddy current inspection to verify whether there is a crack. If there is a crack, replace the cracked main fitting of the MLG with a new or serviceable main fitting.

(j) If any sealant damage or corrosion is found during any inspection required by either paragraph (g)(2) or (h)(4) of this AD, do the actions specified in Table 3 of this AD in accordance with part B of the applicable service bulletin, until the terminating action required by paragraph (l) of this AD is accomplished.

TABLE 3.—CORRECTIVE ACTIONS FOR SEALANT DAMAGE OR CORROSION

Do the inspection specified in—	Within—	Repeat at intervals not to exceed—	Until the action specified in—
(1) Paragraph (g)(1) of this AD.	5 days after doing the inspection required by (g)(2) or (h)(4) of this AD, as applicable.	5 days	Paragraph (j)(2) or (l) of this AD is done.
(2) Paragraph (g)(3) of this AD.	500 flight cycles after doing the inspection required by paragraph (g)(2) or (h)(4) of this AD, as applicable.	500 flight cycles	Paragraph (l) of this AD is done.

(k) If there is an indication of a crack during any inspection required by paragraph (g)(3) or (h)(5) of this AD, before further flight, replace the cracked main fitting of the MLG with a new or serviceable main fitting in accordance with part C of the applicable service bulletin; or do the terminating action required by paragraph (l) of this AD before further flight.

New Requirement of This Ad

Terminating Action—Replacement

(l) Within 15 months after the effective date of this AD, replace both main fittings of the MLG with new main fittings having new part numbers, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 601R–32–093, Revision B, dated July 14, 2005. Doing this replacement terminates all requirements of paragraphs (g), (h), (i), (j), and (k) of this AD.

Note 2: Bombardier Service Bulletin 601R–32–093, Revision B, refers to Messier-Dowty Service Bulletin M–DT SB17002–32–24, dated October 9, 2003; and Messier-Dowty Service Bulletin M–DT SB17002–32–25, Revision 1, dated October 17, 2003; as additional sources of service information for replacing the MLG main fitting.

Actions Accomplished in Accordance With Earlier Issues of Service Bulletin

(m) Actions done before the effective date of this AD in accordance with the service bulletins listed in Table 4 of this AD are acceptable for compliance with the corresponding action specified in this AD.

TABLE 4.—EARLIER ISSUES OF SERVICE BULLETINS

Service Bulletin	Revision level	Date
Bombardier Service Bulletin 601R–32–093	Original	October 17, 2003.
Bombardier Service Bulletin 601R–32–093	A	September 21, 2004.

Parts Installation

(n) As of the effective date of this AD, no person may install a main fitting of the MLG, Bombardier P/N 601R85001–3 or 601R85001–4; also referred to as Messier-Dowty P/N 17064–101, 17064–102, 17064–103, or 17064–104; on any airplane.

Alternative Methods of Compliance (AMOCs)

(o)(1) The Manager, New York Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(p) Canadian airworthiness directive CF–2004–18R1, dated September 21, 2005, also addresses the subject of this AD.

Material Incorporated by Reference

(q) You must use the applicable service bulletin identified in Table 5 of this AD to perform the actions that are required by this AD, unless the AD specifies otherwise.

TABLE 5.—ALL MATERIAL INCORPORATED BY REFERENCE

Service Bulletin	Revision level	Date
Bombardier Alert Service Bulletin A601R–32–099, including Appendices A, B, and D, and excluding Appendix C.	Original	September 15, 2004.
Bombardier Alert Service Bulletin A601R–32–099, including Appendices A, B, and D, and excluding Appendix C.	A	December 13, 2004.
Bombardier Alert Service Bulletin A601R–32–099, including Appendices A, B, and D, and excluding Appendix C, Revision A, dated December 13, 2004.	B	June 16, 2005.
Bombardier Service Bulletin 601R–32–093	B	July 14, 2005.

(1) The Director of the Federal Register approved the incorporation by reference of the documents identified in Table 6 of this AD in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

TABLE 6.—NEW MATERIAL INCORPORATED BY REFERENCE

Service Bulletin	Revision level	Date
Bombardier Alert Service Bulletin A601R–32–099, including Appendices A, B, and D, and excluding Appendix C.	A	December 13, 2004.
Bombardier Alert Service Bulletin A601R–32–099, including Appendices A, B, and D, and excluding Appendix C, Revision A, dated December 13, 2004.	B	June 16, 2005.
Bombardier Service Bulletin 601R–32–093	B	July 14, 2005.

(2) On October 21, 2004 (69 FR 59790, October 6, 2004), the Director of the Federal Register approved the incorporation by reference of Bombardier Alert Service Bulletin A601R–32–099, including Appendices A, B, and D, and excluding Appendix C, dated September 15, 2004.

(3) Contact Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada, for a copy of this service information. You may review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Room PL–401, Nassif Building, Washington, DC; on the Internet at *http://dms.dot.gov*; or at the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on December 21, 2006.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–223 Filed 1–11–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2006–25673; Airspace Docket No. 06–ASW–13]

RIN 2120–AA66

Modification of VOR Federal Airway V–2; East Central United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies VOR Federal Airway V–2 over the East Central United States to support modified arrival and departure procedures to the Detroit Metropolitan Wayne County Airport (DTW), Detroit, Michigan. These procedures were modified in conjunction with the Midwest AirSpace Enhancement (MASE) project. The FAA is taking this action to enhance safety and to improve the efficient use of the navigable airspace assigned to the Chicago and Cleveland Air Route Traffic Control Centers (ARTCC).

DATES: *Effective Date:* 0901 UTC, March 15, 2007. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Steve Rohring, Airspace and Rules, Office of System Operations Airspace and Aeronautical Information Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

On September 6, 2006, the FAA published in the **Federal Register** a notice of proposed rulemaking to realign V–2 over the East Central United States (71 FR 52502). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received in response to the proposal.

VOR Federal Airways are published in paragraph 6010 of FAA Order 7400.9P dated September 1, 2006, and effective September 15, 2006, which is incorporated by reference in 14 CFR 71.1. The VOR Federal Airway listed in this document will be published subsequently in the Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 71 to modify VOR Federal Airway V–2 over the East Central United States. This action supports arrival and departure procedures to DTW that were modified in conjunction with MASE. Further, this action enhances safety and improves the efficient use of the navigable airspace within the areas of responsibility for Chicago and Cleveland ARTCCs.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environment Policy Act in accordance with 311a., FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures''. This airspace action is not expected to cause any potentially significant environment impacts, and no extraordingary circumstances exist that warrant preparation of environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

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

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9P, Airspace Designations and Reporting Points, dated September 1, 2006, and effective September 15, 2006, is amended as follows:

Paragraph 6010 VOR Federal airways.

* * * * *

V–2 [Revised]

From Seattle, WA; Ellensburg, WA; Moses Lake, WA; Spokane, WA; Mullan Pass, ID; Missoula, MT; Helena, MT; INT Helena 119° and Livingston, MT, 322° radials; Livingston; Billings, MT; Miles City, MT; 24 miles, 90 miles, 55 MSL, Dickinson, ND; 10 miles, 60 miles, 38 MSL, Bismarck, ND; 14 miles, 62 miles, 34 MSL, Jamestown, ND; Fargo, ND; Alexandria, MN; Gopher, MN; Nodine, MN; Lone Rock, WI; Madison, WI; Badger, WI; Muskegon, MI; Lansing, MI; Salem, MI; INT Salem 082° and Aylmer, ON, Canada, 261° radials; Aylmer; INT Aylmer 086° and Buffalo, NY, 259° radials; Buffalo; Rochester, NY; Syracuse, NY; Utica, NY; Albany, NY; INT Albany 084° and Gardner, MA, 284° radials; to Gardner. The airspace within Canada is excluded.

* * * * *

Issued in Washington, DC, on January 5, 2007.

Edith V. Parish,

Manager, Airspace and Rules.

[FR Doc. E7–322 Filed 1–11–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2006–26599; Airspace Docket No. 06–ASW–11]

RIN 2120–AA66

Change to Controlling Agency of Restricted Area 2312; Fort Hauchuca, AZ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the controlling agency for Restricted Area 2312 (R–2312), Fort Hauchuca, AZ. Specifically, this action amends the controlling agency from ''Libby [Army Air Field] AAF [Airport Traffic Control Tower] ATCT'' to ''Albuquerque [Air Route Traffic Control Center] ARTCC.'' This is an administrative change that does not alter the boundaries, designated altitudes, time of designation, or activities conducted within R–2312. The FAA is taking this action at the request of the United States (U.S.) Army and the U.S. Air Force because Libby AAF ATCT is not a 24-hour facility and R–2312 is not fully contained within the airspace delegated to Libby AAF ATCT by Albuquerque ARTCC.

DATES: *Effective Date:* 0901 UTC, March 15, 2007.

FOR FURTHER INFORMATION CONTACT: Steve Rohring, Airspace and Rules, Office of System Operations Airspace and AIM, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Background

On March 13 and March 17, 2006, respectively, the U.S. Army and the U.S. Air Force requested that the FAA take action to amend the controlling agency for R–2312, Fort Hauchuca, AZ from ''Libby AAF ATCT'' to ''Albuquerque ARTCC.'' The reason for the change is because Libby AAF ATCT is not a 24-hour facility and R–2312 is not fully contained within the airspace delegated to Libby AAF ATCT by Albuquerque ARTCC.

The Rule

At the request of the U.S. Army and the U.S Air Force, the FAA is amending the controlling agency for R–2312, Fort Hauchuca, AZ from ''Libby AAF ATCT'' to ''Albuquerque ARTCC''. This is an administrative change that does not alter the boundaries, designated altitudes, time of designation, or activities conducted within R–2312. Therefore, notice and public procedures under 5 U.S.C. 553(b) are unnecessary.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with 311d., FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures.'' This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—SPECIAL USE AIRSPACE

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

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 73.23 [Amended]

■ 2. § 73.23 is amended as follows:

* * * * *

R–2312 Fort Huachuca, AZ [Amended]

Under Controlling Agency, by removing the words ''Libby AAF ATCT'' and inserting the words ''Albuquerque ARTCC.''

* * * * *

Issued in Washington, DC, on January 4, 2007.

Edith V. Parish,

Manager, Airspace and Rules.

[FR Doc. E7–323 Filed 1–11–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2006–26646; Airspace Docket No. 06–ASW–12]

RIN 2120–AA66

Change to Time of Designation of Restricted Area 6320; Matagorda, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the time of designation for Restricted Area 6320 (R–6320), Matagorda, TX. Specifically, this action amends the time of designation from ''Continuous'' to ''Intermittent by [Notice to Airmen] NOTAM.'' This rule makes no other changes to R–6320. The FAA is issuing this amendment because R–6320 is no longer continuously needed for the aerostat balloon, used in support of U.S. National Security interests.

EFFECTIVE DATE: 0901 UTC, March 15, 2007.

FOR FURTHER INFORMATION CONTACT: Steve Rohring, Airspace and Rules, Office of System Operations Airspace and AIM, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Background

In response to public concern, the FAA approached the United States (U.S.) Custom Service and the U.S. Air Force Air Combat Command with a request to reduce the time of designation for R–6320. On June 15, 2006, the U. S. Customs Service and the U.S. Air Force concurred with reducing the time of designation from ''Continuous'' to ''Intermittent by NOTAM.'' The reason for the change is because R–6320 is no longer continuously needed for the aerostat balloon.

The Rule

The FAA is amending the time of designation for R–6320 from ''Continuous'' to ''Intermittent by NOTAM.'' This rule makes no other changes to R–6320. This action reduces the burden on the public by reducing the time of designation. Therefore, notice and public procedures under 5 U.S.C. 553(b) are unnecessary.

Section 73.63 of Title 14 CFR part 73 was republished in FAA Order 7400.8M, dated January 6, 2006.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with 311c., FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures''. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—SPECIAL USE AIRSPACE

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

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 73.63 [Amended]

■ 2. § 73.63 is amended as follows:

* * * * *

R–6320 Matagorda, TX [Amended]

Under Time of designation, by removing the word ''Continuous'' and inserting the words ''Intermittent by NOTAM.''

* * * * *

Issued in Washington, DC on January 5, 2007.

Edith V. Parish,

Manager, Airspace and Rules.

[FR Doc. E7–392 Filed 1–11–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 121

[Docket No. FAA–2006–24277; Amendment No. 121–330]

RIN 2120–AI75

Fire Penetration Resistance of Thermal/Acoustic Insulation Installed on Transport Category Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA extends, by 24 months, the date for operators to comply with the fire penetration resistance requirements of thermal/acoustic insulation used in transport category airplanes manufactured after September 2, 2007. This extension is from September 2, 2007, to September 2, 2009. This action is necessary to allow airframe manufacturers enough time, after getting an acceptable certification test facility, to select and certificate appropriate installations.

DATES: This amendment becomes effective February 12, 2007.

FOR FURTHER INFORMATION CONTACT: Jeff Gardlin, FAA, Airframe and Cabin Safety Branch, ANM–115, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2136, facsimile (425) 227–1149, e-mail: *jeff.gardlin@faa.gov.*

SUPPLEMENTARY INFORMATION:

Availability of Rulemaking Documents

You can get an electronic copy using the Internet by:

(1) Searching the Department of Transportation's electronic Docket Management System (DMS) Web page (*http://dms.dot.gov/search*);

(2) Visiting the FAA's Regulations and Policies Web page at *http://www.faa.gov/regulations_policies/;* or

(3) Accessing the Government Printing Office's Web page at *http://www.gpoaccess.gov/fr/index.html.*

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9680. Make sure to identify the amendment number or docket number of this rulemaking.

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. If you are a small entity and you have a question regarding this document, you may contact its local FAA official, or the person listed under **FOR FURTHER INFORMATION CONTACT**. You can find out more about SBREFA on the Internet at *http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44701. Under that section, the FAA is charged with promoting safe flight of civil aircraft in air commerce by prescribing minimum standards required in the interest of safety for the design and performance of aircraft. This regulation is within the scope of that authority, because it prescribes new safety standards for the design of transport category airplanes.

Background

We issued a notice of proposed rulemaking (NPRM) on April 3, 2006 (71 FR 16678) to extend the compliance date of 49 CFR 121.312(e)(3) because of unforeseen difficulties in establishing acceptable test equipment for showing compliance with that regulation. As discussed in the NPRM, that section requires that transport category airplanes manufactured after September 2, 2007, comply with the provisions of 14 CFR 25.856(b) when entering part 121 service. Section 25.856(b), in turn, requires that thermal/acoustic insulation installed in the lower half of the fuselage of those airplanes resist penetration of an external fire. The performance criteria are contained in Appendix F, part VII of part 25.

Based on difficulties in obtaining and qualifying the necessary test equipment that arose following publication of the requirement, we determined that the compliance date for § 121.312(e)(3) should be extended. This is discussed in detail in the NPRM.

Discussion of Comments

Nine commenters responded to the NPRM. Two commenters, Daher-Lhotellier and Cogebi, are affiliated insulation material manufacturers that do not support extending the compliance date. These commenters contended that materials meeting the rule are available and that compliance within the existing date is possible. They provided no further information. The basis of the proposed extension was that manufacturers were not able to show that materials that are optimized for cost and weight would reliably meet the requirement. We agree there are materials that satisfy the test requirements of the regulation, but these are heavier or more expensive than envisioned by the rule. The commenters did not address this point in their comments. We therefore do not agree the current compliance date should be maintained.

All other commenters (Airbus, Airline Pilots Association (ALPA), Air Transport Association (ATA), Association of European Airlines (AEA), Aerospace Industries Association (AIA), Boeing, and Bombardier) supported an extension to the compliance date.

ALPA agreed that an extension of the compliance date is warranted, but had other comments on the basic requirement. These comments included expanding the number of airplanes affected, and the portion of the airplane that must be protected with insulation meeting the requirement. ALPA had made these same comments during the original rulemaking. These comments went beyond the scope of the NPRM, which simply addresses the compliance date for newly manufactured airplanes. However, as discussed in the original rulemaking, we have determined that broadening the applicability of the rule would have a very small benefit, and significant cost.

Airbus, Boeing, Bombardier, AIA and AEA all contended the test equipment is still not sufficiently developed to support a fixed compliance date. They maintained the scatter in test results is too wide for a certification standard.

We do not agree. The FAA William J. Hughes Technical Center has worked aggressively to resolve the issues with the test equipment, and has made significant progress in eliminating differences between test facilities. The most significant issue was the difference in performance between two test burners with slightly different configurations. We have developed small modifications that bring the two configurations into alignment. These modifications have been distributed to the test facilities that required them. In addition, we have conducted a series of tests with different materials to confirm the modifications do, in fact, work. It should be noted that all test methods, and in particular, fire test methods, have variability. This test method is consistent with other fire test methods in terms of the variation in results from one test to the next. As discussed below, some of the variation in test results is not because of the test method or equipment.

We have also identified variability in materials that can lead to variability in test results. In the tests cited by these commenters, many of the materials tested were ''off the shelf'' and not necessarily developed to comply with an aviation safety standard. More recent efforts to develop materials whose properties were carefully controlled have shown the test results can be very consistent, if the material being tested is itself very consistent.

Airbus, Boeing, and AIA commented the burner used in the test method is obsolete, and no longer available. They stated this contributes to difficulties in obtaining consistency among facilities and within a facility.

While the burner is no longer commercially available; there are numerous burners already in industry. As discussed above, the FAA Technical Center has developed refinements to the burner that standardize its performance. However, as the supply of burners is limited, we have also developed an alternative burner that eliminates many of the parameters that are currently the source of performance variations. This design will be documented and the plans made available to anyone requesting them. The new burner can be fabricated from standard parts and should eliminate concerns that the old burner is out of production.

Airbus commented there are no commercially available test facilities. At the time the comment was made, no commercial facilities had requested FAA acceptance. However, since the NPRM was published, two facilities have requested and received FAA review and would be eligible to conduct certification testing if they so choose.

Airbus also commented the late availability of the associated advisory circular (AC) 25.856–2 has contributed to the need for further extension. Airbus noted the final AC was published in January 2006, and not concurrently with the final rule. They stated the lack of published guidance affected their ability to begin designing suitable solutions.

Part of the reason the AC publication was delayed was to permit as much consideration as possible of the equipment issues that had arisen. We had to balance the need to issue the AC as soon as possible with the need to make it as comprehensive as possible. The absence of the AC did not, however, limit any manufacturer's ability to propose, and gain acceptance for, methods of compliance. The FAA has worked with each affected manufacturer to develop methods of compliance. While the ideal situation would have been to have the AC available concurrent with the final rule, this should not have inhibited the development of methods of compliance.

Bombardier, Boeing and Airbus, with supporting comments from AEA and AIA, contended there are no, or limited, materials available that satisfy the cost/weight criteria specified in the original rulemaking. We believe that part of this comment stemmed from the prior problems with test equipment, and the potential for certain materials to pass at one facility, but fail at another. Since the material used to establish cost and weight in the original rulemaking is still available, we do not agree there are no materials available. However, we agree the scatter in test results that prompted this rule introduced uncertainty, and reluctance on the part of the manufacturers to commit to a material.

Bombardier commented on specific areas of the airplane that may be more complex to address than others, as well as some alternative approaches to providing protection from flame penetration. These comments were not directly related to the subject of the compliance date. Nonetheless, we agree

that some areas of the airplane are more complicated than others, but this was accounted for in the rulemaking. In terms of alternative approaches, an applicant is free to propose an approach that provides an equivalent level of safety.

Boeing expressed a concern that the local Aircraft Certification Offices will not have enough information with which to review, and find acceptable, test facilities. As noted above, two facilities have been reviewed and accepted to date. The FAA plans to make such reviews a priority and there have been no unforeseen difficulties in successfully accomplishing the facility review.

Boeing and Airbus both indicated that they cannot comply, even with a 12 month extension. They stated their current production schedules and design requirements mean that compliance with the existing proposal will cause severe disruption of their schedules and cause them to implement materials that are heavier, or more costly than can be developed soon. This in turn would require them to change configurations twice: once to meet the compliance date, and again to optimize the materials, after they complete their development. They proposed an additional 12 month extension, for a total of 24 months to minimize disruption of their production.

We have carefully considered these comments, as they are fundamental to the impact of the rule. When the original rule was promulgated, we determined that a four year compliance time was sufficient for newly manufactured airplanes. This assessment presumed that materials and test equipment were readily available and that manufacturers would begin to address compliance immediately. However, we have acknowledged the test equipment was not readily available in a condition to always provide reliable test results, and that this brought into question the suitability of certain materials presumed to be acceptable. Since this rule does add weight and cost to the airplane, the balance between the total cost impact and the safety benefit is very important. If the cost of implementating the rule is much more significant than anticipated, the justification for the rule may be revisited. Since we believe the rule provides a significant safety benefit, we must maintain the balance between the cost impact, and the safety benefit provided. Clearly, for various reasons, two major airplane manufacturers are not prepared to comply with the rule, even allowing for a 12 month extension from the original compliance date. While we do not agree that all the reasons for this lie with the issues associated with the test method, we believe that the current proposal will result in significantly greater economic impact than was anticipated.

We have worked closely with each of the affected airplane manufacturers to address compliance questions and certification methodology. This has involved on-site visits and inspection of airplane design details, in addition to numerous discussions. These reviews give us a good appreciation of the magnitude of the design changes required to achieve compliance, which are substantial. Since a significant amount of the compliance time was absorbed with test equipment issues, the airplane manufacturers are significantly behind in implementing designs. Even though we had concluded that a 12 month extension would be sufficient, the two largest airplane manufactures are clearly not postured to accommodate compliance in that timeframe using materials that they consider optimal and that they intend to use for future compliance. We agree that they could not comply within the current proposed timeframe without a substantial cost impact that we did not originally anticipate.

Considering all of the above we have concluded that an additional 12 month extension, for a total of 24 months, is appropriate to implement this requirement in keeping with the original cost/benefit balance of the rule. In making this decision, we have considered that we would very likely receive petitions for exemption to address specific certification programs if the current proposal is maintained. The potential for further extensions is a significant factor in changing the proposal. Barring some unforeseen event, we do not envision any more changes to the compliance date. The final rule is changed accordingly.

Notwithstanding the 24 month extension, we would expect the manufacturers to implement the required design changes as early as possible, to improve the safety of the fleet.

Paperwork Reduction Act

There are no current or new requirements for information collection associated with this amendment.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to these regulations.

Regulatory Evaluation, Regulatory Flexibility Analysis, International Trade Impact Assessment, and Unfunded Mandate Assessment

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this final rule.

Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If the expected cost impact is so minimal that a proposed or final rule does not warrant a full evaluation, this order permits that a statement to that effect and the basis for it be included in the preamble if a full regulatory evaluation of the cost and benefits is not prepared. Such a determination has been made for this final rule. The reasoning for this determination follows:

A two-year postponement of the new thermal acoustic insulation standards would spare manufactures an added setup cost of slightly less than $60 million at an expected societal loss of $4 million in benefits. The Improved Flammability Standards for Thermal/Acoustic Insulation final regulatory evaluation (July, 2002) estimated the new insulation requirements would produce present value benefits of $222.6 million with present value costs of

$108.4 million (Table M). The two-year benefit/cost delay dichotomy is because of large set up costs and a relatively short postponement of corresponding benefits. The benefits increase slowly with a gradual increase in the fleet because of annual deliveries of new production airplanes with the new thermal/acoustic insulation.

As shown in the 2002 final regulatory evaluation nearly half of the regulatory evaluation estimated $108 million present value costs are the setup costs ($58.1 million in present value), which are incurred in the two years before installing the improved insulation on new production airplanes. These setup costs occur because of configuration management, or the cost resulting from engineering time to change airplane configuration—such as fully accounting for all parts, tools, and shop manual changes. To be in compliance with the new requirements the industry would first have to install a heavier insulation, before lighter weight insulation becomes fully available. Two different types of insulation materials require configuration management costs to double.

Thus this final rule results in large cost savings with a minor loss in social benefits. The FAA has, therefore, determined that this final rule is not a ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866, and is not ''significant'' as defined in DOT's Regulatory Policies and Procedures.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354) (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.'' The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

With this rule airplane manufacturers will avoid incurring an added configuration management cost. While these manufacturers are not small entities, the small entity operators are expected to save fuel burn expense, as the one-year interim fix insulation is heavier. Thus this rule is cost relieving and does not impose a significant economic impact on a substantial number of small entities.

We did not receive comments following the NPRM about the cost impact on small entities.

Therefore, as the FAA Administrator, I certify that this rule will not have a significant economic impact on a substantial number of small entities.

International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39) prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this final rule and has determined that it provides the same cost relief to domestic and international entities and thus has a neutral trade impact.

Unfunded Mandate Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (adjusted annually for inflation with the base year 1995) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $128.1 million in lieu of $100 million. This final rule does not contain such a mandate.

Executive Order 13132, Federalism

The FAA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. We determined that this action will not have a substantial direct effect on the States, or the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government, and therefore does not have federalism implications.

Regulations Affecting Intrastate Aviation in Alaska

Section 1205 of the FAA Reauthorization Act of 1996 (110 Stat. 3213) requires the FAA, when modifying its regulations in a manner affecting intrastate aviation in Alaska, to consider the extent to which Alaska is not served by transportation modes other than aviation, and to establish appropriate regulatory distinctions. In the NPRM, we requested comments on whether the proposed rule should apply differently to intrastate operations in Alaska. We didn't receive any comments, and we have determined, based on the administrative record of this rulemaking, that there is no need to make any regulatory distinctions applicable to intrastate aviation in Alaska.

Environmental Analysis

FAA Order 1050.1E identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 3f and involves no extraordinary circumstances.

Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA has analyzed this final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 18, 2001). We have determined that it is not a ''significant energy action'' under the executive order because it is not a ''significant regulatory action'' under Executive Order 12866, and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

List of Subjects in 14 CFR Part 121

Aircraft, Aviation safety, Reporting and recordkeeping requirements, Safety, Transportation.

The Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends Chapter I of Title 14, Code of Federal Regulations as follows:

PART 121—OPERATING REQUIREMENTS: DOMESTIC, FLAG, AND SUPPLEMENTAL OPERATIONS

■ 1. The authority citation for part 121 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 40119, 44101, 44701–44702, 44705, 44709–44711, 44713, 44716–44717, 44722, 44901, 44903–44904, 44912, 46105.

■ 2. Amend § 121.312 by revising paragraph (e)(3) to read as follows:

§ 121.312 Materials for compartment interiors.

* * * * *

(e) * * *

(3) For airplanes with a passenger capacity of 20 or greater, manufactured after September 2, 2009, thermal/acoustic insulation materials installed in the lower half of the fuselage must meet the flame penetration resistance requirements of § 25.856 of this chapter, effective September 2, 2003.

Issued in Washington, DC, on January 4, 2007.

Marion C. Blakey,

Administrator.

[FR Doc. E7–338 Filed 1–11–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 125 and 135

[Docket No. FAA–2004–18596; Amendment No. SFAR 106]

RIN 2120–AI30

Use of Certain Portable Oxygen Concentrator Devices Onboard Aircraft

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; technical amendment.

SUMMARY: The Federal Aviation Administration (FAA) is making minor technical changes to a final rule published in the **Federal Register** on July 12, 2005 (70 FR 40156). That final rule created Special Federal Aviation Regulation 106 (SFAR 106). In that final rule the FAA inadvertently failed to make conforming amendments to additionally apply the SFAR to parts 125 and 135 as proposed, and to include references in those parts to the existence of SFAR 106 published in part 121.

EFFECTIVE DATES: Effective on February 12, 2007.

FOR FURTHER INFORMATION CONTACT: David L. Catey, Air Transportation Division, AFS–200, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–3732.

SUPPLEMENTARY INFORMATION: The Federal Aviation Administration (FAA) published SFAR 106, ''Use of Certain Portable Oxygen Concentrator Devices onboard Aircraft,'' in the **Federal Register** on July 12, 2005 (70 FR 40156). We inadvertently failed to attach notes to parts 125 and 135 of Title 14 of the Code of Federal Regulations (14 CFR) that would direct operators subject to those regulations to the body of SFAR 106. When the FAA published the notice of proposed rulemaking (NPRM) that offered the proposed SFAR to the public for comment, we clearly stated that the proposed regulation would apply to civil aircraft in parts 121, 125, and 135. The NPRM was published in the **Federal Register** on July 14, 2004 (69 FR 42324), and in the heading we noted that the proposal applied to 14 CFR Parts 121, 125, and 135. The applicability for an SFAR to a specific part of 14 CFR is not specifically cited in the Applicability section of the regulatory language, but rather cited in the heading of the SFAR and the parts affected contain an editorial note referring readers to the text of the SFAR. When the final rule was published, we failed to include those notes to parts 125 and 135. This technical amendment will add the editorial notes to parts 125 and 135 that direct the reader to the text of SFAR 106 and ensure that readers know the regulation applies to operations conducted under those parts. This amendment will not impose any additional restrictions on operators affected by these regulations.

SFAR 106 permits passengers to carry on and use certain portable oxygen concentrator devices (POCs) onboard aircraft if the aircraft operator ensures that the conditions specified in the SFAR for their use are met. Aircraft operators can now offer medical oxygen service as they did before SFAR 106 was enacted, or they can arrange for passengers to carry on and use one of the devices covered in SFAR 106. SFAR 106 is an enabling rule, which means that no aircraft operator is required to allow passengers to operate these devices onboard, but they may allow them to be operated onboard. If one of these devices is allowed by the aircraft operator to be carried on board, the conditions in the SFAR must be met. SFAR 106 allows for the use of five specific POC devices the FAA has found to be acceptable.

Need for the Correction

As stated above, this correction is needed to make clear that the conditions and regulations of SFAR 106 are also applicable to operations conducted under parts 125 and 135, as proposed in the NPRM and intended in the final rule.

Technical Amendment

The technical amendment will correct the omission of the editorial notes that direct operators under parts 125 and 135 to SFAR 106 in part 121.

List of Subjects

14 CFR Part 125

Aircraft, Airmen, Aviation safety, Reporting and recordkeeping requirements

14 CFR Part 135

Air taxis, Aircraft, Aviation safety, Reporting and recordkeeping requirements.

■ Accordingly, Title 14 of the Code of Federal Regulations (CFR) parts 125 and 135 are amended as follows:

PART 125—CERTIFICATION AND OPERATIONS: AIRPLANES HAVING A SEATING CAPACITY OF 20 OR MORE PASSENGERS OR A MAXIMUM PAYLOAD CAPACITY OF 6,000 POUNDS OR MORE; AND RULES GOVERNING PERSONS ON BOARD SUCH AIRCRAFT.

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

Authority: 49 U.S.C. 106(g), 40113, 44701–44702, 44705, 44710–44711, 44713, 44716–44717, 44722.

■ 2. Special Federal Aviation Regulation No. 106 is added to part 125 to read as follows:

SPECIAL FEDERAL AVIATION REGULATION NO. 106

Editorial Note: For the text of SFAR No. 106, see part 121 of this chapter.

PART 135—OPERATING REQUIREMENTS: COMMUTER AND ON-DEMAND OPERATIONS AND RULES GOVERNING PERSONS ON BOARD SUCH AIRCRAFT

■ 3. The authority citation for part 135 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44702, 44705, 44709, 44711–44713, 44715–44717, 44722.

■ 4. Special Federal Aviation Regulation No. 106 is added to part 135 to read as follows:

SPECIAL FEDERAL AVIATION REGULATION NO. 106

Editorial Note: For the text of SFAR No. 106, see part 121 of this chapter.

Issued in Washington, DC, on January 4, 2007.

Rebecca B. MacPherson,

Assistant Chief Counsel for Regulations.

[FR Doc. E7–339 Filed 1–11–07; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1407

Portable Generators; Final Rule; Labeling Requirements

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Commission (Commission or CPSC) is issuing a final rule requiring manufacturers to label portable generators with performance and technical data related to performance and safety. The required warning label informs purchasers that: ''Using a generator indoors CAN KILL YOU IN MINUTES;'' ''Generator exhaust contains carbon monoxide. This is a poison you cannot see or smell;'' ''NEVER use inside a home or garage, EVEN IF doors and windows are open;'' ''Only use OUTSIDE and far away from windows, doors, and vents.'' The warning label also includes pictograms. The Commission believes that providing this safety information will help reduce unreasonable risks of injury associated with portable generators.[1]

DATES: This regulation becomes effective May 14, 2007 and applies to any portable generator manufactured or imported on or after that date.

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SUPPLEMENTARY INFORMATION:

A. Background

The total yearly estimated non-fire related carbon monoxide (CO) deaths for each of the years 1999 through 2002 are 109, 138, 130 and 188, respectively. Since 1999, the percentage of estimated CO poisoning deaths specifically associated with generators has been increasing annually. In 1999, generators were associated with 7 (6%) of the total yearly estimated CO poisoning deaths for that year. In 2000, 2001 and 2002, they were associated with 19 (14%), 22 (17%) and 46 (24%) deaths out of the total estimates for each of those years.

On October 12, 2005, the staff was directed to undertake a thorough review of the status of portable generator safety. As part of this review, the staff was requested to assess the sufficiency of warning labels to address the CO poisoning hazard posed by portable generators that are used within or near residences. In response to this request, CPSC staff prepared a draft notice of proposed rulemaking (NPR), in which the staff proposed that manufacturers be required to label portable generators with a CO-poisoning warning label. On August 15, 2006, the Commission voted unanimously (2–0) to approve the publication of a **Federal Register** notice issuing an NPR for portable-generator labeling requirements. This notice was published August 24, 2006. 71 FR 50003.

B. The Product

Portable generators offer a means of providing electrical power to a location that either temporarily lacks it or is not provided with electrical service at all. A portable generator has an internal combustion engine to produce rotational energy, which is used to generate electricity. The engine may be fueled by gasoline, diesel, natural gas, or liquid propane. It is the engine that produces carbon monoxide as a byproduct of combustion.

Estimates of sales of portable generators for consumer use vary, but could be more than a million units annually. The most popular of these generators are gasoline-powered and are priced in the $500 to $800 range. The output of the majority of light duty generators sold to consumers in 2005 was in the 3.5 kW to 6.5 kW range. This is the size of most of the units involved in the fatal CO poisoning incidents CPSC staff investigated in which the rating of the involved generator was identified.

C. Relevant Statutory Provisions

Section 27(e) of the Consumer Product Safety Act (CPSA) authorizes the Commission, by rule, to ''require any manufacturer of consumer products to provide the Commission with such performance and technical data related to performance and safety as may be required to carry out the purposes of this Act, and to give such notification of such performance and technical data at the time of original purchase to prospective purchasers and to the first purchaser of such product for purposes other than resale, as it determines necessary to carry out the purposes of this Act.'' As provided in section 2(b)(1) of the Consumer Product Safety Act (15 U.S.C. 2051(b)(1)), one purpose of the CPSA is ''to protect the public against unreasonable risks of injury associated with consumer products.''

Failure to comply with a rule under section 27(e) is unlawful under section 19(a)(8) of the CPSA. 15 U.S.C. 2068(a)(8). Any person who knowingly violates this requirement is subject to a civil penalty of up to $8,000 per violation. 15 U.S.C. 2069; 64 FR 51963.

D. Explanation of the Rule

In 2002, CPSC staff assessed the effectiveness of current CO poisoning warnings found on the product and within the owner's manuals of several models of portable generators found on store shelves. Staff found that the guidance provided for avoiding the hazard was typically twofold: (1) Do not use in a confined or enclosed space, and (2) provide proper ventilation. None of the evaluated warnings defined ''confined or enclosed space'' or ''proper ventilation.''

The Commission believes these instructions and warnings do not adequately advise users how to avoid the CO poisoning hazard. Furthermore, the incident data includes fatalities where it appears that the victims attempted to provide adequate ventilation, to open confined areas, or to do both by, for example, opening doors, opening windows, and running exhaust fans. Prior research has shown that tools with gasoline-powered engines produce CO that ''can rapidly accumulate, even in areas that appear to be well-ventilated, resulting in dangerous and fatal concentrations within minutes.''[2] Thus, evidence suggests that the methods consumers typically use to provide ventilation or to open confined areas are insufficient to prevent hazardous levels of CO buildup. Even locating a generator outdoors can be insufficient if the generator is near

[1] Acting Chairman Nancy A. Nord and Commissioner Thomas H. Moore each filed a statement. The statements are available from the Office of the Secretary or on the Commission's Web site at *http://www.cpsc.gov*.

[2] Earnest, G.S., Carbon Monoxide Poisonings from Small, Gasoline-Powered, Internal Combustion Engines: Just What is a ''Well-Ventilated Area''?, American Industrial Hygiene Association Journal, November 1997.

enough to openings to the home or other occupied structure to allow CO to permeate and subsequently accumulate indoors. CPSC is aware of at least 5 deaths that occurred when a generator was situated outdoors but near openings to the home. In addition, the Centers for Disease Control and Prevention recently reported the results of a study of post-hurricane related generator use in 2005 that found up to 50% of non-fatal CO poisoning incidents involved generators operated outdoors but within one to seven feet from the home.[3]

The Commission believes that there are too many unknown variables to be able to recommend one single safe distance for the location of a portable generator relative to a home or dwelling. Variables such as the wind speed and direction relative to openings to indoor spaces, relative proximity of other structures in the area that could create wind vortices, direction in which the engine exhaust is pointing, and a multitude of other factors complicate attempts to define a safe distance. Notwithstanding the issue of defining a safe operating distance, the Commission believes that warning labels must instruct consumers to keep generators outdoors and away from air intakes during use.

In 2003, the staff developed recommended warning language for engine-driven tools, with particular focus on portable generators, as a follow-up to the staff's assessment of the inadequacy of current warnings. This was later provided to the Underwriters Laboratories (UL) voluntary standard development committee. In February 2006, staff developed a further refined warning label for portable generators and presented it to UL in response to their request for CPSC staff comments on a proposed UL Outline of Investigation. UL incorporated staff 's proposed warning label into their Outline of Investigation, which became effective April 2006 and serves as the requirements with which a product must conform in order to be eligible to bear the UL mark. This document is not a consensus standard. The Commission believes a final rule is needed to ensure that all products will bear the proposed warning label as opposed to only those that seek UL's mark.

E. Description of the Rule

The warning label appears at fig. 1 (and fig. 3 for the on-package label). The warning label provides technical data, i.e., it indicates the presence of carbon monoxide in the portable generator exhaust and informs that carbon monoxide is a poison you cannot see or smell. The label uses the phrase ''you cannot see or smell'' rather than terms such as ''odorless'' and ''colorless,'' because the latter terminology may be less familiar and understandable to some consumers.

The label also includes statements which connect the technical data with safety concerns. Specifically, the label warns: ''Using a generator indoors CAN KILL YOU IN MINUTES.'' The phrase ''in minutes'' is intended to emphasize the imminence of the carbon monoxide poisoning hazard to provide consumers with a better understanding of the speed with which incapacitation can occur. In addition, research indicates that information about hazard scenarios affects consumers' risk judgments. Thus, the label includes a description not just of the hazard, carbon monoxide, but of the primary hazard scenario associated with CO-poisoning deaths, i.e., using a generator indoors. The label also warns, ''NEVER use inside a home or garage, EVEN IF doors and windows are open.'' The label warns specifically against use in the home and in garages, since these are known places in which consumers have used generators. The label includes prescriptive advice to ''Only use OUTSIDE and far away from windows, doors, and vents,'' so consumers can know what positive action they can take to avoid the hazard, rather than focusing exclusively on prohibited behaviors, or what consumers should not do. This is consistent with the requirements of ANSI Z535.4–2002, which is the primary U.S. voluntary consensus standard on product safety signs and labels, and with warning design guidelines in general. The accompanying pictograms are based on the pictograms developed by the Underwriters Laboratories Standards Technical Panel. Research shows that labels with pictograms tend to capture a consumer's attention more readily than a label without pictograms.

F. Unreasonable Risk of Injury

Portable generators are powered by gasoline, diesel, or propane engines and exhaust CO. If the generator is used in enclosed or even partially enclosed spaces, the CO can very quickly build to hazardous levels. Serious injury can also result when the generator is placed outdoors but near an open window or vent and the exhaust is pulled into a house. In the 6-year period from 2000 through 2005, the Commission is aware of at least 222 deaths related to CO poisoning associated with generators.[4] Non-fatal CO injuries can have serious consequences since permanent brain or neurological damage can result.

A well-designed warning label should inform the consumer of the CO hazard associated with generators and how to avoid the hazard while using the generator. A label placed in a prominent position on the generator is expected to reinforce this information each time the consumer used the generator. For example, the proposed label reminds the consumer that generator exhaust contains CO, which cannot be seen or smelled, and can quickly kill. The label also clarifies that a generator should only be used outside and far away from windows and vents and should not be used inside a home or garage. This information is important since some consumers have apparently been aware that a CO hazard was associated with generators, but believed that they would avoid the hazard by running the generator in a garage with the door open or outside the house, and did not understand that it was necessary to place it away from open windows and vents.[5] The costs of a warning label include the one-time cost of designing the label and the continuing costs of printing and applying the labels to the generators and packages. These costs are expected to be low—less than one dollar per generator. Based on the hazards associated with carbon monoxide poisoning from portable generators, and the low cost of labeling generators, the Commission finds that there is an unreasonable risk of injury associated with portable generators.

G. Environmental Considerations

The National Environmental Policy Act and the Council on Environmental Quality Act regulations and CPSC procedures for environmental review require the Commission to assess the possible environmental effects associated with the labeling requirement for portable generators. Labeling rules

[3] CDC, Carbon Monoxide Poisoning After Two Major Hurricanes—Alabama and Texas, August–October 2005, MMWR March 10, 2006; 55(09); 236–239.

[4] Natalie E. Marcy and Debra S. Ascone, ''Incidents, Deaths and In-Depth Investigations Associated with Carbon Monoxide from Engine-Driven Generators and other Engine-Driven Tools, 1990–2004,'' CPSC Memorandum to Janet Buyer, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission, Washington, DC (1 December 2005) and Robin L. Ingle, ''Non-fire Carbon Monoxide Fatalities Associated with Engine-Driven Generators and Other Engine Driven Tools in 2004 and 2005,'' CPSC Memorandum to Janet Buyer, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission, Washington, DC (3 January 2006).

[5] Timothy P. Smith, ''Human Factors Assessment for the Small Engine-Driven Tools Project,'' CPSC Memorandum to Janet L. Buyer, U.S. Consumer Product Safety Commission, Washington, DC (18 June 2002).

are not expected to have an adverse impact on the environment and are considered to fall within the ''categorical exclusions'' for the purposes of the National Environmental Policy Act according to the CPSC regulations that cover its ''environmental review'' procedures (16 CFR Part 1021.5(c)(2)). Thus, the Commission concludes that no environmental assessment or environmental impact statement is required in this proceeding.

H. Impact on Small Business

When an agency issues a final rule such as the labeling requirement for portable generators, the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601 *et seq.*, generally requires the agency to prepare a final regulatory flexibility analysis describing the impact of the rule on small businesses and other small entities. Section 605 of the RFA provides that an agency is not required to prepare a regulatory flexibility analysis if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The Commission's Directorate for Economic Analysis prepared a preliminary assessment of the impact of a rule to require labeling on portable generators. That assessment reported that, while small manufacturers will be responsible for ensuring that their generators are properly labeled, the labeling requirement is not expected to pose a significant burden to small business because the cost of adding the labels per generator is expected to be less than a dollar per generator set. The incremental cost of the rule issued today is likely to be minimal.

Based on the foregoing assessment, the Commission certifies that the rule issued today to require labeling for portable generators will not have a significant adverse impact on a substantial number of small businesses or other small entities.

I. Executive Order 12988

As provided for in Executive Order 12988 (February 5, 1996), the CPSC states that the preemptive effect of these regulations is as follows. The preemption provisions of section 26 of the CPSA apply only to ''consumer product safety standards.'' By definition in the CPSA, section 27(e) rules are not consumer product safety standards. There is, therefore, no express preemption for a final rule under section 27(e) of the CPSA. Preemption of state requirements could still occur if, for example, it is impossible to comply with both this rule and a state requirement.

J. Effective Date

Part 1407 requires a label on any portable generator manufactured or imported on or after May 11, 2007.[6]

K. Response to Comments on the NPR

In response to the **Federal Register** notice proposing labeling requirements for portable generators, the Commission received 19 comments. The comments were largely positive and supported the proposed labeling, but two comments explicitly requested that the Commission withdraw the NPR. Many of the comments, even those that supported the general intent and approach of the rule, raised specific issues or concerns.

1. Procedural Issues and Choice of Statutes

Comments: Two comments claim that the Federal Hazardous Substances Act (FHSA), not the CPSA, is the appropriate statute under which to address through labeling the CO-poisoning risk associated with portable generators. If, as the commenters claim, the risk of injury is one which could be eliminated or reduced by action under the FHSA, then the Commission, pursuant to section 30(d) of the CPSA, would have been required to find by rule that it was in the public interest to regulate the risk of injury under the CPSA (''section 30(d) finding'').[7]

These commenters also claim that the label proposed in the NPR appears to be the type of warning that Section 7 of the CPSA contemplates, since the NPR characterizes the risk of CO poisoning associated with generator emission as an ''unreasonable risk of injury.''[8]

Response: The FHSA defines ''hazardous substance'' as including any ''substance or mixture of substances which (I) is toxic * * * if [it] may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use * * *.'' Hazardous substances are misbranded if they do not bear the labeling required by section 2(p)(1) of the FHSA, 15 U.S.C. 1261(p)(1). In order to label a product under the authority of the FHSA, the product must constitute or contain a hazardous substance.

The commenters analogize the labeling of portable generators to the labeling of charcoal packaging under the FHSA, in that charcoal, when burned, generates carbon monoxide. A significant difference between charcoal and portable generators, however, is that charcoal, as a substance which is toxic, constitutes a hazardous substance, and its packaging is therefore required to be labeled under the FHSA. In contrast, portable generators, when sold, are empty. Portable generators as sold thus do not contain any hazardous substance, or any substance, such as gasoline, that would produce the hazardous substance. A more appropriate analogy to portable generators might be gasoline containers that, when sold empty, are subject to the authority of the CPSA. Because the risk of injury associated with carbon monoxide poisoning from portable generators cannot be eliminated or adequately reduced by action under the FHSA, no finding under section 30(d)of the CPSA is required.

Commenters also suggest that the label proposed in the NPR appears to be the type of warning that Section 7 of the CPSA contemplates, since the NPR characterizes the risk of CO poisoning associated with generator emission as an ''unreasonable risk of injury.'' Section 27(e) of the CPSA authorizes the Commission to issue rules requiring a consumer product manufacturer to provide the Commission and consumers with ''performance and technical data related to performance and safety as may be required to carry out the purposes of this Act .'' One of the purposes of the CPSA, as provided in section 2(b)(1) of the CPSA, is ''to protect the public against unreasonable risks of injury associated with consumer products.'' The risk of CO poisoning posed by portable generators was fully addressed in the NPR (71 FR 50003) and the use of section 27(e) to protect the public against risk of injury is completely appropriate. This is not to say that it would be inappropriate to adopt a CO warning label for generators under section 7 of the CPSA. Indeed, the Commission intends to consider that approach in connection with its ongoing generator rulemaking (71 FR 74472).

[6] Note that the rule does not apply to any portable generator that is an ''accessory'' to a motor vehicle as defined in 49 U.S.C. 30102(a)(7).

[7] Section 30(d) of the CPSA provides that a risk of injury which is associated with a consumer product and which could be eliminated or reduced to a sufficient extent by action under the Federal Hazardous Substances Act, the Poison Prevention Packaging Act of 1970, or the Flammable Fabrics Act may be regulated under the CPSA only if the Commission by rule finds that it is in the public interest to regulate such risk of injury under the CPSA.

[8] Section 7(a) of the CPSA provides that the Commission may promulgate a consumer product safety standard requiring that a consumer product be marked with or accompanied by clear and adequate warnings or instructions. Any requirement of such a standard is to be ''reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product.'' Id.

2. Scope and Definition Issues

Comments: Two comments address scope and definition issues related to the proposed rule. One comment seeks clarification on whether fuel-cell portable generators are included within the scope of the rule. Another comment proposes that the definition of a ''portable generator'' reflect the definition within Underwriters Laboratories' Outline of Investigation for Portable Engine-Generator Assemblies, UL 2201.

Response: The CPSC rule is intended to generally cover the same range of portable generators as UL 2201. Therefore, Section 1407.2(b) is revised to read, ''A portable generator is an internal combustion engine-driven electric generator rated no higher than 15 kilowatts and 250 volts that is intended to be moved for temporary use at a location where utility-supplied electric power is not available. It has receptacle outlets for the alternating-current (AC) output circuits, and may have alternating- or direct-current (DC) sections for supplying energy to battery charging circuits. '' As specified in this definition, portable generators that are covered under this rule must have an internal combustion engine and receptacle outlets for AC output circuits. (The generator may have other outlets, for example, for low voltage DC accessories.) Fuel-cell portable generators are not be covered by the rule. The rule also does not cover generators that fall within the definition of ''motor vehicle equipment,'' or otherwise fall outside the Commission's jurisdiction under the CPSA.

3. Effective Date of Rule

Comments: Three comments from portable generator manufacturers state that they will need at least six months, rather than the 90 days proposed in the NPR, from issuance of the final regulation in the **Federal Register** to comply with the new requirements.

Response: As noted by the staff of the CPSC Directorate for Economic Analysis, the time and resources required by manufacturers to redesign their portable generator labels are likely to be low since the content and format of the labeling will be specified in the rule. The Commission, therefore, believes that most manufacturers should be able to comply with the requirements within 90 days of publication of the final rule. Nevertheless, some manufacturers may have to reschedule other work and shift resources such as labor from other projects. There would be some costs associated with these adjustments and these costs could be alleviated somewhat by delaying the effective date of the rule. To provide some relief to manufacturers that might have trouble incorporating the label change within 90 days, the Commission has decided to post-pone the effective date of the rule such that the label would be required on any portable generator manufactured or imported 120 days after the publication of the final rule in the **Federal Register**.

4. Labeling Text Issues

(a) Multiple Languages

Comments: Five comments address the issue of whether the message text of the proposed labeling should also be required in a language other than English. Two comments support the addition of other languages, and one of these suggests that Spanish be the second language to include. Two comments oppose requiring additional languages. The remaining comment does not take a position on the matter, but suggests that Spanish is the appropriate language to include if another language is added.

Response: The staff's previous analyses of generator-related incident data have revealed no pattern of incidents involving people who could not read English. To confirm this, the staff of the CPSC Directorate for Epidemiology (EP) selected and thoroughly examined a random sample of 25 out of 150 in-depth investigations into generator-related CO-poisoning deaths that occurred in the 2002 to 2005 time frame. None of the examined investigation reports described the victims' literacy in English, Spanish, or any other language. Consequently, these investigations provide no basis for concluding that labeling in Spanish would have prevented deaths.

According to the 2000 U.S. census, most people who speak a language other than English at home speak Spanish, with Chinese ranking a very distant second (Shin & Bruno, 2003).[9] Additionally, the National Center for Education Statistics (NCES) has found that about 35 percent of American adults who have below basic literacy in English prose [10] spoke Spanish before starting school; only 9 percent could not speak either English or Spanish (NCES, 2005). Adding Spanish to an English-language warning label, therefore, would be expected to improve its readability among the U.S. population more than adding any other language. Nevertheless, the overall impact of adding Spanish to a label may be small. In the case of portable generators, Synovate DuraTrend™ consumer survey data obtained by the EC staff show that only 5.6 percent of generator purchasers in 2005 were Hispanic. Furthermore, many of these people are likely to be literate in English; for example, less than half of all adult Hispanics in the U.S. have below basic literacy in English prose (NCES, 2005). Thus, Hispanics with below basic literacy in English prose—the sub-population most likely to include individuals who cannot read English yet can read Spanish, and who would potentially benefit the most from the addition of Spanish to the proposed warning label—almost certainly represent less than five percent of all generator purchasers in the U.S., and may comprise substantially less than this. Some of these people may also lack basic literacy in Spanish and, therefore, would be unable to read a label even if it included written Spanish. Despite these findings, the Commission does not dismiss the potential usefulness of providing the information in the labeling in Spanish, especially in regions of the country with large Hispanic populations. Thus, the rule does not prohibit manufacturers from providing a Spanish-language version of the labeling in addition to the prescribed English-language label. If the product label is provided by the manufacturer in additional languages, however, the staff believes that additional-language versions of the label should appear adjacent to or below the English-language version of the product label. This formatting is consistent with ANSI Z535.4—2002, the most recent published version of the American National Standard for Product Safety Signs and Labels. The staff further recommends that any additional-language versions of the label, whether they be on the product or on the generator package, be no larger than the English-language version of the label. Thus, the final rule includes these requirements at § 1407.3(a)(1) and § 1407.3(a)(2).

(b) Signal Word Choice

Comments: Four comments assert that the signal word WARNING is more appropriate than DANGER for the proposed labeling. Arguments made by the commenters include that the use of DANGER is inconsistent with the hierarchy specified in the ANSI Z535

[9] Among the 262.4 million people in the U.S. aged 5 years or older, 47.0 million (18 percent) speak a language other than English at home. About 60 percent of these (28.1 million) speak Spanish and about 0.4 percent (2.0 million) speak Chinese.

[10] Those with below basic literacy in English prose lack the skills necessary to perform simple everyday literacy activities such as reading and understanding information in short commonplace continuous texts.

series of standards and that its use might reduce the perceived risk associated with the WARNING hazards of fire during refueling, electrocution from use in wet conditions, and electrocution from connection to a commercial power source.

Response: According to the ANSI Z535 series of standards, the selection of a signal word for a hazard label should be made based on the seriousness of the hazard situation or scenario. For example, ANSI Z535.4—2002, the most recent published version of the American National Standard for Product Safety Signs and Labels, defines DANGER as an ''imminently hazardous situation which, if not avoided, will result in death or serious injury'' (Section 4.13.1). The latest revision of ANSI Z535.4 clarifies that use of the term—will'' in this definition indicates an event that is nearly, but not absolutely, certain (Annex E, due for publication 2006). While the mere presence of carbon monoxide in portable generator exhaust could lead to death or serious injury, the use of generators indoors—the hazard scenario specifically highlighted in the label—would almost certainly result in death or serious injury due to a generator's high rate of CO production (for example, see Inkster, 2004). The CPSC continues to believe, therefore, that DANGER is the appropriate signal word for the proposed labeling.

The Commission cannot confirm the assertion that using DANGER for the CO poisoning hazard would necessarily reduce the perceived hazard associated with the WARNING hazards mentioned. One could argue instead that the use of DANGER simply increases the perceived hazard associated with CO poisoning without having any effect on consumer perceptions related to the other hazards being warned about on the product. Additionally, the selection of a signal word for a given hazard is supposed to be based on the standard signal-word definitions (for example, those used in ANSI Z535.4), which denote the seriousness of the hazard situation or scenario, not on how the signal word might impact the perceptions of hazard labels that use other signal words. To the extent that a hazard situation or scenario is serious enough to demand the use of DANGER, one would expect and hope that people exposed to the hazard label would correctly interpret this as meaning that the hazard situation is more serious than a hazard label that relies on a less serious signal word such as WARNING or CAUTION. Accordingly, the final rule requires that the label include the signal word DANGER.

(c) Message Text Issues

Comments: Five comments are associated with the specific message text of the proposed labeling. Two comments express concerns that the message text has not been independently tested—for example, through the use of focus groups—and suggest various alternatives to the wording of this text. Both also argue that the phrase, ''* * * WILL KILL YOU IN MINUTES'' is not accurate. One comment includes the results of focus group testing, performed on low-literacy individuals by a contractor for the U.S. Environmental Protection Agency (EPA), which found that some people had difficulty understanding the phrase ''partly enclosed area'' and misinterpreted the word ''gas'' as gasoline. The contractor recommended that ''partly enclosed area'' be deleted from the label. One comment states that the label does not alert consumers to the symptoms of CO poisoning or refer users to the manual for additional instructions. Another comment states that the phrase, ''Please read the manual before use,'' is already attached to the generator in another label and that, therefore, the packaging label should be identical to the product label if one is used. One comment recommends the addition of the phrase, ''FOR OUTDOOR USE ONLY,'' after the initial sentence of the proposed labeling.

Response: As referenced in the comment summary, above, an independent contractor performed focus group testing on the proposed product label with low literacy individuals as part of the EPA's efforts to develop a flood-cleanup brochure. This testing identified two specific comprehension problems with the message text of the proposed labeling. First, testing revealed that some low-literacy individuals had difficulty understanding the phrase ''partly enclosed area.'' The available CPSC data on CO poisoning deaths associated with portable generators show that most incidents in which the generator was reportedly used in an enclosed or partially enclosed area occurred either within the home or in a garage or enclosed carport (Marcy & Ascone, 2005). Thus, the staff believes it would be acceptable to remove ''partly enclosed area'' from the proposed labeling, as recommended by the EPA's contractor. The staff is concerned, however, about simply deleting this phrase, since its absence could mislead some into believing that generators are only hazardous if used in fully enclosed areas. Thus, the staff recommends adding the phrase, ''EVEN IF doors and windows are open,'' to the end of the revised portion of the warning. The entire relevant statement, therefore, is changed in the final rule from, ''NEVER use in the home or in partly enclosed areas such as garages, '' to, ''NEVER use inside a home or garage, EVEN IF doors and windows are open.''

The testing also revealed that ''gas'' may be misinterpreted as ''gasoline'' by some low literacy individuals. To address this comment, the label is revised to read as follows: ''Exhaust contains carbon monoxide, a poison gas you cannot see or smell,'' with, ''Generator exhaust contains carbon monoxide. This is a poison you cannot see or smell.'' Because they address the specific comprehension problems identified with the message text during testing, these revisions should make the proposed labeling more understandable to all generator users. The CPSC staff believes that an explanation of the intended function of a portable generator, which the EPA 's testing contractor also recommended adding, is unnecessary for a product label since people who do not know this information are unlikely to purchase, rent, borrow, or otherwise use a portable generator. Thus, the final rule does not include an explanation of the intended function of a portable generator.

The staff agrees that the sentence, ''Using a generator indoors WILL KILL YOU IN MINUTES,'' is questionable because death may occur in a longer time frame than what most people would deem ''in minutes'' and because generator use indoors may result in severe CO poisoning rather than death. The staff is also concerned that people who have previously used a generator indoors and survived could question the credibility of a label that states death is essentially inevitable. If the label is not credible, people may choose to ignore the safety message. Therefore, the Commission has revised this statement to read, ''Using a generator indoors CAN KILL YOU IN MINUTES.'' This revision has no effect on the appropriateness of using DANGER as the signal word for this label, as discussed earlier, since the use of generators indoors would still almost certainly result in death or serious injury due to a portable generator's high rate of CO production. The revised phrase simply emphasizes the possibility that death can occur within minutes.

In its 2003 memorandum that proposed warning labels to accompany portable generators, the CPSC staff specifically recommended against including a description of CO-poisoning symptoms within the product label because this information would add a substantial amount of text to the label

and was believed to be of limited value for a label to be affixed to the product itself (Smith, 2003). The staff continues to support this position. Regarding the statement, ''See product manual for more details,'' which originally appeared at the bottom of the on-product label in the staff's 2003 memorandum (Smith, 2003), the staff does not believe this statement should be required on portable generators because the information that is provided in the labeling required in this final rule addresses the key safety information of which people must be aware when using a generator and generator manufacturers may include a statement that refers users to the product manual elsewhere on the generator. As pointed out in one public comment, some manufacturers already include the phrase, '' Please read the manual before use,'' in other generator labels. For the packaging label, however, the statements, ''Avoid other generator hazards. READ MANUAL BEFORE USE,'' are needed since this label may very well be the only label on the packaging that will alert the purchaser to possible hazards associated with generator use. Therefore, the provision has been retained in the final rule.

The CPSC staff believes it would be inappropriate to add the phrase, ''FOR OUTDOOR USE ONLY,'' after the initial sentence of the message text in the proposed labeling. Placing this phrase after the initial sentence interrupts the logical flow of the warning from the explanation of the hazard situation to the descriptions of the appropriate hazard avoidance behaviors. A more appropriate location for this phrase, if it were used, would be at the beginning of the message text as the first sentence of the warning. However, the staff is concerned that using this phrase as the first sentence would tend to de-emphasize the description of the hazard situation and its consequences (that is, ''Using a generator indoors CAN KILL YOU IN MINUTES.''), could lead people to stop reading further because it is a highly familiar phrase that people are likely to believe they already understand, and is redundant with the already-present and more-detailed admonition to use the generator outside and far away from windows, doors, and vents. Thus, although this statement would not add a substantial amount of text to the label, the Commission does not believe it should be added to the labeling and the statement is not included in the final rule. However, manufacturers are not prohibited from including a statement of this kind elsewhere on the product, packaging, or product manual.

5. Labeling Pictogram and Symbol Issues

(a) Prohibition Symbol Choice

Comments: Four comments propose the use of a circle-slash symbol rather than an ''X'' symbol to indicate prohibited actions in the pictograms that appear in the proposed labeling. Arguments made within these comments in favor of the circle-slash symbol include the fact that it is consistent with the ANSI Z535 series of standards, is internationally recognized, and obscures less of the underlying pictogram than an ''X.'' One comment states that a transparent circle-slash symbol may be superior since it does not obscure the underlying pictorials.

Response: The CPSC staff acknowledges that the ANSI Z535 series of standards recommends the use of a circle-slash symbol to indicate prohibited actions in pictograms. When developing the proposed labeling, the CPSC staff chose to use ''X'' symbols rather than circle-slash symbols because both the circle-slash and ''X'' symbols are commonly recognized as conveying the prohibition concept (Dreyfuss, 1972; Wogalter & Leonard, 1999), there was no evidence that English-reading consumers would have difficulty understanding the meaning of an ''X'' symbol, and the only known evidence of comprehension problems with either prohibition symbol were those encountered with the circle-slash symbol by some Latin American individuals during charcoal-pictogram testing previously performed for the CPSC (Requirements for Labeling of Retail Containers of Charcoal, 1996). The staff also found that circle-slash symbols tended to obscure more of the underlying pictograms than did ''X'' symbols of the same size. For example, the circle portion of the circle-slash symbols tended to obscure the outlines of the home and garage pictograms, making these portions of the pictograms difficult to discern. Since publication of the **Federal Register** notice regarding the NPR, the staff has become aware of an internal Douglas Aircraft research report that identified possible comprehension problems with the use of an ''X'' to indicate prohibition. For example, the researchers found that a graphic using an ''X'' to indicate that a part should not be touched was misinterpreted by some as meaning the opposite, indicating where the person should touch (Johnson, 1974, as cited in Johnson, 2006). In light of this research, the staff agrees that the use of ''X'' symbols rather than circle-slash symbols to indicate prohibition in the proposed labeling may not be preferable. The final rule, therefore, includes the opaque circle-slash symbols rather than ''X'' symbols. Additionally, to avoid problems with the circle-slash obscuring the outlines of the home and garage, the final rule uses smaller circle-slash symbols, centered over the generator pictograms. Although a transparent circle-slash symbol would not obscure the underlying symbol, its use is inconsistent with the prohibition symbol recommended in the ANSI Z535 series of standards.

(b) Use of Hazard-Avoidance Pictograms

Comments: Three comments are associated with the staff's decision to use pictograms depicting hazard avoidance behavior in the proposed labeling. Two comments state that these pictograms have not been independently tested, and question whether the pictograms of the generator will be readily recognized. One of these comments suggests that the standard hazardous gas/vapors pictogram, which shows a person inhaling gas, might be a better choice since it had undergone successful consumer testing. One comment, which includes the results of EPA-sponsored focus group testing on the proposed product label, reports that some low-literacy individuals had difficulty recognizing the generator pictogram. The contractor recommended enlarging this pictogram to improve the likelihood that it will be correctly identified.

Response: The CPSC staff had originally considered the use of the hazardous gas/vapors pictogram referred to in the comments, but expressed reservations about its use since the gas in the pictogram is visible even though carbon monoxide is not (Smith, 2003, 2006). The staff continues to be concerned about this potential for confusion. In addition, although testing has revealed that most people can recognize the referenced pictogram as indicating hazardous gas or vapors (Mayer & Laux, 1989), this pictogram provides no information regarding appropriate hazard-avoidance behaviors. In fact, since this pictogram could indicate hazardous gases with varying degrees of lethality, the appropriate hazard-avoidance behavior may vary substantially among different hazardous gases. For example, some products that release hazardous gases might be safely used within an open garage, but this is not true for an operating portable generator. The final rule uses pictograms depicting appropriate and inappropriate behaviors

specific to portable generators to avoid this ambiguity.

As discussed earlier, an independent contractor performed focus-group testing on the proposed product label with low-literacy individuals as part of the EPA's efforts to develop a flood-cleanup brochure. The only identified problem with the pictograms that appear in the proposed labeling was that some people had difficulty recognizing the graphic of the generator. These test results, however, almost certainly underestimate the extent to which the generator graphic would be recognized in a real-life scenario. For example, testing was not performed with the label affixed to a generator. When presented in the appropriate context, generator graphics are more likely to be recognized (Wogalter, Silver, Leonard, & Zaikina, 2006). Additionally, the EPA testing found that some of the participants in the testing did not even know what a generator was. People who do not know the intended function of a portable generator are unlikely to purchase, rent, borrow, or otherwise use a portable generator, and would not be expected to correctly identify a graphic of this product. Nevertheless, to improve the likelihood that people will correctly identify the generator graphic as a portable generator and to increase the overall legibility of the pictograms, the CPSC has slightly increased the size of the pictograms in the final rule, as recommended by the EPA's testing contractor. The Commission also notes that Section 1407.3(a)(1) of the final rule specifies that ''[a] different representation of the generator [within the proposed labeling] may be substituted for accuracy if consumers are more likely to recognize the substituted representation as the generator to which this label is affixed.'' Manufacturers, therefore, may substitute a graphic of the specific generator to which the label will be affixed if they so choose.

(c) Other Hazard-Avoidance Pictogram Issues

Comments: Five comments are associated with specific features of the hazard-avoidance pictograms that appeared within the proposed labeling. Two comments suggest deleting the symbol depicting the use of a generator within a garage. This pictogram, according to three comments, could be interpreted as meaning that one should not store the generator in a garage. Two comments claim that the two-headed arrow graphic that appears in the pictogram depicting appropriate behavior could be misinterpreted. One of these states that the two-headed arrow graphic could be interpreted as meaning that use both in and away from the home is acceptable; the commenter suggests that this arrow be replaced with a single-headed arrow that points away from the home. The other comment claims that this graphic could be interpreted as meaning that the person should connect the generator by electrical wire to a commercial power supply as a backup, and recommended deleting the pictogram entirely.

Response: The Commission believes that both pictograms that depict inappropriate behaviors—one showing generator use within a home or enclosed space and one showing generator use within a garage—are necessary to convey the key safety message. Relying solely on the pictogram of the generator within a home or enclosed space to indicate inappropriate behavior, as recommended by the commenters, could lead people to believe that generators are only hazardous if used within a completely enclosed space. Many CO-poisoning deaths associated with portable generators occurred when the generator was being used in a garage with the door at least partially open. The pictogram depicting generator use in the garage as being inappropriate directly addresses incidents of this type. Although the CPSC acknowledges that one could infer from these pictograms that generators should not be stored in the home or garage, alternative pictograms such as the poisonous gas/vapors pictogram are also open to various interpretations regarding appropriate and inappropriate behaviors specific to portable generators, as discussed in the response to the previous topic. As demonstrated by the earlier discussion of comprehension problems encountered with common prohibition symbols, virtually no hazard pictogram or symbol will be understood by all people. For this reason, explanatory text is very often recommended or required,[11] especially for complex hazards (Wogalter, Silver, Leonard, & Zaikina, 2006). The CPSC believes that the explanatory message text that appears in the label should limit the extent to which misinterpretations of the pictograms would prevent people from understanding the overall message of the labeling.

Regarding the use of a double-headed arrow in the pictogram depicting the appropriate use of a portable generator, the American National Standard Criteria for Safety Symbols, ANSI Z535.3, recommends the consistent use of arrow graphics to represent different types of movement or spatial relationships. Single-headed arrows are used to represent the motion of objects or components or to represent the exertion of pressure or force; in contrast, double-headed arrows are used to represent the idea of keeping a safe distance away from a hazard (ANSI Z535.3–2002, Figure A1). Thus, the use of a double-headed arrow is appropriate, and the direct replacement of the double-headed arrow with a single-headed one, as recommended by one commenter, would suggest the movement of the home toward the generator, which is opposite the intended meaning and could create critical confusion among the intended audience. Despite this, in the final rule issued today, the original appropriate-use pictogram is replaced with a pictogram that avoids the possible misinterpretations identified by the commenters yet remains consistent with ANSI Z535.3. This pictogram employs a single-headed arrow but places the arrow on the opposite side of the generator pictogram to suggest the movement of the generator away from the home. The length of the arrow has also been shortened so the generator pictogram is not located immediately adjacent to the graphic of the home.

6. Explicit Safe Distance

Comments: Six comments point out that the proposed labeling does not include an explicit distance (for example, measured in feet) that should be maintained between the generator and the home or other partially enclosed area. Some suggest that this distance could be inserted within the message text or within the pictogram depicting the generator being kept away from the home. One comment suggests a minimum distance of 10 feet; another comment suggests at least 15 feet.

Response: The CPSC agrees that explicitly identifying a safe operating distance between the generator and the home or other partially enclosed area would be more useful than relying on terms such as ''far,'' but has been unable to develop a consensus as to what distance is adequate given the widely varying conditions under which portable generators may be used. As discussed in the staff's 2006 briefing package on portable generator safety, some portable generator manufacturers currently provide minimum clearance requirements for placement of the

[11] ANSI Z535.3–2002 requires explanatory text for any symbol without demonstrated understandability; for example, one that is not understood by at least 85 percent of the target audience using the methodology specified in Annex B of the standard. Research suggests that few safety symbols can meet this requirement, so accompanying text is almost always required.

generator; however, these distances appear to represent the clearances needed to allow for adequate combustion and cooling airflow, not to avoid CO poisoning (Buyer, 2006). Variables such as the speed and direction of wind relative to openings to indoor spaces and the relative proximity of other structures to the generator complicate attempts to define a reasonably safe distance.

In a study of nonfatal CO-poisoning incidents following two major hurricanes in 2005, the Centers for Disease Control and Prevention (CDC) found that half of those interviewed who had been involved in generator-related incidents had placed the generator outside in the open, but that all of these individuals had placed the generator within seven feet of the home (CDC, 2006). Thus, a ''reasonably safe'' distance likely would be greater than seven feet. However, available data do not allow the Commission to reach consensus on how much farther than seven feet would constitute a reasonably safe distance. The phrase ''far away,'' used in the label required by this final rule, while not as explicit as a specified distance, still emphasizes the need to keep the generator well away from, rather than immediately outside, the home or other partially enclosed areas.

7. Labeling Placement

Comments: Three comments address the proposed location or placement of the label on the product. Two comments state that it is not technically feasible to meet a requirement that the label be placed on a part of the generator that, if removed, would impair the operation of the generator. The commenters propose an alternative requirement that the label be placed on a part of the portable generator that cannot be removed without the use of tools. One comment suggests that the label be located close to the ''on/off'' switch, the starter, or the power outlets, and suggests that the label be more ''active'' by requiring the user to take an action that draws attention to the label each time the generator is used.

Response: The Commission is not opposed to the commenters' proposed alternative requirement that the label be placed on a part that cannot be removed without the use of tools. Therefore, section 1407.3(a)(1)(iii)(A) of the final rule states, ''On a part of the portable generator that cannot be removed without the use of tools.'' Regarding the comment about making the label more ''active'' by requiring the user to take an action that draws attention to the label each time the generator is used, the Commission believes that such a requirement is unnecessary at this time since the label is already required to be placed in a location that is prominent and conspicuous to an operator while performing at least two of the following tasks: Filling the fuel tank, accessing the receptacle panel, and starting the engine (see section 1407.3(a)(1)(iii)(B) of the final rule).

8. Need for Packaging Label

Comments: Two comments propose that the requirement for a packaging label be dropped from the rule. Both believe this label is unnecessary since the packaging will be discarded.

Response: The intent of the packaging label is to directly provide potential purchasers of portable generators with information at the point of purchase emphasizing the danger of CO poisoning, and to reinforce the warning when the generator is removed from the packaging at home, not to assist consumers while they are operating the generator after the packaging is discarded. The packaging label provides the CO poisoning information irrespective of sales staff interaction or other messaging at the point of sale. Without the information presented by the packaging label, purchasers may not discover until they are home that they do not have an appropriate place to operate the generator. Accordingly, the proposed requirement for the packaging label is retained in this final rule.

9. Missing Manual Warning

Comments: One comment notes that a previous CPSC staff memo included a recommendation for a product-manual warning, which included information about CO-poisoning symptoms, and that the NPR does not include a recommendation for such a warning.

Response: The rule does not include specific recommendations for CO-poisoning warnings to appear within the manuals that accompany portable generators because prior analyses of the CO-poisoning information provided on the product and within the product manuals found that the product labeling was often far more deficient (Smith, 2002). Since the on-product labeling is available to consumers even after the product manual is lost, discarded, or otherwise not available, improved product labels are of paramount importance. The Commission does agree, however, that providing more detailed information about CO poisoning within the product manual, including information about the symptoms of CO poisoning, would be advantageous, and the staff may consider additional requirements of this type as part of the CPSC 's ongoing activities associated with improving portable generator safety.

10. Extension Cord Warning

Comments: One comment notes that increasing the distance between the generator and any partially enclosed spaces necessarily increases the distance between the generator and the load, which could result in some consumers using extension cords with insufficient capacity. The commenter suggests that a warning label that states, ''ONLY USE PROPERLY SIZED EXTENSION CORDS IN GOOD CONDITION,'' be affixed to the generator's electrical panel.

Response: The Commission agrees that the capacity and condition of extension cords to be used with portable generators must be adequate to support the intended load and allow the generator to be kept far away from homes and other partially enclosed areas. However, this issue is outside the scope of this rulemaking.

11. Alternatives to Labeling

Comments: Three comments suggest that labeling alone is not sufficient to address the CO-poisoning hazard and recommend technical solutions such as reduced CO emissions or integrated CO monitors that will automatically shut off the generator if necessary.

Response: Specific technical approaches to addressing the CO poisoning hazard associated with portable generators are outside the scope of this rule and are addressed in a separate Commission rulemaking commenced with the recent publication of an advance notice of proposed rulemaking, 71 FR 74472 (December 12, 2006).

L. Conclusion

For the reasons stated in this preamble, the Commission finds that a requirement for a carbon monoxide warning statement on portable generators is necessary to help protect the public against the risk of CO poisoning associated with such products.

List of Subjects in 16 CFR Part 1407

Consumer protection, labeling.

■ Therefore, for the reasons stated in the preamble, the Commission amends Title 16 of the Code of Federal Regulations by adding a new Part 1407 to read as follows:

PART 1407—PORTABLE GENERATORS: REQUIREMENTS TO PROVIDE PERFORMANCE AND TECHNICAL DATA BY LABELING

Sec.
1407.1 Purpose, scope, and effective date.
1407.2 Definitions.
1407.3 Providing performance and technical data to purchasers by labeling.

Authority: 15 U.S.C. 2076(e).

§ 1407.1 Purpose, scope, and effective date.

This part 1407 establishes requirements under section 27(e) of the Consumer Product Safety Act (15 U.S.C. 2076(e)) for manufacturers to provide consumers with a specified notification concerning the carbon monoxide poisoning hazard associated with the use of portable generators. The notification is intended to provide consumers with technical and performance information related to the safety of portable generators. This part applies to any generator manufactured or imported on or after May 14, 2007.

§ 1407.2 Definitions.

(a) The definitions in section 3 of the Consumer Product Safety Act (15 U.S.C. 2052) apply to this part 1407.

(b) A portable generator is an internal combustion engine-driven electric generator rated no higher than 15 kilowatts and 250 volts that is intended to be moved for temporary use at a location where utility-supplied electric power is not available. It has receptacle outlets for the alternating-current (AC) output circuits, and may have alternating- or direct-current (DC) sections for supplying energy to battery charging circuits.

§ 1407.3 Providing performance and technical data to purchasers by labeling.

(a) Notice to purchasers. Manufacturers of portable generators shall give notification of performance and technical data related to performance and safety to prospective purchasers of such products at the time of original purchase and to the first purchaser of such product for purposes other than resale, in the manner set forth below.

(1) On-product label. The CO poisoning hazard label shown in fig. 1 shall be used on the product. A different representation of the generator may be substituted for accuracy if consumers are more likely to recognize the substituted representation as the generator to which this label is affixed. Alternate-language versions of this label may appear on the product in addition to the label specified in figure 1. If the product label is also provided by the manufacturer in additional language(s), it shall appear adjacent to or below the English-language version of the product label, and shall be no larger than the English-language version of the label. Versions of the product label that are in a language other than English may appear without the pictograms that appear in the English-language versions.

(i) The signal word ''DANGER'' shall be in letters not less than 0.15 inch (3.8 mm) high. The remaining text shall be in type whose uppercase letters are not less than 0.1 inch (2.5 mm) high.

(ii) The signal word ''DANGER'' shall appear in white letters on a safety red background. The safety alert symbol shown in fig. 2 shall appear immediately before and next to the signal word and be no smaller than the height of the signal word with the base of the triangle on the same horizontal line as the base of the signal word. The solid portion of the triangle (within the lines of the triangle, around the exclamation mark) shall be white and the exclamation mark shall be safety red. The prohibition circle-slash symbols shall be opaque.

(iii) The on-product hazard label shown in fig. 1 shall be located:

(A) On a part of the portable generator that cannot be removed without the use of tools, and

(B) On a location that is prominent and conspicuous to an operator while performing at least two of the following actions: Filling the fuel tank, accessing the receptacle panel, and starting the engine.

(iv) The on-product hazard label shown in fig. 1 shall be designed to remain permanently affixed, intact, legible, and largely unfaded in the environment in which the product is expected to be operated and stored over the life of the product.

(2) Carbon monoxide poisoning hazard label for package. The CO poisoning hazard label shown in fig. 3 shall be affixed to the principal display panel(s) of the package, as well as the surface containing the top flaps of the package. The principal display panel(s) of the package is the portion(s) of the outer packaging that is designed to be most prominently displayed, shown, presented, or examined under conditions of retail sale. Any panel of the package that includes text in a language other than English shall also include a CO poisoning hazard label in that language. Alternate-language versions of the label, in addition to the label specified in figure 3, may also appear on the top flaps of the package as long as they are physically separate from one another. A different representation of the generator may be substituted for accuracy if consumers are more likely to recognize the substituted representation as the generator contained within the packaging.

(i) The signal word ''DANGER'' shall be in letters not less than 0.15 inch (3.8 mm) high. The remaining text shall be in type whose uppercase letters are not less than 0.1 inch (2.5 mm) high.

(ii) The signal word ''DANGER'' shall appear in white letters on a safety red background. The safety alert symbol shown in fig. 2 shall appear immediately before and next to the signal word and be no smaller than the height of the signal word with the base of the triangle on the same horizontal line as the base of the signal word. The solid portion of the triangle (within the lines of the triangle, around the exclamation mark) shall be white and the exclamation mark shall be safety red. The prohibition circle-slash symbols shall be opaque.

(b) [Reserved]

Figure 1 On-product carbon monoxide poisoning hazard label

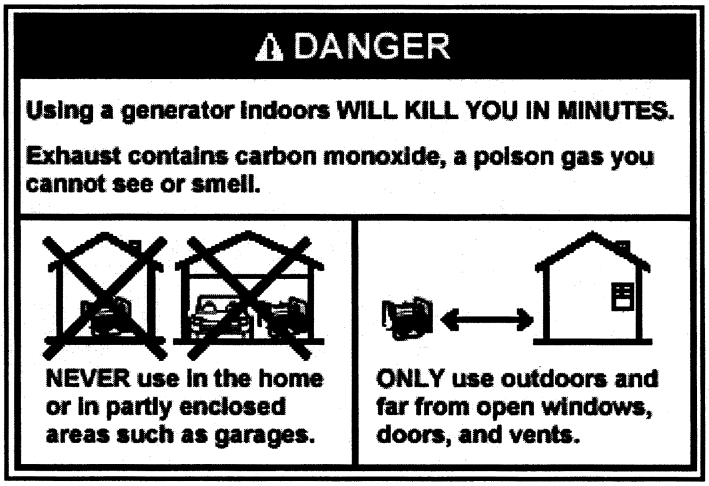
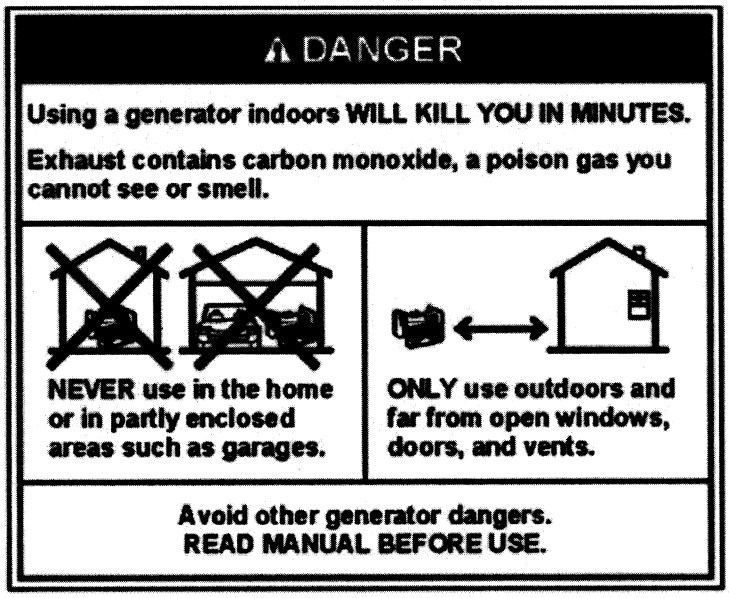


Figure 2 Safety Alert Symbol

Figure 3 Carbon monoxide poisoning hazard label for package



Note: The following appendix will not appear in the code of Federal Regulations.

Appendix—List of Relevant Documents

1. Memorandum from Timothy P. Smith, Engineering Psychologist, Division of Human Factors, Directorate for Engineering Sciences, to Janet L. Buyer, Project Manager, Division of Combustion and Fire Sciences, Directorate for Engineering Sciences, ''Product labels for generators to address carbon monoxide poisonings,'' May 26, 2006.

2. Memorandum from Robert Franklin, Economist, Directorate for Economic Analysis,''Economic Issues Related to a CO Warning Label on Portable Generators,'' December 27, 2006.

3. Memorandum from Natalie E. Marcy, Mathematical Statistician, Division of Hazard Analysis, Directorate of Epidemiology, and Debra S. Ascone, Mathematical Statistician, Division of Hazard Analysis, Directorate for Epidemiology, to Janet Buyer, Project Manager, Division of Combustion and Fire Sciences, Directorate for Engineering Sciences, '' Incidents, Deaths, and In-Depth Investigations Associated with Carbon Monoxide from Engine-Driven Generators and Other Engine-Driven Tools, 1990–2004,'' December 1, 2005.

4. Memorandum from Robin L. Ingle, Health Statistician, Division of Hazard Analysis, Directorate for Epidemiology, to Janet Buyer, Project Manager, Division of Combustion and Fire Sciences, Directorate for Engineering Sciences, ''Non-fire Carbon Monoxide Fatalities Associated with Engine-Driven Generators and Other Engine-Driven Tools in 2004 and 2005,'' January 13, 2006.

5. Memorandum from Robert Franklin, Directorate for Economic Analysis, ''Effective Date of CO Warning Label for Generators—Response to Comments,'' December 27, 2006.

Dated: January 5, 2007.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 07–80 Filed 1–11–07; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 11

[Docket No. RM07–5–000]

Update of the Federal Energy Regulatory Commission's Fees Schedule for Annual Charges for the Use of Government Lands

December 21, 2006.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule; update of Federal land use fees.

SUMMARY: In accordance with the Commission's regulations, the Commission by its designee, the Executive Director, is updating its schedule of fees for the use of government lands. The yearly update is based on the most recent schedule of fees for the use of linear rights-of-way prepared by the United States Forest Service. Since the next fiscal year will cover the period from October 1, 2006 through September 30, 2007 the fees in this notice will become effective October 1, 2006. The fees will apply to fiscal year 2007 annual charges for the use of government lands.

The Commission has concluded, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB that this rule is not a ''major rule'' as defined in section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C 804(2).

EFFECTIVE DATE: October 1, 2006.

FOR FURTHER INFORMATION CONTACT: Fannie Kingsberry, Division of Financial Services, Office of the Executive Director, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–6108.

SUPPLEMENTARY INFORMATION: *Document Availability:* In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

From FERC's Home Page on the Internet, this information is available in the eLibrary (formerly FERRIS). The full text of this document is available on eLibrary in PDF and MSWord format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

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List of Subjects in 18 CFR Part 11

Electric power, Reporting and recordkeeping requirements.

Thomas R. Herlihy,

Executive Director, Office of the Executive Director.

■ Accordingly, the Commission, effective October 1, 2006, amends part 11 of Chapter I, Title 18 of the Code of Federal Regulations, as follows:

PART 11—[AMENDED]

■ 1. The authority citation for part 11 continues to read as follows:

Authority: 16 U.S.C. 791a–825r; 42 U.S.C. 7101–7352.

■ 2. In part 11, Appendix A is revised to read as follows.

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2007

State	County	(Fee/acre/yr)
	.	
ALABAMA	ALL COUNTIES	$29.20
ARKANSAS	ALL COUNTIES	21.90
ARIZONA	COCHISE, GILA, GRAHAM, LA PAZ, MOHAVE, NAVAJO, PIMA, YAVAPAI, YUMA, COCONINO, (NORTH OF COLORADO R.).	7.28
	COCONINO (SOUTH OF COLORADO R.), GREENLEE, MARICOPA, PINAL, SANTA CRUZ	29.20
CALIFORNIA	IMPERIAL, INYO, LASSEN, MODOC, RIVERSIDE, SAN BERNARDINO	14.60
	SISKIYOU	21.90
	ALAMEDA, ALPINE, AMADOR, BUTTE, CALAVERAS, COLUSA, CONTRA COSTA, DEL NORTE, EL DORADO, FRESNO, GLENN, HUMBOLDT, KERN, KINGS, LAKE, MADERA, MARIPOSA, MENDICINO, MERCED, MONO, NAPA, NEVADA, PLACER, PLUMAS, SACRAMENTO, SAN BENITO, SAN JOAQUIN, SANTA CLARA, SHASTA, SIERRA, SOLANO, SONOMA, STANISLAUS, SUTTER, TEHAMA, TRINITY, TULARE KINGS, TUOLUMNE, YOLO, YUBA.	36.49
	LOS ANGELES, MARIN, MONTEREY, ORANGE, SAN DIEGO, SAN FRANCISCO, SAN LUIS OBISPO, SAN MATEO, SANTA BARBARA, SANTA CRUZ, VENTURA.	43.81
COLORADO	ADAMS, ARAPAHOE, BENT, CHEYENNE, CROWLEY, ELBERT, EL PASO, HUERFANO, KIOWA, KIT CARSON, LINCOLN, LOGAN, MOFFAT, MONTEZUMA, MORGAN, PUEBLO, SEDGEWICK, WASHINGTON, WELD, YUMA.	7.28
	BACA, BROOMFIELD, DOLORES, GARFIELD, LAS ANIMAS, MESA, MONTROSE, OTERO, PROWERS, RIO BLANCO, ROUTT, SAN MIGUEL.	14.60

State	County	(Fee/acre/yr)
	ALAMOSA, ARCHULETA, DBOULDER, CHAFFEE, CLEAR CREEK, CONEJOS, COSTILLA, CUSTER, DENVER, DELTA, DOUGLAS, EAGLE, FREMONT, GILPIN, GRAND, GUNNISON, HINSDALE, JACKSON, JEFFERSON, LAKE, LA PLATA, LARIMER, MINERAL, OURAY, PARK, PITKIN, RIO GRANDE, SAGUACHE, SAN JUAN, SUMMIT, TELLER.	29.20
CONNECTICUT	ALL COUNTIES	7.28
FLORIDA	BAKER, BAY, BRADFORD, CALHOUN, CLAY, COLUMBIA, DIXIE, DUVAL, ESCAMBIA, FRANKLIN, GADSDEN, GILCHRIST, GULF, HAMILTON, HOLMES, JACKSON, JEFFERSON, LAFAYETTE, LEON, LIBERTY, MADISON, NASSAU, OKALOOSA, SANTA ROSA, SUWANNEE, TAYLOR, UNION, WAKULLA, WALTON, WASHINGTON.	43.81
	ALL OTHER COUNTIES	72.97
GEORGIA	ALL COUNTIES	43.81
IDAHO	CASSIA, GOODING, JEROME, LINCOLN, MINIDOKA, ONEIDA, OWYHEE, POWER, TWIN FALLS	7.28
	ADA, ADAMS, BANNOCK, BEAR LAKE, BENEWAH, BINGHAM, BLAINE, BOISE, BONNER, BONNEVILLE, BOUNDARY, BUTTE, CAMAS, CANYON, CARIBOU, CLARK, CLEARWATER, CUSTER, ELMORE, FRANKLIN, FREMONT, GEM, IDAHO, JEFFERSON, KOOTENAI, LATAH, LEMHI, LEWIS, MADISON, NEZ PERCE, PAYETTE, SHOSHONE, TETON, VALLEY, WASHINGTON.	21.90
ILLINOIS	ALL COUNTIES	21.90
INDIANA	ALL COUNTIES	36.49
KANSAS	MORTON	14.60
	ALL OTHER COUNTIES	7.28
KENTUCKY	ALL COUNTIES	21.90
LOUISIANA	ALL COUNTIES	43.81
MAINE	ALL COUNTIES	21.90
MICHIGAN	ALGER, BARAGA, CHIPPEWA, DELTA, DICKINSON, GOGEBIC, HOUGHTON, IRON, KEWEENAW, LUCE, MACKING, MARQUETTE, MENOMINEE, ONTONAGON, SCHOOLCRAFT.	21.90
	ALL OTHER COUNTIES	29.20
MINNESOTA	ALL COUNTIES	21.90
MISSISSIPPI	ALL COUNTIES	29.20
MISSOURI	ALL COUNTIES	21.90
MONTANA	BIG HORN, BLAINE, CARTER, CASCADE, CHOUTEAU, CUSTER, DANIELS, MCCONE, MEAGHER, DAWSON, FALLON, FERGUS, GARFIELD, GLACIER, GOLDEN VALLEY, HILL, JUDITH BASIN, LIBERTY, MUSSELSHELL, PETROLEUM, PHILLIPS, PONDERA, POWDER RIVER, PRAIRIE, RICHLAND, ROOSEVELT, ROSEBUD, SHERIDAN, TETON, TOOLE, TREASURE, VALLEY, WHEATLAND, WIBAUX, YELLOWSTONE.	7.28
	BEAVERHEAD, BROADWATER, CARBON, DEER LODGE, FLATHEAD, GALLATIN, GRANITE, JEFFERSON, LAKE, LEWIS & CLARK, LINCOLN, MADISON, MINERAL, MISSOULA, PARK, POWELL, RAVALLI, SANDERS, SILVER BOW, STILLWATER, SWEET GRASS.	21.90
NEBRASKA	ALL COUNTIES	7.28
NEVADA	CHURCHILL, CLARK, ELKO, ESMERALDA, EUREKA, HUMBOLDT, LANDER, LINCOLN, LYON, MINERAL, NYE, PERSHING, WASHOE, WHITE PINE.	3.65
	CARSON CITY, DOUGLAS, STORY	36.49
NEW HAMPSHIRE	ALL COUNTIES	21.90
NEW MEXICO	CHAVES, CURRY, DE BACA, DONA ANA, EDDY, GRANT, GUADALUPE, HARDING, HIDALGO, LEA, LUNA, MCKINLEY, OTERO, QUAY, ROOSEVELT, SAN JUAN, SOCORRO, TORRENCE.	7.28
	RIO ARRIBA, SANDOUAL, UNION	14.60
	BERNALILLO, CATRON, CIBOLA, COLFAX, LINCOLN, LOS ALAMOS, MORA, SAN MIGUEL, SANTA FE, SIERRA, TAOS, VALENCIA.	29.20
NEW YORK	ALL COUNTIES	29.20
NORTH CAROLINA	ALL COUNTIES	43.81
NORTH DAKOTA	ALL COUNTIES	7.28
OHIO	ALL COUNTIES	29.20
OKLAHOMA	BEAVER, CIMARRON, ROGER MILLS, TEXAS	14.60
	LE FLORE, MC CURTAIN	21.90
	ALL OTHER COUNTIES	7.28
OREGON	HARNEY, LAKE, MALHEUR	7.28
	BAKER, CROOK, DESCHUTES, GILLIAM, GRANT, JEFFERSON, KLAMATH, MORROW, SHERMAN, UMATILLA, UNION, WALLOWA, WASCO, WHEELER,.	14.60
	COOS, CURRY, DOUGLAS, JACKSON, JOSEPHINE	21.90
	BENTON, CLACKAMAS, CLATSOP, COLUMBIA, HOOD RIVER, LANE, LINCOLN, LINN, MARION, MULTNOMAH, POLK, TILLAMOOK, WASHINGTON, YAMHILL.	29.20
PENNSYLVANIA	ALL COUNTIES	29.20
PUERTO RICO	ALL	43.81
SOUTH CAROLINA	ALL COUNTIES	43.81
SOUTH DAKOTA	BUTTE, CUSTER, FALL RIVER, LAWRENCE, MEAD, PENNINGTON	21.90
	ALL OTHER COUNTIES	7.28
TENNESSEE	ALL COUNTIES	29.20
TEXAS	CULBERSON, EL PASO, HUDSPETH	7.28
	ALL OTHER COUNTIES	43.81
UTAH	BEAVER, BOX ELDER, CARBON, DUCHESNE, EMERY, GARFIELD, GRAND, IRON, JUAB, KANE, MILLARD, SAN JUAN, TOOELE, UINTAH, WAYNE.	7.28
	WASHINGTON	14.60
	CACHE, DAGGETT, DAVIS, MORGAN, PIUTE, RICH, SALT LAKE, SANPETE, SEVIER, SUMMIT, UTAH, WASATCH, WEBER.	21.90

State	County	(Fee/acre/yr)
VERMONT	ALL COUNTIES	29.20
VIRGINIA	ALL COUNTIES	29.20
WASHINGTON	ADAMS, ASOTIN, BENTON, CHELAN, COLUMBIA, DOUGLAS, FRANKLIN, GARFIELD, GRANT, KITTITAS, KLICKITAT, LINCOLN, OKANOGAN, SPOKANE, WALLA WALLA, WHITMAN, YAKIMA,.	$14.60
	FERRY, PEND OREILLE, STEVENS	21.90
	CLALLAM, CLARK, COWLITZ, GRAYS HARBOR ISLAND, JEFFERSON, KING, KITSAP, LEWIS, MASON, PACIFIC, PIERCE, SAN JUAN, SKAGIT, SKAMANIA, SNOHOMISH, THURSTON, WAHKIAKUM, WHATCOM.	29.20
WEST VIRGINIA	ALL COUNTIES	29.20
WISCONSIN	ALL COUNTIES	21.90
WYOMING	ALBANY, CAMPBELL, CARBON, CONVERSE, GOSHEN, HOT SPRINGS, JOHNSON, LARAMIE, LINCOLN, NATRONA, NIOBRARA, PLATTE, SHERIDAN, SWEETWATER, FREMONT, SUBLETTE, UINTA, WASHAKIE.	7.28
	BIG HORN, CROOK, PARK, TETON, WESTON	21.90
ALL OTHER ZONES		5.74

[FR Doc. E6–22365 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2004P–0183]

RIN 0910–ZA27

Food Labeling: Nutrient Content Claims, Expansion of the Nutrient Content Claim ''Lean''

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its food labeling regulations for the expanded use of the nutrient content claim ''lean'' on the labels of foods categorized as ''mixed dishes not measurable with a cup'' that meet certain criteria for total fat, saturated fat, and cholesterol content. This final rule responds to a nutrient content claim petition submitted by Nestlé Prepared Foods Co. (Nestlé) under the Federal Food, Drug, and Cosmetic Act (the act). This action is also being taken to provide reliable information that would assist consumers in maintaining healthy dietary practices.

DATES: This final rule is effective January 12, 2007.

FOR FURTHER INFORMATION CONTACT: Vincent de Jesus, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1774.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 25, 2005 (70 FR 71041), FDA published a proposed rule to amend the definition of the nutrient content claim ''lean'' (21 CFR 101.62) to include foods categorized as ''mixed dishes not measurable with a cup'' that are regulated by FDA and that meet the criteria in the rule for total fat, saturated fat, and cholesterol. FDA issued this proposed rule in response to a petition filed under section 403(r)(4) of the act (21 U.S.C. 343(r)(4)) and in part 101 (21 CFR part 101) in § 101.69. Section 403(r)(2)(A)(i) of the act (21 U.S.C. 343(r)(2)(A)(i)) states that a nutrient content claim may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary of Health and Human Services (the Secretary) (and, by delegation, FDA). Section 403(r)(4) of the act sets out the procedures that FDA is to follow upon receiving a nutrient content claim petition.

On January 9, 2004, Nestlé (the petitioner) submitted a petition requesting that the agency amend the nutrient content claim regulation for ''lean'' (21 CFR 101.62(e)) to include ''mixed dishes not measurable with a cup'' as defined in the ''Reference amounts customarily consumed per eating occasion'' regulation (21 CFR 101.12), based on certain qualifying criteria for total fat, saturated fat, and cholesterol. FDA filed the petition for comprehensive review in accordance with section 403(r)(4) of the act on April 22, 2004.

FDA's definition of the nutrient content claim ''lean'' includes flesh foods, such as seafood and game meat products, which are foods that are similar to the U.S. Department of Agriculture (USDA)-regulated meat and poultry products, and also includes meal-type products (i.e., main dishes and meal products), which are included in the USDA definition. Prior to the publication of this final rule, FDA's definition of ''lean,'' did not extend to foods categorized as ''mixed dishes not measurable with a cup.'' Such foods, e.g., burritos, egg rolls, enchiladas, pizza, quiches, and sandwiches, are generally similar to the foods subject to the definition of ''main dish'' (21 CFR 101.13(m)) but do not meet the weight criterion for ''main dish'' foods (6 ounces (oz) per labeled serving). The Reference Amount Customarily Consumed (RACC) for ''mixed dishes not measurable with a cup'' is 140 grams (g) (5 oz) (21 CFR 101.12(b), Table 2), which is 1 oz less than the 6 oz per labeled serving required to qualify as a ''main dish.'' Thus, food products categorized as ''mixed dishes not measurable with a cup'' and that weigh less than 6 oz were not eligible to bear a ''lean'' nutrient content claim under § 101.62(e).

FDA considered the evidence presented in the petition as part of its review, as well as information previously considered by the agency in the January 6, 1993, nutrient content claim final rule (58 FR 2302). Based on the available evidence, FDA acknowledged the following in the proposed rule (70 FR 71041 at 71044):

- ''mixed dishes not measurable with a cup'' have found their way into the American diet and serve as a convenient ''meals-on-the-go'' eating option that is consistent with America's changing lifestyle;
- This category has become a well established product category that consumers have come to rely on; and
- There is a growing interest in healthful alternatives to traditional food options, including vegetarian alternatives.

FDA believes that portable food products, particularly those that are

nutrient (i.e., total fat, saturated fat, and cholesterol) and portion controlled, serve a useful purpose in assisting consumers in selecting a diet that is consistent with current dietary recommendations (e.g., Dietary Guidelines for Americans 2005). In this final rule, the agency concludes that providing a ''lean'' definition for ''mixed dishes not measurable with a cup'' will provide more consistency with similar USDA products and help consumers construct a diet that is consistent with current dietary recommendations (i.e., limiting dietary intake of saturated fat and cholesterol). The agency determined that the nutrient requirements for ''mixed dishes not measurable with a cup'' required in this final rule would allow it to achieve criteria which would enable consumers to maintain intakes of fat within current dietary recommendations without being unnecessarily restrictive. The agency is basing the nutrient criteria for total fat, saturated fat, and cholesterol on the current criteria for main dishes (21 CFR 101.13(m)), but applying the criteria to the RACC (140 grams (g)) for ''mixed dishes not measurable with a cup'' rather than the minimum weight for main dishes (170.1 g). The agency chose the main dish minimum weight requirement of 170.1 g (6 oz) for use in its calculations, rather than the 283.4 g (10 oz) minimum weight requirement for meal products because main dishes are closer to ''mixed dishes not measurable with a cup'' in portion, size, and contribution to the overall diet.

II. Summary of Comments and the Agency's Response

The agency received comments to the proposed rule from an individual consumer, a food manufacturer, an industry trade organization, a public interest foundation, and the petitioner. Three comments supported the proposed rule. One comment noted the need for consumer education for developing understanding of the nutrient content claim ''lean'' and the role of calories and nutrients in the diet. The remaining comments requested changes to the proposed rule. The latter comments and FDA's responses are set forth in this section (section II of this document), except the comment addressing the agency's regulatory impact analysis is discussed in the ''Analysis of Impact'' section of this document.

(Comment 1) One comment opposed the proposed rule because the proposed fat levels are too high. The comment did not provide any specific information or data in support of their position.

(Response) FDA disagrees with the comment. As we discussed in the proposed rule, the agency believes that the method we chose to establish total fat, saturated fat, and cholesterol levels (i.e., calculating the percent of the proportion of the weight of the RACC for ''mixed dishes not measurable with a cup'' (140 g) to the minimum weight of main dishes (170.1 g) and multiplying the percent by the nutrient criteria for total fat, saturated fat, and cholesterol for main dishes) is less restrictive than the other options considered and would potentially allow more foods for increased consumer choice. Moreover, we stated that consumers could achieve a diet using ''lean'' ''mixed dishes not measurable with a cup'' that is consistent with current dietary recommendations (70 FR 71041 at 71047). We retain this view in the final rule and this comment has not provided us with any information to support revising the proposed method for determining total fat, saturated fat, and cholesterol levels.

(Comment 2) Another comment opposing the proposed rule recommended that, if ''lean'' is considered to be a claim that represents ''healthier'' food options, nutrient eligibility criteria be modified for both FDA- and USDA- regulated foods to include limitations in ''negative'' nutrients'' (such as sodium) and include ''good'' nutrient requirements.

(Response) FDA disagrees with the comment. The term ''lean'' is a description of fat content. As a nutrient content claim, ''lean'' was first established by the USDA as a descriptor to allow consumers to distinguish between products of varying fat content (56 FR 60302, November 27, 1991). FDA subsequently established the claim ''lean'' for products that it regulated that had a contribution to the diet that was similar to the USDA-regulated products (i.e., seafood, game meat, meal products, and main dish products) (58 FR 632, January 6, 1993). FDA has already established other nutrient content claims to address a wider range of nutrients other than the nutrients describing fat content (e.g. healthy (21 CFR 101.65(d))). FDA believes that all nutrient requirements for the claim ''lean'' should remain descriptors of fat content in order for ''lean'' to continue to allow consumers to distinguish between products of varying fat content. Therefore, FDA is making no changes in response to this comment.

(Comment 3) One comment stated that FDA and USDA nutrient content claim requirements for foods in the ''mixed dishes not measurable with a cup'' category should be consistent and that different criteria will be confusing and provide no benefit for consumers or manufacturers.

(Response) FDA is aware of the difference between the FDA and USDA nutrient requirements as it acknowledged this difference in the proposed rule, and the agency considered these differences in developing FDA's proposed definition for ''lean.'' FDA has concluded, as described in the proposed rule, that FDA-regulated ''mixed dishes not measurable with a cup'' may not play a comparable role in the diet to that of meat and poultry products, may not contribute to the total dietary intake of total fat, saturated fat, and cholesterol like meat and poultry products, and may not be consumed in the same manner as USDA-regulated meal-type products. Because of the similarity in portion size and contribution to the overall diet to FDA-regulated main dishes, FDA has concluded that it is more appropriate to base the nutrient criteria for total fat, saturated fat, and cholesterol on the current criteria for main dishes, but apply the criteria to the RACC for ''mixed dishes not measurable with a cup.'' Calculating the nutrient criteria for ''mixed dishes not measurable with a cup'' per RACC from the current nutrient content criteria on the minimum weight for main dishes provides criteria for ''mixed dishes not measurable with a cup'' that are comparable in their contribution of total fat, saturated fat, and cholesterol on a per 100-g basis to that contributed by main dishes on a per 100-g basis. Moreover, the comment provided no basis for its assertion that the definition provides no benefit and would be confusing to consumers or manufacturers. Therefore, FDA is making no changes in response to this comment.

FDA is adopting as a final rule, without change, the proposed amendment to the ''lean'' definition in § 101.62(e) by allowing eligible foods categorized as ''mixed dishes not measurable with cup'' use of the nutrient content claim ''lean.''

III. Analysis of Economic Impacts

A. Regulatory Impact Analysis

FDA has examined the impacts of the final rule under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages;

distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action as defined by the Executive order.

Regulatory options

We considered regulatory options as follows: (1) Take no new regulatory action; and (2) adopt as final the proposed regulatory action allowing ''mixed dishes not measurable with a cup'' to contain a ''lean'' claim based on the proposed criteria of 8 grams of total fat, 3.5 grams or less of saturated fat, and 80 milligrams of cholesterol per reference amount customarily consumed.

Option (1): Take No New Regulatory Action

The first regulatory option, take no action, would require denying the Nestlé petition requesting that FDA authorize a nutrient content claim ''lean'' for ''mixed dishes not measurable with a cup.'' Taking no regulatory action to amend the definition of ''lean'' is the state of the world and our baseline. By convention, we treat the option of taking no new regulatory action as the baseline for determining the costs and benefits of the other options. Therefore, we associate neither costs nor benefits with this option. The consequences of taking no action are reflected in the costs and benefits of the other options.

Option (2): Adopt as Final the Proposed Regulatory Action

• *Benefits*

In the analysis of the proposed rule, we used sales data from the 1997 Economic Census, the prevalence of reduced-fat claims from FDA's Food Label and Packaging Survey, and the fat contents of representative ''mixed dishes not measurable with a cup'' from USDA's National Nutrient Database for Standard Reference to estimate the reduction in fat consumption to be between 0 and 0.02 percent, with a mean of 0.01 percent that would result from this rule. Moreover, we suggested that the magnitude of the reduction in total fat intake from consuming ''lean'' ''mixed dishes not measurable with a cup'' may be tempered if consumers supplement their ''lean'' selections with other higher-fat selections from other food categories. Finally, we suggested that there would be a price premium for ''mixed dishes not measurable with a cup,'' and to the extent that income and overweight status are negatively correlated, consumers at risk of overweight related diseases may be comparatively less likely to purchase ''lean'' ''mixed dishes not measurable with a cup'' than their higher-income counterparts with less-acute, weight-related health risks. This could mitigate overall health benefits from what they otherwise would be.

(Comment 4) One comment stated that our estimate of 0.67 percent of total food consumption represented by ''mixed dishes not measurable with a cup'' that could qualify for the ''lean'' claim, understates the full impact of this rule because it neglects to account for dynamic aspects of the market including growing consumer interest in healthier diets, and new product development. In addition, the comment suggested that the discussion of possible consumption behavior that would mitigate any reduction in fat intake, such as increased consumption of higher fat-containing foods to compensate for the consumption of reduced fat ''lean'' ''mixed dishes not measurable with a cup,'' is inappropriate for policies designed to promote the consumption of lean foods. The comment also stated that the discussion on possible diminishing effect on health benefits if there is a price premium for ''lean'' ''mixed dishes not measurable with a cup,'' and if incomes and health risks from overweight status are negatively correlated, is also inappropriate for the same reason. Finally, the comment suggested that any policy measure tending to increase consumption of lean foods, including a successful publicity campaign to increase consumption of green vegetables, could have both the ''compensating'' and price premium distributional effects.

(Response) FDA disagrees that our estimate of 0.67 percent of total food purchases that could potentially make a ''lean'' claim is inappropriate for this analysis because it does not consider dynamic aspects of consumption and production that would favor such products. While we do not disagree with the possibility of a general trend toward healthier diets and lifestyles, we believe the trend would just as likely affect the markets for food products from all categories as it would ''mixed dishes not measurable with a cup.'' Moreover, to characterize uncertainty in our methods used in the analysis, we estimated the upper end of the range for the reduction in fat intake that would result from this rule, to be 100 percent more than the mid-point which was estimated using the 0.67 percent share of total purchases that could potentially make a ''lean'' claim. Consequently, we believe that our estimated range incorporates a wide range of uncertainty, and is reasonable and based on sound data and assumptions.

In regulatory analyses, it is frequently easier to obtain quantitative estimates of the costs compared to the benefits of a rule because credible cost data is usually easier to obtain. The relative scarcity of quantitative estimates of benefits elevates the importance of qualitative descriptions in the benefits analysis. In the analysis of the proposed rule, FDA framed the qualitative discussion of the benefits from allowing the ''lean'' claim on ''mixed dishes not measurable with a cup'' on the theoretical framework used by Teisl and Levy in a study to address a related question (Ref. 1).

Consistent with Teisl and Levy, FDA assumed that consumer demand for a food product depends on its price, taste characteristics, and nutritional characteristics. The results obtained by Teisl and Levy indicate that all three characteristics are important determinants of consumer purchase behavior, and also that there is evidence of ''switching'' consumption behavior among many food products so that overall nutrient consumption (e.g., fat in that study) tends to remain constant or change less than predicted by a simple comparison of the nutrient contents of the products. In the analysis of the proposed rule we did not quantitatively estimate the size of the ''switching'' effect, but rather suggested its existence in order to fully describe the range of benefits of the final rule.

Consistent with our theoretical model, we also addressed the implications of a premium on the price for ''lean'' labeled ''mixed dishes not measurable with a cup,'' which may affect the size of the health benefits from the rule. The qualitative discussion is of heightened importance since evidence exists of a negative correlation between obesity and health risks from overweight status and income (Ref. 2). We agree that any regulation that promotes the consumption of lean foods, including a successful publicity campaign to increase consumption of green vegetables, could have both the ''compensating'' and price premium effects, and in the analysis of the proposed rule we applied that concept to ''mixed dishes not measurable with a cup.''

• *Costs*

There were no comments on the analysis of the costs, including estimates made of the voluntarily incurred change-over costs from the proposed rule. All costs incurred by manufacturers of ''mixed dishes not measurable with a cup'' who choose to label their products as ''lean'' would be voluntarily incurred because no manufacturer would incur them if it were not profitable to do so. We reproduce the estimated annualized voluntarily incurred re-labeling and reformulation costs estimated in the

analysis of the proposed rule using both a 3-percent and 7-percent discount rate.

TABLE 1.—ANNUALIZED VOLUNTARILY INCURRED CHANGE-OVER COSTS FOR PROPOSED RULE

	12-Month Time Period	24-Month Time Period
3-percent discount rate		
5 percent (low)	$32,000	$21,000
mean	$250,000	$151,000
95 percent (high)	$515,000	$308,000
7-percent discount rate		
5 percent (low)	$72,000	$46,000
mean	$561,000	$326,000
95 percent (high)	$1,158,000	$666,000

In table 1 of this document, we report the annualized change-over costs for the proposed rule computed assuming discount rates of 3 percent and 7 percent over an infinite time horizon for assumed 12- and 24-month periods for relabeling and reformulation. For a 12-month period, all costs are assumed to be incurred in the beginning of the second year. For a 24-month period, all costs are assumed to be incurred in the beginning of the third year. Because producers choose the time period for the reformulation and relabeling of products, the actual time periods for the changes can be of any length, with the costs differing from those in the table. From our labeling cost and reformulation models, however, we expect that costs would be substantially higher for time periods under 12 months, and substantially lower for time periods over 24 months (Refs. 3 and 4). We also expect that the time periods chosen would be shorter and the costs higher, the greater the perceived consumer response to these product claims.

B. Regulatory Flexibility Analysis

We have examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires the agency to analyze regulatory options that would minimize the economic impact of the rule on small entities.

As previously explained, the final rule will not generate any compliance costs for any small entities because it does not require small entities to undertake any new activity. No small business will choose to use the ''lean'' nutrient content claim authorized by this rule unless it believes that doing so will increase private benefits by more than it increases private costs. Accordingly, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Under the Regulatory Flexibility Act, no further analysis is required.

C. Unfunded Mandates

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532(a)) requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing any final rule ''that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Environmental Impact

FDA has determined under 21 CFR 25.32(p) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

FDA concludes that the labeling provisions of this final rule are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the food labeling nutrient content claim ''lean'' is a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 U.S.C. 1320.3(c)(2)).

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule will have a preemptive effect on State law. Section 4(a) of the Executive Order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Section 403A of the act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a)(5) of the act (21 U.S.C.

343–1(a)(5)) provides that: * * * no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—* * * ''(5) any requirement respecting any claim of the type described in section 403(r)(1) made in the label or labeling of food that is not identical to the requirement of section 403(r) * * *.''

Currently, this provision operates to preempt States from imposing nutrient content claim labeling requirements concerning the claim ''lean'' because FDA has imposed such requirements under section 403(r) of the act. This final rule amends existing food labeling regulations to add a definition for the claim ''lean'' for eligible foods categorized as ''mixed dishes not measurable with a cup.'' Although this rule has a preemptive effect, in that it would preclude States from promulgating any nutrient content claim labeling requirements for the claim ''lean'' that are not identical to those required by this final rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act. Section 403A(a)(5) of the act displaces both State legislative requirements and State common law duties. *Medtronic* v. *Lohr*, 518 U.S. 470, 503 (1996) (Breyer, J., concurring in part and concurring in judgment); *id. at 510* (O'Connor, J., joined by Rehnquist, C.J., Scalia, J., and Thomas, J., concurring in part and dissenting in part); *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality opinion); *id. at 548–49* (Scalia, J., joined by Thomas, J., concurring in judgment in part and dissenting in part).

FDA believes that the preemptive effect of the final rule is consistent with Executive Order 13132. Section 4(e) of the Executive order provides that ''when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' FDA provided the States with an opportunity for appropriate participation in this rulemaking when it sought input from all stakeholders through publication of the proposed rule in the **Federal Register** on November 25, 2005 (70 FR 71041). FDA received no comments from any states on the proposed rulemaking.

In addition, on February 16, 2006, FDA's Division of Federal and State Relations provided notice by fax and email transmission to State health commissioners, State agriculture commissioners, food program directors, and drug program directors as well as FDA field personnel, of FDA's intended amendment to add a definition for the claim ''lean'' for eligible foods categorized as ''mixed dishes not measurable with a cup'' (21 CFR 101.62(e)). The notice provided the States with further opportunity for input on the rule. It advised the States of the publication of the proposed rule and encouraged State and local governments to review the notice and to provide any comments to the docket (docket number 2004P–0183), opened in the November 25, 2005 **Federal Register**, by a date 75 days from the date of the notice (i.e., by March 2, 2006), or to contact certain named individuals. FDA received no comments in response to this notice. The notice has been filed in the above numbered docket.

In conclusion, the agency believes that it has complied with all of the applicable requirements under the Executive order and has determined that the preemptive effects of this rule are consistent with Executive Order 13132.

VIII. References

The following references have been placed on display in the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Teisl, M. and A. Levy, ''Does Nutrition Labeling Lead to Healthier Eating?'' *Journal of Food Distribution Research*, October 1997.

2. Drewnowski, A., and S. Specter, ''Poverty and Obesity: The Role of Energy Density and Energy Costs,'' The American Journal of Clinical Nutrition, Vol. 79, No. 1: 6–16, January 2004.

3. RTI International, ''Cost of Reformulating Foods and Cosmetics, Final Report,'' prepared for Ed Puro, FDA, Center for Food Safety and Applied Nutrition (CFSAN), prepared by White, W.J., E. Gledhill, S. Karns, and M. Muth, RTI Project Number 08184.003, July 2002.

4. RTI International, ''FDA Labeling Cost Model, Final Report,'' prepared for Amber Jessup, FDA, CFSAN, prepared by Muth, M., E. Gledhill, and S. Karns, RTI Project Number 06673.010, January 2003.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. Section 101.62 is amended by revising paragraph (e) to read as follows:

§ 101.62 Nutrient content claims for fat, fatty acid, and cholesterol content of foods.

* * * * *

(e) *''Lean'' and ''extra lean'' claims.* (1) The term ''lean'' may be used on the label or in labeling of foods except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m) provided that the food is a seafood or game meat product and as packaged contains less than 10 g total fat, 4.5 g or less saturated fat, and less than 95 mg cholesterol per reference amount customarily consumed and per 100 g;

(2) The term defined in paragraph (e)(1) of this section may be used on the label or in labeling of a mixed dish not measurable with a cup as defined in § 101.12(b) in table 2, provided that the food contains less than 8 g total fat, 3.5 g or less saturated fat and less than 80 mg cholesterol per reference amount customarily consumed;

(3) The term defined in paragraph (e)(1) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) or main dish products as defined in § 101.13(m) provided that the food contains less than 10 g total fat, 4.5 g or less saturated fat, and less than 95 mg cholesterol per 100 g and per labeled serving;

(4) The term ''extra lean'' may be used on the label or in the labeling of foods except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m) provided that the food is a discrete seafood or game meat product and as packaged contains less than 5 g total fat, less than 2 g saturated fat, and less than 95 mg cholesterol per reference amount customarily consumed and per 100 g; and

(5) The term defined in paragraph (e)(4) of this section may be used on the label or in labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m) provided that the food contains less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g and per labeled serving.

* * * * *

Dated: January 8, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–330 Filed 1–11–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 807, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, and 892

[Docket No. 2006N–0335]

Medical Devices; Reprocessed Single-Use Devices; Requirement for Submission of Validation Data; Withdrawal

ACTION: Direct final rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) published a direct final rule that appeared in the **Federal Register** of September 25, 2006 (71 FR 55729), that would have amended certain classification regulations for reprocessed single-use devices (SUDs) whose exemption from premarket notification (510(k)) requirements have been terminated and other reprocessed SUDs already subject to premarket notification for which validation data, as specified under the Medical Device User Fee and Modernization Act of 2002, are necessary in a 510(k). FDA stated in the direct final rule that, if it received a significant adverse comment by December 11, 2006, FDA would publish a notice of withdrawal. FDA received two comments and considers at least one of these comments a significant adverse comment and, therefore, is withdrawing the direct final rule. Accordingly, the agency will consider the comments received under our usual procedures for notice and comment in connection with the notice of proposed rulemaking that was published in the **Federal Register** of September 25, 2006 (71 FR 55748) as a companion to the direct final rule.

DATES: The direct final rule published at 71 FR 55729 on September 25, 2006, is withdrawn as of January 12, 2007.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4040.

Authority: Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the direct final rule published on September 25, 2006 (71 FR 55729), is withdrawn.

Dated: January 9, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–105 Filed 1–9–07; 2:49 pm]

BILLING CODE 4160–01–S

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4022 and 4044

Benefits Payable in Terminated Single-Employer Plans; Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing and Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation's regulations on Benefits Payable in Terminated Single-Employer Plans and Allocation of Assets in Single-Employer Plans prescribe interest assumptions for valuing and paying benefits under terminating single-employer plans. This final rule amends the regulations to adopt interest assumptions for plans with valuation dates in February 2007. Interest assumptions are also published on the PBGC's Web site (*http://www.pbgc.gov*).

DATES: Effective February 1, 2007.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion, Manager, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: The PBGC's regulations prescribe actuarial assumptions—including interest assumptions—for valuing and paying plan benefits of terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions are intended to reflect current conditions in the financial and annuity markets.

Three sets of interest assumptions are prescribed: (1) A set for the valuation of benefits for allocation purposes under section 4044 (found in Appendix B to Part 4044), (2) a set for the PBGC to use to determine whether a benefit is payable as a lump sum and to determine lump-sum amounts to be paid by the PBGC (found in Appendix B to Part 4022), and (3) a set for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology (found in Appendix C to Part 4022).

This amendment (1) adds to Appendix B to Part 4044 the interest assumptions for valuing benefits for allocation purposes in plans with valuation dates during February 2007, (2) adds to Appendix B to Part 4022 the interest assumptions for the PBGC to use for its own lump-sum payments in plans with valuation dates during February 2007, and (3) adds to Appendix C to Part 4022 the interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology for valuation dates during February 2007.

For valuation of benefits for allocation purposes, the interest assumptions that the PBGC will use (set forth in Appendix B to part 4044) will be 5.13 percent for the first 20 years following the valuation date and 4.80 percent thereafter. These interest assumptions represent an increase (from those in effect for January 2007) of 0.25 percent for the first 20 years following the valuation date and 0.25 percent for all years thereafter.

The interest assumptions that the PBGC will use for its own lump-sum payments (set forth in Appendix B to part 4022) will be 3.00 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. These interest assumptions represent an increase (from those in effect for January 2007) of 0.25 percent in the immediate annuity rate and are otherwise unchanged. For private-sector payments, the interest assumptions (set forth in Appendix C to part 4022) will be the same as those used by the PBGC for determining and paying lump sums (set forth in Appendix B to part 4022).

The PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the valuation and payment of benefits in plans with valuation dates during February 2007, the PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

The PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects

29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 4044

Employee benefit plans, Pension insurance, Pensions.

■ In consideration of the foregoing, 29 CFR parts 4022 and 4044 are amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 160, as set forth below, is added to the table.

Appendix B to Part 4022—Lump Sum Interest Rates for PBGC Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	*
160	2–1–07	3–1–07	3.00	4.00	4.00	4.00	7	8

■ 3. In appendix C to part 4022, Rate Set 160, as set forth below, is added to the table.

Appendix C to Part 4022—Lump Sum Interest Rates for Private-Sector Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	*
160	2–1–07	3–1–07	3.00	4.00	4.00	4.00	7	8

PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS

■ 4. The authority citation for part 4044 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.

■ 5. In appendix B to part 4044, a new entry for February 2007, as set forth below, is added to the table.

Appendix B to Part 4044—Interest Rates Used to Value Benefits

* * * * *

For valuation dates occurring in the month—	The values of i_t are:					
	i_t	for t =	i_t	for t =	i_t	for t =
*	*	*	*	*	*	*
February 2007	.0513	1–20	.0480	>20	N/A	N/A

Issued in Washington, DC, on this 9th day of January 2007.

Vincent K. Snowbarger,

Interim Director, Pension Benefit Guaranty Corporation.

[FR Doc. E7–336 Filed 1–11–07; 8:45 am]

BILLING CODE 7709–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: Base (1% annual chance) Flood Elevations (BFEs) and modified BFEs are made final for the communities listed below. The BFEs and modified BFEs are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The date of issuance of the Flood Insurance Rate Map (FIRM) showing BFEs and modified BFEs for each community. This date may be obtained by contacting the office where the maps are available for inspection as indicated on the table below.

ADDRESSES: The final BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The

respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: William R. Blanton, Jr., Engineering Management Section, Mitigation Division, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3151.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Mitigation Division Director of FEMA has resolved any appeals resulting from this notification.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community. The BFEs and modified BFEs are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act. This final rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. An environmental impact assessment has not been prepared.

Regulatory Flexibility Act. As flood elevation determinations are not within the scope of the Regulatory Flexibility Act, 5 U.S.C. 601–612, a regulatory flexibility analysis is not required.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This final rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This final rule meets the applicable standards of Executive Order 12988.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

■ Accordingly, 44 CFR part 67 is amended as follows:

PART 67—[AMENDED]

■ 1. The authority citation for part 67 continues to read as follows:

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

§ 67.11 [Amended]

■ 2. The tables published under the authority of § 67.11 are amended as follows:

Flooding source(s)	Location of referenced elevation	*Elevation in feet (NGVD) +Elevation in feet (NAVD) # Depth in feet above ground Modified	Communities affected
Bexar County, Texas and Incorporated Areas Docket No.: FEMA–B–7460			
San Antonio River	Approximately 500 feet upstream of Rd 3 along River Road	*510	City of San Antonio, Bexar County (Unincorporated Areas).
	Just downstream of Roosevelt Avenue	*579	
	Just upstream of Josephine Street	*656	
San Pedro Creek	At the confluence with San Antonio River	*599	City of San Antonio, Bexar County.
	At confluence with Apache Creek (above Rail Road)	*628	
	Approximately 100 feet downstream of West Myrtle Street	*656	
Symphony Lane Spillflow	At convergence with San Antonio River	*554	City of San Antonio, Bexar County.
	Just upstream of East Pyron Avenue	*558	

Depth in feet above ground.
* National Geodetic Vertical Datum.
+ North American Vertical Datum.

ADDRESSES

Bexar County (Unincorporated Areas)

Maps are available for inspection at Vista Verde Building, Suite 420, 233 North Pecos St., San Antonio, TX 78207.

City of San Antonio

Maps are available for inspection at Municipal Plaza, 114 W. Commerce St., 7th Floor, San Antonio, TX 78205.

Town of Vinalhaven, Knox County, Maine Docket No.: FEMA–B–7465			
Atlantic Ocean	At Crockett Cove	+10	Town of Vinalhaven.
	At Carvers Pond	+10	
	At Old Harbor, Northern Shore	+11	
	At Eastern Shore of Carvers Habor	+11	
	At Northern end of Carvers Harbor	+12	
	At Coombs Neck, Northern Shore	+13	
	At Sand Cove	+14	
	At Clam Cove of Roberts Harbor	+16	

Flooding source(s)	Location of referenced elevation	*Elevation in feet (NGVD) +Elevation in feet (NAVD) # Depth in feet above ground Modified	Communities affected
	At Southern point of Vinalhaven Island opposite Carvers Island.	+18	

* National Geodetic Vertical Datum.
# Depth in feet above ground.
+ North American Vertical Datum.

ADDRESSES

Maps are available for inspection at the Town of Vinalhaven, Town Office, West Main, Vinalhaven, Maine 04863.

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

Dated: January 5, 2007.

David I. Maurstad,

Director, Mitigation Division, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. E7–340 Filed 1–11–07; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 060216045–6045–01; I.D. 010807B]

Fisheries of the Exclusive Economic Zone Off Alaska; Inseason Adjustment to the 2007 Aleutian Islands Atka Mackerel Total Allowable Catch Amounts

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

ACTION: Temporary rule; inseason adjustment; request for comments.

SUMMARY: NMFS is adjusting the annual total allowable catch amount (TAC) for the Central and Western Aleutian District Atka mackerel fisheries. This action is necessary because NMFS has determined these TACs are incorrectly specified. This action will ensure the A and B season harvests of Central and Western Aleutian District Atka mackerel do not exceed the appropriate amount based on the best available scientific information for Atka mackerel in the Aleutian Islands subarea. This action is consistent with the goals and objectives of the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP).

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), January 12, 2007, through 2400 hrs, A.l.t., April 15, 2007, unless otherwise modified or superceded through publication of a notification in the **Federal Register**.Comments must be received at the following address no later than 4:30 p.m., A.l.t., January 29, 2007.

ADDRESSES: Send comments to Sue Salveson, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, Attn: Ellen Sebastian. Comments may be submitted by:

- Mail to: P.O. Box 21668, Juneau, AK 99802;
- Hand delivery to the Federal Building, 709 West 9th Street, Room 420A, Juneau, Alaska;
- FAX to 907–586–7557;
- E-mail to *AIATKAMACK-TAC07@noaa.gov* and include the subject line of the e-mail comment the document identifier: AIATKAMACK-TAC07 (E-mail comments, with or without attachments, are limited to 5 megabytes); or
- Webform at the Federal eRulemaking Portal: *http/www.regulations.gov*. Follow the instructions at that site for submitting comments.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the Bering Sea and Aleutian Islands (BSAI) according to the FMP prepared by the North Pacific Fishery Management Council (Council) under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2007 TAC of Atka mackerel in the Central Aleutian District of the BSAI is 38,000 metric tons (mt) as established by the 2006 and 2007 harvest specification for groundfish in the BSAI (71 FR 19894, March 3, 2006). In accordance with § 679.20(a)(8)(ii), the 2007 A and B season allowances of Atka mackerel in the Central Aleutian District of the BSAI are each 17,575 mt, and the 2007 A and B season Harvest Limit Area (HLA) limits of Atka mackerel in the Central Aleutian District of the BSAI are each 10,545 mt.

The 2007 TAC of Atka mackerel in the Western Aleutian District of the BSAI is 17,500 mt as established by the 2006 and 2007 harvest specification for groundfish in the BSAI (71 FR 19894, March 3, 2006). In accordance with § 679.20(a)(8)(ii), the 2007 A and B season allowances of Atka mackerel in the Western Aleutian District of the BSAI are each 8,750 mt, and the 2007 A and B season Harvest Limit Area (HLA) limits of Atka mackerel in the Western Aleutian District of the BSAI are each 5,250 mt.

In December 2006, the Council recommended a 2007 Atka mackerel TAC of 29,600 mt for the Central Aleutian District and 9,600 mt for the Western Aleutian District. These amounts are less than the TACs as established by the 2006 and 2007 harvest specification for groundfish in the BSAI (71 FR 19894, March 3, 2006). The TACs recommended by the Council are based on the Stock Assessment and Fishery Evaluation report (SAFE), dated November 2006, which NMFS has determined is the best available scientific information for this fishery.

Steller sea lions occur in the same location as the Aleutian Islands Atka mackerel fishery and are listed as endangered under the Endangered Species Act (ESA). Atka mackerel is a principal prey species for Steller sea lions in the Aleutian Islands subarea. The seasonal apportionment of Atka mackerel harvest is necessary to ensure the groundfish fisheries are not likely to cause jeopardy of extinction or adverse modification of critical habitat for Steller sea lions. The regulations at § 679.20(a)(ii)(8)(A) require the Atka

mackerel TAC specified for each subarea or district of the BSAI to be divided equally, after subtraction of the jig gear allocation and reserves, into two seasonal allowances corresponding to the A and B seasons defined at § 679.23(e)(3).

In accordance with § 679.25(a)(2)(i)(B), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that, based on the November 2006 SAFE report for this fishery, the current Central and Western Aleutian District Atka mackerel TACs are incorrectly specified. Consequently, the Regional Administrator is adjusting the 2007 Atka mackerel TAC to 29,600 mt in the Central Aleutian District and 9,600 mt in the Western Aleutian District of the BSAI. In accordance with § 679.20(a)(8)(ii) the 2007 A and B season apportionments for Atka mackerel after deducting the CDQ reserve are each adjusted to 13,690 mt in the Central Aleutian District and 4,440 mt in the Western Aleutian District of the BSAI. Consequently, the 2007 A and B season HLA limits are each adjusted to 8,214 mt for the Central Aleutian District and 2,664 mt for the Western Aleutian District of the BSAI.

Pursuant to § 679.20(a)(8), Tables 4, 12, and 14 of the 2006 and 2007 final harvest specifications for groundfish in the BSAI (71 FR 10894, March 3, 2006) are revised for the 2007 Atka mackerel TACs consistent with this adjustment.

TABLE 4—2006 AND 2007 SEASONAL AND SPATIAL ALLOWANCES, GEAR SHARES, AND CDQ RESERVE OF THE BSAI ATKA MACKEREL TAC[1]

[Amounts are in metric tons]

Subarea and component	2006 TAC	2006 CDQ reserve	2006 CDQ reserve HLA limit[4]	2006 ITAC	2006 Seasonal allowances[2]			
					A season[3]		B season[3]	
					Total	HLA limit[4]	Total	HLA limit[4]
Western AI District	15,500	1,163	698	14,338	7,169	4,301	7,169	4,301
Central AI District	40,000	3,000	1,800	37,000	18,500	11,100	18,500	11,100
EAI/BS subarea[5]	7,500	563	n/a	6,938	n/a	n/a	n/a	n/a
Jig (1%)[6]	n/a	n/a	n/a	69	n/a	n/a	n/a	n/a
Other gear (99%)	n/a	n/a	n/a	6,868	3,434	n/a	3,434	n/a
Total	63,000	n/a	n/a	n/a	29,103	n/a	29,103	n/a
Western AI District	9,600	720	432	8,880	4,440	2,664	4,440	2,664
Central AI District	29,600	2,220	1,332	27,380	13,690	8,214	13,690	8,214
EAI/BS subarea[5]	7,500	563	n/a	6,938	n/a	n/a	n/a	n/a
Jig (1%)[6]	n/a	n/a	n/a	69	n/a	n/a	n/a	n/a
Other gear (99%)	n/a	n/a	n/a	6,868	3,434	n/a	3,434	n/a
Total	46,700	n/a	n/a	n/a	21,564	10,878	21,564	10,878

[1] Regulations at §§ 679.20(a)(8)(ii) and 679.22(a) establish temporal and spatial limitations for the Atka mackerel fishery.
[2] The seasonal allowances of Atka mackerel are 50 percent in the A season and 50 percent in the B season.
[3] The A season is January 1 (January 20 for trawl gear) to April 15 and the B season is September 1 to November 1.
[4] Harvest Limit Area (HLA) limit refers to the amount of each seasonal allowance that is available for fishing inside the HLA (see § 679.2). In 2006 and 2007, 60 percent of each seasonal allowance is available for fishing inside the HLA in the Western and Central Aleutian Districts.
[5] Eastern Aleutian District and the Bering Sea subarea.
[6] Regulations at § 679.20 (a)(8)(i) require that up to 2 percent of the Eastern Aleutian District and the Bering Sea subarea ITAC be allocated to jig gear. The amount of this allocation is 1 percent. The jig gear allocation is not apportioned by season.

TABLE 12—2006 AND 2007 LISTED BSAI AMERICAN FISHERIES ACT CATCHER/PROCESSOR GROUNDFISH SIDEBOARD LIMITS

[Amounts are in metric tons]

Target species	Area	1995 - 1997			2006 ITAC available to trawl C/Ps	2006 C/P sideboard limit	2007 ITAC available to trawl C/Ps	2007 C/P sideboard limit
		Retained catch	Total catch	Ratio of retained catch to total catch				
Pacific cod trawl	BSAI	12,424	48,177	0.258	42,171	10,880	32,171	8,300
Sablefish trawl	BS	8	497	0.016	1,199	19	1,148	18
	AI	0	145	0.000	638	0	582	0
Atka mackerel	Central AI	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	A season[1]	n/a	n/a	0.115	18,500	2,128	13,690	1,574
	HLA limit[2]	n/a	n/a	n/a	11,100	1,277	8,214	945
	B season[1]	n/a	n/a	0.115	18,500	2,128	13,690	1,574
	HLA limit[2]	n/a	n/a	n/a	11,100	1,277	8,214	945
	Western AI	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	A season[1]	n/a	n/a	0.200	7,169	1,434	4,440	888
	HLA limit[2]	n/a	n/a	n/a	4,301	860	2,664	533
	B season[1]	n/a	n/a	0.200	7,169	1,434	4,440	888
	HLA limit[2]	n/a	n/a	n/a	4,301	860	2,664	533
Yellowfin sole	BSAI	100,192	435,788	0.230	81,346	18,710	91,495	21,044
Rock sole	BSAI	6,317	169,362	0.037	35,275	1,305	37,400	1,384

TABLE 12—2006 AND 2007 LISTED BSAI AMERICAN FISHERIES ACT CATCHER/PROCESSOR GROUNDFISH SIDEBOARD LIMITS—Continued

[Amounts are in metric tons]

Target species	Area	1995 - 1997			2006 ITAC available to trawl C/Ps	2006 C/P sideboard limit	2007 ITAC available to trawl C/Ps	2007 C/P sideboard limit
		Retained catch	Total catch	Ratio of retained catch to total catch				
Greenland turbot	BS	121	17,305	0.007	1,607	11	1,543	11
	AI	23	4,987	0.005	723	4	693	3
Arrowtooth flounder	BSAI	76	33,987	0.002	11,050	22	15,300	31
Flathead sole	BSAI	1,925	52,755	0.036	16,575	597	18,700	673
Alaska plaice	BSAI	14	9,438	0.001	6,800	7	12,750	13
Other flatfish	BSAI	3,058	52,298	0.058	2,975	173	4,250	247
Pacific ocean perch	BS	12	4,879	0.002	1,190	2	2,516	5
	Eastern AI	125	6,179	0.020	2,849	57	3,012	60
	Central AI	3	5,698	0.001	2,808	3	2,971	3
	Western AI	54	13,598	0.004	4,703	19	4,969	20
Northern rockfish	BSAI	91	13,040	0.007	4,163	29	4,625	32
Shortraker rockfish	BSAI	50	2,811	0.018	537	10	537	10
Rougheye rockfish	BSAI	50	2,811	0.018	207	4	207	4
Other rockfish	BS	18	621	0.029	426	12	750	22
	AI	22	806	0.027	502	14	502	14
Squid	BSAI	73	3,328	0.022	1,084	24	1,084	24
Other species	BSAI	553	68,672	0.008	24,650	197	22,950	184

[1] The seasonal apportionment of Atka mackerel in the open access fishery is 50 percent in the A season and 50 percent in the B season. Listed AFA catcher/processors are limited to harvesting no more than zero in the Eastern Aleutian District and Bering Sea subarea, 20 percent of the annual ITAC specified for the Western Aleutian District, and 11.5 percent of the annual ITAC specified for the Central Aleutian District.

[2] Harvest Limit Area (HLA) limit refers to the amount of each seasonal allowance that is available for fishing inside the HLA (see § 679.2). In 2006 and 2007, 60 percent of each seasonal allowance is available for fishing inside the HLA in the Western and Central Aleutian Districts.

TABLE 14—2006 AND 2007 BSAI AMERICAN FISHERIES ACT CATCHER VESSEL SIDEBOARD LIMITS

[Amounts are in metric tons]

Species	Fishery by area/season/processor/gear	Ratio of 1995-1997 AFA CV catch to 1995 1997 TAC	2006 initial TAC	2006 Catcher vessel sideboard limits	2007 initial TAC	2007 Catcher vessel sideboard limits
Pacific cod	BSAI	n/a	n/a	n/a	n/a	n/a
	Jig gear	0.0000	3,589	0	2,738	0
	Hook-and-line CV	n/a	n/a	n/a	n/a	n/a
	Jan 1 - Jun 10	0.0006	164	0	125	0
	Jun 10 - Dec 31	0.0006	109	0	83	0
	Pot gear CV	n/a	n/a	n/a	n/a	n/a
	Jan 1 - Jun 10	0.0006	8,192	5	6,239	4
	Sept 10 - Dec 31	0.0006	5,461	3	4,159	2
	CV < 60 feet LOA using hook-and-line or pot gear	0.0006	1,274	1	970	1
	Trawl gear CV	n/a	n/a	n/a	n/a	n/a
	Jan 20 - Apr 1	0.8609	29,520	25,414	22,520	19,387
	Apr 1 - Jun 10	0.8609	4,217	3,630	3,217	2,770
	Jun 10 - Nov 1	0.8609	8,434	7,261	6,434	5,539
Sablefish	BS trawl gear	0.0906	1,199	109	1,148	104
	AI trawl gear	0.0645	638	41	582	38
Atka mackerel	Eastern AI/BS	n/a	n/a	n/a	n/a	n/a
	Jig gear	0.0031	69	0	69	0
	Other gear	n/a	n/a	n/a	n/a	n/a
	Jan 1 - Apr 15	0.0032	3,434	11	3,434	11
	Sept 1 - Nov 1	0.0032	3,434	11	3,434	11
	Central AI	n/a	n/a	n/a	n/a	n/a
	Jan - Apr 15	0.0001	18,500	2	13,690	1
	HLA limit	0.0001	11,100	1	8,214	1
	Sept 1 - Nov 1	0.0001	18,500	2	13,690	1
	HLA limit	0.0001	11,100	1	8,214	1
	Western AI	n/a	n/a	n/a	n/a	n/a
	Jan - Apr 15	0.0000	7,169	0	4,440	0
	HLA limit	n/a	4,301	0	2,664	0
	Sept 1 - Nov 1	0.0000	7,169	0	4,440	0
	HLA limit	n/a	4,301	0	2,664	0
Yellowfin sole	BSAI	0.0647	81,346	5,263	91,495	5,920

TABLE 14—2006 AND 2007 BSAI AMERICAN FISHERIES ACT CATCHER VESSEL SIDEBOARD LIMITS—Continued

[Amounts are in metric tons]

Species	Fishery by area/season/processor/gear	Ratio of 1995-1997 AFA CV catch to 1995 1997 TAC	2006 initial TAC	2006 Catcher vessel sideboard limits	2007 initial TAC	2007 Catcher vessel sideboard limits
Rock sole	BSAI	0.0341	35,275	1,203	37,400	1,275
Greenland Turbot	BS	0.0645	1,607	104	1,543	100
	AI	0.0205	723	15	693	14
Arrowtooth flounder	BSAI	0.0690	11,050	762	15,300	1,056
Alaska plaice	BSAI	0.0441	6,800	300	12,750	562
Other flatfish	BSAI	0.0441	2,975	131	4,250	187
Pacific ocean perch	BS	0.1000	1,190	119	2,516	252
	Eastern AI	0.0077	2,849	22	3,012	23
	Central AI	0.0025	2,808	7	2,971	7
	Western AI	0.0000	4,703	0	4,969	0
Northern rockfish	BSAI	0.0084	4,163	35	4,625	39
Shortraker rockfish	BSAI	0.0037	537	2	537	2
Rougheye rockfish	BSAI	0.0037	207	1	207	1
Other rockfish	BS	0.0048	426	2	750	4
	AI	0.0095	502	5	502	5
Squid	BSAI	0.3827	1,084	415	1,084	415
Other species	BSAI	0.0541	24,650	1,334	22,950	1,242
Flathead Sole	BS trawl gear	0.0505	16,575	837	18,700	944

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) and 679.25(c)(2) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would allow for harvests that exceed the appropriate A and B season apportionments for Atka mackerel based on the best scientific information available. The Atka mackerel fishery is harvested rapidly and completely in the early part of the A season. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of December 13, 2006, and additional time for prior public comment would result in conservation concerns for the ESA-listed Steller sea lions.

The AA also finds good cause to waive the 30–day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Under § 679.25(c)(2), interested persons are invited to submit written comments on this action to the above address until January 29, 2007.

This action is required by § 679.22 and is exempt from review under Executive Order 12866.

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

Dated: January 8, 2007.

James P. Burgess,

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

[FR Doc. 07–107 Filed 1–9–07; 2:49 pm]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 72, No. 8
Friday, January 12, 2007

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

Office of the Secretary

7 CFR Part 7

RIN 0560–AG90

Selection and Functions of Farm Service Agency State and County Committees

AGENCY: Office of the Secretary, USDA.

ACTION: Proposed rule; correction.

SUMMARY: This document corrects a proposed rule published November 28, 2006, proposing to amend the regulations governing the selection and functions of Farm Service Agency (FSA) State and county committees in accordance with the Soil Conservation and Domestic Allotment Act, as amended. A correction is needed because the proposed rule incorrectly stated the duties of the State committees.

DATES: Effective Date: January 12, 2007.

FOR FURTHER INFORMATION CONTACT: Tom Witzig, Regulatory Review Group, Economic and Policy Analysis Staff, Farm Service Agency (FSA), United States Department of Agriculture (USDA), Stop 0572, 1400 Independence Ave., SW., Washington, DC 20250–0572. *Telephone:* (202) 205–5851; *e-mail: Tom.Witzig@wdc.usda.gov*. Persons with disabilities who require alternative means for communication (Braille, large print, audio tape, etc.) should contact the USDA Target Center at (202) 720–2600 (voice and TDD).

SUPPLEMENTARY INFORMATION: This rule corrects the proposed rule published in the **Federal Register** on November 28, 2006 (71 FR 68755) proposing to amend the regulations governing the selection and functions of FSA State and county committees. In FR Doc. E6–20052, section 7.22 stated that the State committees ''shall be generally responsible for carrying out in the State all farm programs and farm loan programs or any other functions assigned by the Secretary or a designee of the Secretary.'' In fact, the State committees currently are not, and are not proposed to be, responsible for carrying out farm loan programs. This document corrects the proposed rule to remove the reference to farm loan programs.

In proposed rule FR Doc. E6–20052 published on November 28, 2006 (71 FR 68755) make the following correction. On page 68761, in the first column, revise § 7.22 to read as follows:

§ 7.22 State committee duties.

The State committee, subject to the general direction and supervision of the Deputy Administrator, shall be generally responsible for carrying out in the State all farm programs or any other functions assigned by the Secretary or a designee of the Secretary.

Signed in Washington, DC, on January 4, 2007.

Mike Johanns,

Secretary of Agriculture.

[FR Doc. E7–298 Filed 1–11–07; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–26812; Directorate Identifier 2006–NM–199–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A318, A319, A320, and A321 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede an existing airworthiness directive (AD) that applies to certain Airbus Model A318–100, A319–100, A320–200, A321–100, and A321–200 series airplanes; and Model A320–111 airplanes. The existing AD currently requires modification of the electrical bonding of all structures and systems installed inside the center fuel tank. That AD results from fuel system reviews conducted by the manufacturer. This proposed AD would require modification of additional bonding points inside the center fuel tank. This proposed AD results from a report that additional bonding points need to be modified in order to prevent electrical arcing in the center fuel tank. We are proposing this AD to prevent electrical arcing in the center fuel tank due to inadequate bonding, which could result in an explosion of the center fuel tank and consequent loss of the airplane.

DATES: We must receive comments on this proposed AD by February 12, 2007.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- *DOT Docket Web site:* Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, Room PL–401, Washington, DC 20590.
- *Fax:* (202) 493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

Contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France, for service information identified in this proposed AD.

FOR FURTHER INFORMATION CONTACT: Tim Dulin, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–2141; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed in the **ADDRESSES** section. Include the docket number ''Docket No. FAA–2007–26812; Directorate Identifier 2006–NM–199–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *http://dms.dot.gov*.

Examining the Docket

You may examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the Docket Management System receives them.

Discussion

The FAA has examined the underlying safety issues involved in fuel tank explosions on several large transport airplanes, including the adequacy of existing regulations, the service history of airplanes subject to those regulations, and existing maintenance practices for fuel tank systems. As a result of those findings, we issued a regulation titled ''Transport Airplane Fuel Tank System Design Review, Flammability Reduction and Maintenance and Inspection Requirements'' (66 FR 23086, May 7, 2001). In addition to new airworthiness standards for transport airplanes and new maintenance requirements, this rule included Special Federal Aviation Regulation No. 88 (''SFAR 88,'' Amendment 21–78, and subsequent Amendments 21–82 and 21–83).

Among other actions, SFAR 88 requires certain type design (i.e., type certificate (TC) and supplemental type certificate (STC)) holders to substantiate that their fuel tank systems can prevent ignition sources in the fuel tanks. This requirement applies to type design holders for large turbine-powered transport airplanes and for subsequent modifications to those airplanes. It requires them to perform design reviews and to develop design changes and maintenance procedures if their designs do not meet the new fuel tank safety standards. As explained in the preamble to the rule, we intended to adopt airworthiness directives to mandate any changes found necessary to address unsafe conditions identified as a result of these reviews.

In evaluating these design reviews, we have established four criteria intended to define the unsafe conditions associated with fuel tank systems that require corrective actions. The percentage of operating time during which fuel tanks are exposed to flammable conditions is one of these criteria. The other three criteria address the failure types under evaluation: single failures, single failures in combination with a latent condition(s), and in-service failure experience. For all four criteria, the evaluations included consideration of previous actions taken that may mitigate the need for further action.

The Joint Aviation Authorities (JAA) has issued a regulation that is similar to SFAR 88. (The JAA is an associated body of the European Civil Aviation Conference (ECAC) representing the civil aviation regulatory authorities of a number of European States who have agreed to co-operate in developing and implementing common safety regulatory standards and procedures.) Under this regulation, the JAA stated that all members of the ECAC that hold type certificates for transport category airplanes are required to conduct a design review against explosion risks.

On September 9, 2005, we issued AD 2005–19–14, amendment 39–14279 (70 FR 55228, September 21, 2005), for certain Airbus Model A318–100, A319–100, A320–200, A321–100, and A321–200 series airplanes; and Model A320–111 airplanes. That AD requires modification of the electrical bonding of all structures and systems installed inside the center fuel tank. We issued that AD to prevent electrical arcing in the center fuel tank due to inadequate bonding, which could result in an explosion of the center fuel tank and consequent loss of the airplane.

Actions Since Existing AD Was Issued

Since we issued AD 2005–19–14, the European Aviation Safety Agency (EASA), which is the aviation authority for the European Union, informed us that certain bonding points that should be modified were not included in the Accomplishment Instructions of Airbus Service Bulletin A320–28–1104, dated December 2, 2003; Revision 01, dated December 8, 2004; and Revision 02, dated February 21, 2005. Airbus Service Bulletin A320–28–1104, Revision 01, was referenced as the appropriate source of service information for modifying the electrical bonding, as required by AD 2005–19–14.

Relevant Service Information

Airbus has issued Service Bulletin A320–28–1104, Revision 03, including Appendix 01, dated February 23, 2006. The procedures in Revision 03 are essentially the same as those specified in earlier revisions, except that Revision 03 includes additional bonding points that were not included in the original issue, Revision 01, or Revision 02 of the service bulletin. Accomplishing the actions specified in Revision 03 of the service bulletin is intended to adequately address the unsafe condition. EASA mandated the service information and issued EASA airworthiness directive 2006–0176, dated June 26, 2006, to ensure the continued airworthiness of these airplanes in the European Union. EASA airworthiness directive 2006–0176 supersedes French airworthiness directive F–2005–028, dated February 16, 2005, which was referenced in AD 2005–19–14 as the parallel French airworthiness directive.

FAA's Determination and Requirements of the Proposed AD

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. As described in FAA Order 8100.14A, ''Interim Procedures for Working with the European Community on Airworthiness Certification and Continued Airworthiness,'' dated August 12, 2005, the EASA has kept the FAA informed of the situation described above. We have examined the EASA's findings, evaluated all pertinent information, and determined that we need to issue an AD for airplanes of this type design that are certificated for operation in the United States.

This proposed AD would supersede AD 2005–19–14 and would retain the requirements of the existing AD. This proposed AD would also add the requirement to modify additional bonding points.

Clarification of Alternative Method of Compliance (AMOC) Paragraph

We have revised this action to clarify the appropriate procedure for notifying the principal inspector before using any approved AMOC on any airplane to which the AMOC applies.

Explanation of Change in Applicability

We have changed the airplane model designations in the applicability of this proposed AD to be consistent with the parallel EASA airworthiness directive.

Costs of Compliance

The following table provides the estimated costs for U.S. operators to comply with this proposed AD. There are approximately 720 U.S.-registered airplanes. The average labor rate is $80 per hour.

ESTIMATED COSTS

Action	Work hours	Parts	Cost per airplane	Fleet cost
Modification of electrical bonding (required by AD 2005–19–14)	49 to 64	$10 to $370	$3,930 to $5,490	$2,829,600 to $3,952,800
Modification of additional bonding points (new proposed action)	6 to 7	$100	$580 to $660	$417,600 to $475,200

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD 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.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;
2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

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 FAA proposes to amend 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. The Federal Aviation Administration (FAA) amends § 39.13 by removing amendment 39–14279 (70 FR 55228, September 21, 2005) and adding the following new airworthiness directive (AD):

Airbus: Docket No. FAA–2007–26812; Directorate Identifier 2006–NM–199–AD.

Comments Due Date

(a) The FAA must receive comments on this AD action by February 12, 2007.

Affected ADs

(b) This AD supersedes AD 2005–19–14.

Applicability

(c) This AD applies to Airbus Model A318, A319, A320, and A321 airplanes; certificated in any category; except airplanes that have received Airbus Modification 31892 in production.

Unsafe Condition

(d) This AD results from a report that additional bonding points need to be modified in order to prevent electrical arcing in the center fuel tank. We are issuing this AD to prevent electrical arcing in the center fuel tank due to inadequate bonding, which could result in an explosion of the center fuel tank and consequent loss of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Restatement of The Requirements of AD 2005–19–14:

Modification

(f) Within 58 months after October 26, 2005 (the effective date of AD 2005–19–14): Modify the electrical bonding of all structures and systems installed inside the center fuel tank by accomplishing all of the actions in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–28–1104, Revision 01, dated December 8, 2004; or Revision 02, dated February 21, 2005; or Revision 03, including Appendix 01, dated February 23, 2006. After the effective date of this AD, only Revision 03 may be used.

Actions Accomplished According to Previous Issue of Service Bulletin

(g) Actions done before October 26, 2005, in accordance with Airbus Service Bulletin A320–28–1104, dated December 2, 2003, are acceptable for compliance with the corresponding requirements of paragraph (f) of this AD.

New Requirements Of This AD:

Modification (Additional Bonding Points)

(h) For airplanes on which the actions specified in Airbus Service Bulletin A320–28–1104, dated December 2, 2003; Revision 01, dated December 8, 2004; or Revision 02, dated February 21, 2005; have been done before the effective date of this AD: Within 78 months after the effective date of this AD, modify the electrical bonding of the structures and systems identified in the additional actions specified in paragraph 3.B.(3) of the Accomplishment Instructions of Airbus Service Bulletin A320–28–1104, Revision 03, including Appendix 01, dated February 23, 2006.

Alternative Methods of Compliance (AMOCs)

(i)(1) The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

(3) AMOCs approved previously in accordance with AD 2005–19–14, are approved as AMOCs for the corresponding provisions of paragraph (f) of this AD.

Related Information

(j) European Aviation Safety Agency (EASA) airworthiness directive 2006–0176, dated June 26, 2006, also addresses the subject of this AD.

Issued in Renton, Washington, on December 26, 2006.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–315 Filed 1–11–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–26834; Directorate Identifier 2006–NM–235–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A330 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as an incomplete discharge of the extinguishing agent in the fire zone, which could lead, in the worst case, in combination with an engine fire, to a temporary uncontrolled engine fire. The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by February 12, 2007.

ADDRESSES: You may send comments by any of the following methods:

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Fax: (202) 493–2251.
- Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–0001.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://dms.dot.gov*; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5227) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1175; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Streamlined Issuance of AD

The FAA is implementing a new process for streamlining the issuance of ADs related to MCAI. This streamlined process will allow us to adopt MCAI safety requirements in a more efficient manner and will reduce safety risks to the public. This process continues to follow all FAA AD issuance processes to meet legal, economic, Administrative Procedure Act, and **Federal Register** requirements. We also continue to meet our technical decision-making responsibilities to identify and correct unsafe conditions on U.S.-certificated products.

This proposed AD references the MCAI and related service information that we considered in forming the engineering basis to correct the unsafe condition. The proposed AD contains text copied from the MCAI and for this reason might not follow our plain language principles.

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2007–26834; Directorate Identifier 2006–NM–235–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the aviation authority for the European Union, has issued EASA Airworthiness Directive 2006–0297, dated September 29, 2006 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states that one Model A330 operator discovered that the line connection to the discharge head could not be properly secured during engine fire bottle replacement, due to a missing retaining-ring. Inspections revealed that all four discharge-heads line connectors, two per engine, were missing the retaining-ring. It was confirmed later that it was a quality issue.

The function of the retaining-ring is to secure a tight connection between the fire-extinguishing line and the discharge head. In absence of the retaining-ring, in case of activation of the fire extinguishing system, the pressure exerted by the agent on the pipe could compromise the tightness of the connection, leading to an incomplete discharge of the extinguishing agent in the fire zone.

This situation, if not corrected,could lead, in the worst case, in combination with an engine fire, to a temporary uncontrolled engine fire which constitutes an unsafe condition.

The MCAI requires a one-time detailed visual inspection for the presence of the retaining-ring on the discharge head assembly of the engine fire extinguishing system, and repair if necessary. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Airbus has issued Service Bulletin A330–26A3037, dated July 26, 2006. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information provided by the State of Design Authority and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are described in a separate paragraph of the proposed AD. These requirements, if ultimately adopted, will take precedence over the actions copied from the MCAI.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 27 products of U.S. registry. We also estimate that it would take about 4 work-hours per product to comply with this proposed AD. The average labor rate is $80 per work-hour. Required parts would cost about $0 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these costs. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $8,640, or $320 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD 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.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

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 FAA proposes to amend 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. The FAA amends § 39.13 by adding the following new AD:

Airbus: Docket No. FAA–2007–26834; Directorate Identifier 2006–NM–235–AD.

Comments Due Date

(a) We must receive comments by February 12, 2007.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Airbus Model A330 airplanes, all certified models, certificated in any category, all serial numbers up to 755 included.

Reason

(d) The mandatory continuing airworthiness information (MCAI) states that one Model A330 operator discovered that the line connection to the discharge head could not be properly secured during engine fire bottle replacement, due to a missing retaining-ring. Inspections revealed that all four discharge-heads line connectors, two per engine, were missing the retaining-ring. It was confirmed later that it was a quality issue. The function of the retaining-ring is to secure a tight connection between the fire-extinguishing line and the discharge head. In absence of the retaining-ring, in case of activation of the fire extinguishing system, the pressure exerted by the agent on the pipe could compromise the tightness of the connection, leading to an incomplete discharge of the extinguishing agent in the fire zone. This situation if not corrected could lead, in the worst case, in combination with an engine fire, to a temporary uncontrolled engine fire which constitutes an unsafe condition. The MCAI requires a one-time detailed visual inspection for the presence of the retaining-ring on the discharge head assembly of engine fire extinguishing system, and repair if necessary.

Actions and Compliance

(e) Unless already done, do the following actions. Within 900 flight hours from the effective date of this AD: On both engine pylons (left hand and right hand), for all four engine fire extinguisher bottles, two per engine pylon, perform a one-time detailed visual inspection for the presence of the retaining ring on the discharge head of the bottles and apply all applicable corrective actions, in accordance with instructions defined in Airbus Service Bulletin A330–26A3037, dated July 26, 2006. Do all applicable corrective actions before further flight. Aircraft on which the four engine fire extinguishing bottles, 2 per engine pylon, have been removed and re-installed at the opportunity of hydrostatic test of engine fire extinguishing as per Maintenance Review Board Report (MRBR) task 26.21.00/04, are not concerned by this Airworthiness Directive (AD).

Other FAA AD Provisions

(f) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, Attn: Todd Thompson, Aerospace Engineer, 1601 Lind Avenue, SW., Renton, Washington 98057–3356, has the authority to approve AMOCs for this AD, if

requested using the procedures found in 14 CFR 39.19. Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(g) Refer to MCAI European Aviation Safety Agency Airworthiness Directive 2006–0297, dated September 29, 2006, and Airbus Service Bulletin A330–26A3037, dated July 26, 2006, for related information.

Issued in Renton, Washington, on December 28, 2006.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–314 Filed 1–11–07; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1630 and 1631

Proposed Technical Amendment to the Flammability Standards for Carpets and Rugs; Notice of Opportunity for Oral Comment

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule.

SUMMARY: This document provides interested persons the opportunity for the oral presentation or written submissions regarding the proposed technical amendment to the flammability standards for carpets and rugs.

DATES: Requests to make an oral presentation or written submissions must be received by February 12, 2007.

ADDRESSES: Requests should be filed by e-mail to *cpsc-os@cpsc.gov,* by fax to (301) 504–0127, or mailed or delivered, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, Maryland 20814–4408; telephone (301) 504–7923. Requests and submissions should be captioned ''Carpet and Rug Amendment.''

FOR FURTHER INFORMATION CONTACT: Patricia K. Adair, Project Manager, Directorate for Engineering Sciences, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; telephone (301) 504–7536 or e-mail: *padair@cpsc.gov.*

SUPPLEMENTARY INFORMATION: On November 13, 2006, the Consumer Product Safety Commission proposed to amend the flammability standards for carpets and rugs to remove the reference to Eli Lilly Company Product No. 1588 in Catalog No. 79, December 1, 1969, as the standard ignition source and provide a technical specification defining the ignition source. 71 FR 66145. Pursuant to Section 4(d) of the Flammable Fabrics Act, interested persons are hereby given an opportunity for the oral presentation of data, views, or arguments, as well as an opportunity to make written submissions. 15 U.S.C. 1193(d).

Authority: 15 U.S.C. 1193(d)).

Dated: January 8, 2007.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. E7–266 Filed 1–11–07; 8:45 am]

BILLING CODE 6355–01–P

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

36 CFR Parts 1193 and 1194

Telecommunications Act Accessibility Guidelines; Electronic and Information Technology Accessibility Standards

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Notice of meeting.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (Access Board) has established a Telecommunications and Electronic and Information Technology Advisory Committee (Committee) to assist it in revising and updating accessibility guidelines for telecommunications products and accessibility standards for electronic and information technology. This notice announces the dates, time, and location of the third committee meeting, which will be open to the public.

DATES: The meeting is scheduled for February 6–8, 2007 (beginning at 9 a.m. and ending at 5 p.m. on February 6 and 7; and beginning at 9 a.m. on February 8 and ending at 3 p.m.). Notices of future meetings will be published in the **Federal Register.**

ADDRESSES: The meeting will be held at the Transportation Security Administration, 601 South 12th Street (town hall meeting room), Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Timothy Creagan, Office of Technical and Information Services, Architectural and Transportation Barriers Compliance Board, 1331 F Street, NW., suite 1000, Washington, DC 20004–1111. Telephone number: 202–272–0016 (Voice); 202–272–0082 (TTY). Electronic mail address: *creagan@access-board.gov.*

SUPPLEMENTARY INFORMATION: The Board organized the Telecommunications and Electronic and Information Technology Advisory Committee to review its standards for electronic and information technology covered by section 508 of the Rehabilitation Act and to provide recommendations on how they should be updated. The Committee will also address updating the Board's guidelines for telecommunications products covered by section 255 of the Telecommunications Act. The next meeting of the Committee will take place on February 6–8, 2007. A draft meeting agenda is provided below.

Topics to be discussed on Tuesday, February 6, 2007, 9 a.m. to 5 p.m.:

- Federal panel on section 508 exceptions
- Directed discussion on editorial work product of the committee
- Directed discussion on goals of the committee
- Presentation on methodology: Web Content Accessibility Guidelines and section 508 standards approaches
- Presentation on low vision and technology
- Public comment periods

Topics to be discussed on Wednesday, February 7, 2007, 9 a.m. to 5 p.m.:

- Break out sessions of selected subcommittees
- Subcommittee reports
- Presentation on cognition
- Directed discussion on themes
- Public comment periods

Topics to be discussed on Thursday, February 8, 2007, 9 a.m. to 3 p.m.:

- Assistive technology and information technology interoperability panel presentation and discussion
- Goals, future action items, timelines, and next steps
- Public comment periods

Information about the Committee, including future meeting dates and

information on subcommittees is available on the Access Board's website (*http://www.access-board.gov/sec508/update-index.htm*) or at a special website created for the Committee's work (*http://teitac.org*). The site includes a calendar for subcommittee meetings, e-mail distribution lists, and a ''Wiki'' (*http://teitac.org/wiki/TEITAC_Wiki*) which provides interactive online work space.

Committee meetings are open to the public and interested persons can attend the meetings and communicate their views. Members of the public will have opportunities to address the Committee on issues of interest to them and the Committee during public comment periods scheduled on each day of the meeting. Members of groups or individuals who are not members of the Committee are invited to participate on subcommittees that were formed at the first meeting. The Access Board believes that participation of this kind is very valuable to the advisory committee process.

The meeting site is accessible to individuals with disabilities. Sign language interpreters, assistive listening systems, and real-time captioning will be provided. For the comfort of other participants, persons attending Committee meetings are requested to refrain from using perfume, cologne, and other fragrances. Due to security measures at the Transportation Security Administration, all attendees must notify Timothy Creagan (see contact information, above) by January 23, 2007 of their intent to attend the meeting. Pre-registration is required for expeditious entry into the facility and will enable the Board to provide additional information as needed.

Lawrence Roffee,

Executive Director.

[FR Doc. E7–306 Filed 1–11–07; 8:45 am]

BILLING CODE 8150–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 51

[EPA–HQ–OAR–2003–0079, FRL–8268–2]

RIN 2060–AJ99

Phase 2 of the Final Rule To Implement the 8-Hour Ozone National Ambient Air Quality Standard—Notice of Reconsideration—Extension of Public Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Extension of public comment period.

SUMMARY: The EPA is announcing an extension of the public comment period on our proposed Phase 2 of the Final Rule To Implement the 8-Hour Ozone National Ambient Air Quality Standard—Notice of Reconsideration (December 19, 2006). The EPA has received several requests for additional time to comment on the proposal. The EPA has decided to extend the comment period until February 2, 2007. The comment period on the reconsideration notice was originally set to close on January 18, 2007.

DATES: *Comments.* Comments must be received on or before February 2, 2007.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2003–0079, by one of the following methods:

- *www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *E-mail: a-and-r-docket@epamail.epa.gov*.
- *Fax:* 202–566–1741.
- *Mail:* Attention Docket ID No. EPA–HQ–OAR–2003–0079, U.S. Environmental Protection Agency, EPA West (Air Docket), 1200 Pennsylvania Avenue, Northwest, Mailcode: 6102T, Washington, DC 20460. Please include a total of 2 copies.
- *Hand Delivery:* U.S. Environmental Protection Agency, EPA West (Air Docket), 1301 Constitution Avenue, Northwest, Room 3334, Washington, DC 20004, Attention Docket ID No. EPA–HQ–OAR–2003–0079. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions. Direct your comments to Docket ID No. EPA–HQ–OAR–2003–0079. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional instructions on submitting comments, go to the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the U.S. Environmental Protection Agency, Air Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For further information on the issue relating to NO_X RACT for EGU sources in CAIR States, contact Mr. John Silvasi, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, (C539–01), Research Triangle Park, NC 27711, phone number (919) 541–5666, fax number (919) 541–0824 or by e-mail at *silvasi.john@epa.gov* or Ms. Denise Gerth, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, (C539–01), Research Triangle Park, NC 27711, phone number (919) 541–5550, fax number (919) 541–0824 or by e-mail at *gerth.denise@epa.gov*. For further information on the NSR issues discussed in this notice, contact Mr. David Painter, Office of Air Quality Planning and Standards, (C504–03), U.S. EPA, Research Triangle Park, North Carolina 27711, telephone number (919) 541–5515, fax number (919) 541–5509, e-mail: *painter.david@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. What Should I Consider as I Prepare My Comments for EPA?

1. Submitting CBI

Do not submit this information to EPA through *www.regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes 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 docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. Send or deliver information identified as CBI only to the following address: Roberto Morales, OAQPS Document Control Officer (C404–02), U.S. EPA, Research Triangle Park, NC 27711, Attention Docket ID No. EPA–HQ–OAR–2003–0079.

2. Tips for Preparing Your Comments

When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

B. Where Can I Get a Copy of This Document and Other Related Information?

In addition to being available in the docket, an electronic copy of today's notice is also available on the World Wide Web. A copy of today's notice will be posted at *http://www.epa.gov/ttn/naaqs/ozone/o3imp8hr/*.

Dated: January 5, 2007.

William L. Wehrum,

Acting Assistant Administrator, Office of Air and Radiation.

[FR Doc. E7–355 Filed 1–11–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R03–OAR–2006–0817; FRL–8267–8]

Approval and Promulgation of Air Quality Implementation Plans; West Virginia; Redesignation of the Parkersburg, WV Portion of the Parkersburg-Marietta, WV–OH 8-Hour Ozone Nonattainment Area to Attainment and Approval of the Maintenance Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a redesignation request and a State Implementation Plan (SIP) revision for the Parkersburg portion of the Parkersburg-Marietta, WV–OH interstate area (herein referred to as the ''Area'') from nonattainment to attainment of the 8-hour ozone National Ambient Air Quality Standard (NAAQS). The West Virginia Department of Environmental Protection (WVDEP) is requesting that the Wood County, West Virginia (Parkersburg) portion of the Area be redesignated as attainment for the 8-hour ozone NAAQS. The Area is comprised of two counties (Wood County, West Virginia and Washington County, Ohio). EPA is proposing to approve the ozone redesignation request for the Parkersburg portion of the Area. In conjunction with its redesignation request, the WVDEP submitted a SIP revision consisting of a maintenance plan for Parkersburg that provides for continued attainment of the 8-hour ozone NAAQS for the next 12 years. EPA is proposing to make a determination that Parkersburg has attained the 8-hour ozone NAAQS based upon three years of complete, quality-assured ambient air quality ozone monitoring data for 2002–2004. EPA's proposed approval of the 8-hour ozone redesignation request is based on its determination that Parkersburg has met the criteria for redesignation to attainment specified in the Clean Air Act (CAA). EPA is providing information on the status of its adequacy determination for the motor vehicle emission budgets (MVEBs) that are identified in the Parkersburg maintenance plan for purposes of transportation conformity, and is also proposing to approve those MVEBs. EPA is proposing approval of the redesignation request and of the maintenance plan revision to the West Virginia SIP in accordance with the requirements of the CAA.

DATES: Written comments must be received on or before February 12, 2007.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2006–0817 by one of the following methods:

A. *Federal eRulemaking Portal: www.regulations.gov*. Follow the on-line instructions for submitting comments.

B. *E-mail: morris.makeba@epa.gov*.

C. *Mail:* EPA–R03–OAR–2006–0817, Makeba Morris, Chief, Air Quality Planning Branch,

D. Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

E. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2006–0817. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the

Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the West Virginia Department of Environmental Protection, Division of Air Quality, 601 57th Street, SE., Charleston, WV 25304.

FOR FURTHER INFORMATION CONTACT: Amy Caprio, (215) 814–2156, or by e-mail at *caprio.amy@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we'', ''us'', or ''our'' is used, we mean EPA.

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I. What Are the Actions EPA Is Proposing To Take?

On September 8, 2006 WVDEP formally submitted a request to redesignate Parkersburg from nonattainment to attainment of the 8-hour NAAQS for ozone. On September 8, 2006 West Virginia submitted a maintenance plan for Parkersburg as a SIP revision, to ensure continued attainment over the next 12 years. Parkersburg is comprised of Wood County, West Virginia. Parkersburg is currently designated as a basic 8-hour ozone nonattainment area. EPA is proposing to determine that Parkersburg has attained the 8-hour ozone NAAQS and that it has met the requirements for redesignation pursuant to section 107(d)(3)(E) of the CAA. EPA is, therefore, proposing to approve the redesignation request to change the designation of Parkersburg from nonattainment to attainment for the 8-hour ozone NAAQS. EPA is also proposing to approve the maintenance plan SIP revision for Parkersburg, such approval being one of the CAA requirements for approval of a redesignation request. The maintenance plan is designed to ensure continued attainment throughout the Area for the next 12 years. Additionally, EPA is announcing its action on the adequacy process for the MVEBs identified in the Parkersburg maintenance plan, and proposing to approve the MVEBs identified for volatile organic compounds (VOC) and nitrogen oxides (NO_X) for transportation conformity purposes. These MVEBs are state MVEBs for the West Virginia portion of the Area. In a separate submittal, the State of Ohio is establishing MVEBs for the remainder of this area (*i.e.*, Washington County). Concurrently, the State is requesting that EPA approve the maintenance plan as meeting the requirements of CAA 175A(b) with respect to the 1-hour ozone maintenance plan update.

II. What Is the Background for These Proposed Actions?

A. General

Ground-level ozone is not emitted directly by sources. Rather, emissions of NO_X and VOC react in the presence of sunlight to form ground-level ozone. The air pollutants NO_X and VOC are referred to as precursors of ozone. The CAA establishes a process for air quality management through the attainment and maintenance of the NAAQS.

On July 18, 1997, EPA promulgated a revised 8-hour ozone standard of 0.08 parts per million (ppm). This new standard is more stringent than the previous 1-hour ozone standard. EPA designated, as nonattainment, any area violating the 8-hour ozone NAAQS based on the air quality data for the three years of 2001–2003. These were the most recent three years of data at the time EPA designated 8-hour areas. The Area was designated as basic 8-hour ozone nonattainment status in a **Federal Register** notice signed on April 15, 2004 and published on April 30, 2004 (69 FR 23857). On June 15, 2005, the 1-hour ozone NAAQS was revoked in the Area (as well as most other areas of the country). See 40 CFR 50.9(b); 69 FR at 23996 (April 30, 2004); and see 70 FR 44470 (August 3, 2005).

The CAA, Title I, Part D, contains two sets of provisions—subpart 1 and subpart 2—that address planning and control requirements for nonattainment areas. Subpart 1 (which EPA refers to as ''basic'' nonattainment) contains general, less prescriptive requirements for nonattainment areas for any pollutant—including ozone—governed by a NAAQS. Subpart 2 (which EPA refers to as ''classified'' nonattainment) provides more specific requirements for ozone nonattainment areas. Some 8-hour ozone nonattainment areas are subject only to the provisions of subpart 1. Other areas are also subject to the provisions of subpart 2. Under EPA's 8-hour ozone implementation rule, signed on April 15, 2004, an area was classified under subpart 2 based on its 8-hour ozone design value (i.e., the 3-year average annual fourth-highest daily maximum 8-hour average ozone concentration), if it had a 1-hour design value at or above 0.121 ppm (the lowest 1-hour design value in the CAA for subpart 2 requirements). All other areas are covered under subpart 1, based upon their 8-hour design values. In 2004, the Area was designated a basic 8-hour ozone nonattainment area based upon air quality monitoring data from 2001–2003, and is subject to the requirements of subpart 1.

Under 40 CFR part 50, the 8-hour ozone standard is attained when the 3-year average of the annual fourth-highest daily maximum 8-hour average ambient air quality ozone concentration is less than or equal to 0.08 ppm (*i.e.*, 0.084 ppm when rounding is considered). See 69 FR 23857 (April 30, 2004) for further information. Ambient air quality monitoring data for the 3-year period must meet data completeness requirements. The data completeness requirements are met when the average percent of days with valid ambient monitoring data is greater than 90 percent, and no single year has less than 75 percent data completeness as determined in Appendix I of 40 CFR part 50. The ozone monitoring data indicates that Parkersburg has a design value of 0.082 ppm for the 3-year period of 2002–2004 and a design value of design value of 0.078 ppm for the 3-year period of 2003–2005. The ozone monitoring data indicates that Marietta

has a design value of 0.084 ppm for the 3-year period of 2002–2004 and a design value of 0.081 ppm for the 3-year period of 2003–2005. Therefore, the ambient ozone data for the Area indicates no violations of the 8-hour ozone standard. Final monitoring data for 2005 indicates continued attainment of the 8-hour ozone standard in the Area.

B. The Parkersburg-Marietta Area

The Area consists of Wood County, West Virginia and Washington County, Ohio. Prior to its designation as an 8-hour ozone nonattainment area, Parkersburg was a maintenance area for the 1-hour ozone nonattainment NAAQS. See rulemakings for Parkersburg (59 FR 29977, June 10, 1994) and (59 FR 45978, September 6, 1994).

On September 8, 2006 the WVDEP requested that Parkersburg be redesignated to attainment for the 8-hour ozone standard. The redesignation request included 3 years of complete, quality-assured data for the period of 2002–2004, indicating that the 8-hour ozone NAAQS had been achieved in Parkersburg. The data satisfies the CAA requirements that the 3-year average of the annual fourth-highest daily maximum 8-hour average ozone concentration (commonly referred to as the area's design value) must be less than or equal to 0.08 ppm (*i.e.*, 0.084 ppm when rounding is considered). Under the CAA, a nonattainment area may be redesignated if sufficient complete, quality-assured data is available to determine that the area has attained the standard and the area meets the other CAA redesignation requirements set forth in section 107(d)(3)(E).

III. What Are the Criteria for Redesignation to Attainment?

The CAA provides the requirements for redesignating a nonattainment area to attainment. Specifically, section 107(d)(3)(E) of the CAA, allows for redesignation, providing that:

(1) EPA determines that the area has attained the applicable NAAQS;

(2) EPA has fully approved the applicable implementation plan for the area under section 110(k);

(3) EPA determines that the improvement in air quality is due to permanent and enforceable reductions in emissions resulting from implementation of the applicable SIP and applicable Federal air pollutant control regulations and other permanent and enforceable reductions;

(4) EPA has fully approved a maintenance plan for the area as meeting the requirements of section 175A; and

(5) The state containing such area has met all requirements applicable to the area under section 110 and part D.

EPA provided guidance on redesignation in the General Preamble for the Implementation of Title I of the CAA Amendments of 1990, on April 16, 1992 (57 FR 13498), and supplemented this guidance on April 28, 1992 (57 FR 18070). EPA has provided further guidance on processing redesignation requests in the following documents:

- ''Ozone and Carbon Monoxide Design Value Calculations'', Memorandum from Bill Laxton, June 18, 1990;
- ''Maintenance Plans for Redesignation of Ozone and Carbon Monoxide Nonattainment Areas,'' Memorandum from G.T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, April 30, 1992;
- ''Contingency Measures for Ozone and Carbon Monoxide (CO) Redesignations,'' Memorandum from G. T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, June 1, 1992;
- ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992;
- ''State Implementation Plan (SIP) Actions Submitted in Response to Clean Air Act (Act) Deadlines,'' Memorandum from John Calcagni Director, Air Quality Management Division, October 28, 1992;
- ''Technical Support Documents (TSD's) for Redesignation Ozone and Carbon Monoxide (CO) Nonattainment Areas,'' Memorandum from G.T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, August 17, 1993;
- ''State Implementation Plan (SIP) Requirements for Areas Submitting Requests for Redesignation to Attainment of the Ozone and Carbon Monoxide (CO) National Ambient Air Quality Standards (NAAQS) On or After November 15, 1992,'' Memorandum from Michael H. Shapiro, Acting Assistant Administrator for Air and Radiation, September 17, 1993;
- Memorandum from D. Kent Berry, Acting Director, Air Quality Management Division, to Air Division Directors, Regions 1–10, ''Use of Actual Emissions in Maintenance Demonstrations for Ozone and CO Nonattainment Areas,'' dated November 30, 1993;
- ''Part D New Source Review (Part D NSR) Requirements for Areas Requesting Redesignation to Attainment,'' Memorandum from Mary D. Nichols, Assistant Administrator for Air and Radiation, October 14, 1994; and
- ''Reasonable Further Progress, Attainment Demonstration, and Related Requirements for Ozone Nonattainment Areas Meeting the Ozone National Ambient Air Quality Standard,'' Memorandum from John S. Seitz, Director, Office of Air Quality Planning and Standards, May 10, 1995.

IV. Why Is EPA Taking These Actions?

On September 8, 2006 the WVDEP requested redesignation of Parkersburg to attainment for the 8-hour ozone standard, and submitted a maintenance plan for Parkersburg as a SIP revision to assure continued attainment over the next 12 years, until 2018. Concurrently, West Virginia is requesting that EPA approve the maintenance plan as meeting the requirements of CAA 175A(b) with respect to the 1-hour ozone maintenance plan update. EPA is proposing to approve the maintenance plan to fulfill the requirement of section 175A(b) for submission of a maintenance plan update eight years after Parkersburg was redesignated to attainment of the 1-hour ozone NAAQS. EPA believes that such an update must ensure that the maintenance plan in the SIP, provides maintenance of the NAAQS for a period of 20 years after an area is initially redesignated to attainment. EPA can propose approval because the maintenance plan, which demonstrates maintenance of the 8-hour ozone NAAQS through 2018, also demonstrates maintenance of the 1-hour ozone NAAQS through 2018, even though the latter standard is no longer in effect. Parkersburg was redesignated to attainment of the 1-hour ozone NAAQS on September 6, 1994 (59 FR 45978), and the initial 1-hour ozone maintenance plan provided for maintenance through 2005. Marietta was designated Unclassifiable/Attainment under the 1-hour ozone standard. See 40 CFR Part 81.336 (Revised as of July 2001). Section 51.905(e) of the ''Final Rule To Implement the 8-Hour Requirements—Phase 1'' April 30, 2004 (69 FR 23999), specifies the conditions that must be satisfied before EPA may approve a modification to a 1-hour maintenance plan which: (1) Removes the obligation to submit a maintenance plan for the 1-hour ozone NAAQS eight years after approval of the initial 1-hour maintenance plan and/or (2) removes the obligation to implement contingency measures upon a violation of the 1-hour NAAQS. EPA believes that section 51.905(e) of the final rule allows a State to make either one or both of these

modifications to a 1-hour maintenance plan SIP after EPA approves a maintenance plan for the 8-hour NAAQS. The maintenance plan will not trigger the contingency plan upon a violation of the 1-hour ozone NAAQS, but instead upon a violation of the 8-hour ozone NAAQS. EPA believes that the 8-hour standard is now the proper standard which should trigger the contingency plan now that the 1-hour NAAQS has been revoked. EPA has determined that Parkersburg has attained the standard and has met the requirements for redesignation set forth in section 107(d)(3)(E).

V. What Would Be the Effect of These Actions?

Approval of the redesignation request would change the designation of Parkersburg from nonattainment to attainment for the 8-hour ozone NAAQS found at 40 CFR part 81. It would also incorporate into the West Virginia SIP a maintenance plan ensuring continued attainment of the 8-hour ozone NAAQS in Parkersburg for the next 12 years, until 2018. The maintenance plan includes contingency measures to remedy any future violations of the 8-hour NAAQS (should they occur), and identifies the MVEBs for NO_X and VOC for transportation conformity purposes for 2009 and 2018. These MVEBs are displayed in the following table:

TABLE 1.—MOTOR VEHICLE EMISSIONS BUDGETS IN TONS PER DAY (TPD)

Year	NO_X	VOC
2009	4.1	3.0
2018	2.0	1.9

VI. What Is EPA's Analysis of the State's Request?

EPA is proposing to determine that the Area has attained the 8-hour ozone standard and that all other redesignation criteria have been met. The following is a description of how the WVDEP's September 8, 2006 submittal satisfies the requirements of section 107(d)(3)(E) of the CAA.

A. The Parkersburg-Marietta Area Has Attained the 8-Hour Ozone NAAQS

EPA is proposing to determine that the Area has attained the 8-hour ozone NAAQS. For ozone, an area may be considered to be attaining the 8-hour ozone NAAQS if there are no violations, as determined in accordance with 40 CFR 50.10 and Appendix I of part 50, based on three complete, consecutive calendar years of quality-assured air quality monitoring data. To attain this standard, the 3-year average of the fourth-highest daily maximum 8-hour average ozone concentrations measured at each monitor, within the area, over each year must not exceed the ozone standard of 0.08 ppm. Based on the rounding convention described in 40 CFR part 50, Appendix I, the standard is attained if the design value is 0.084 ppm or below. The data must be collected and quality-assured in accordance with 40 CFR part 58, and recorded in the Air Quality System (AQS). The monitors generally should have remained at the same location for the duration of the monitoring period required for demonstrating attainment.

There are two ozone monitors in the Area, one located in Wood County, West Virginia and one located in Washington County, Ohio. As part of its redesignation request, West Virginia submitted ozone monitoring data for the years 2000–2005 for the Area. This data has been quality assured and was recorded in AQS. The fourth high 8-hour daily maximum concentrations, along with the three-year averages, are summarized in Tables 2 and 3.

TABLE 2.—PARKERSBURG'S FOURTH HIGHEST 8-HOUR AVERAGE VALUES; WOOD COUNTY MONITOR, AQS ID 54–107–1002

Year	Annual 4th high reading (ppm)
2000	0.087
2001	0.084
2002	0.095
2003	0.083
2004	0.069
2005	0.084

The average for the 3-year period 2002 through 2004 is 0.082 ppm.

The average for the 3-year period 2003 through 2005 is 0.078 ppm.

TABLE 3.—MARIETTA'S FOURTH HIGHEST 8-HOUR AVERAGE VALUES; WASHINGTON COUNTY MONITOR, AQS ID 39–167–0004

Year	Annual 4th high reading (ppm)
2000	0.082
2001	0.085
2002	0.095
2003	0.080
2004	0.077
2005	0.088

The average for the 3-year period 2002 through 2004 is 0.084 ppm.

The average for the 3-year period 2003 through 2005 is 0.081 ppm.

The air quality data for 2002–2004 show that the entire Area has attained the standard with a design value of 0.082 ppm for Parkersburg and a design value of 0.084 ppm for Marietta. Also, the air quality data for 2003–2005 show that the entire Area is still attaining the standard with a design value of 0.078 ppm for Parkersburg and a design value of 0.081 ppm for Marietta. The data collected at the Area monitors satisfy the CAA requirement that the 3-year average of the annual fourth-highest daily maximum 8-hour average ozone concentration is less than or equal to 0.08 ppm. The WVDEP's request for redesignation for Parkersburg indicates that the data were quality assured in accordance with 40 CFR part 58. The WVDEP uses AQS as the permanent database to maintain its data and quality assures the data transfers and content for accuracy. In addition, as discussed below with respect to the maintenance plan, WVDEP has committed to continue monitoring in accordance with 40 CFR part 58. In summary, EPA has determined that the data submitted by West Virginia and data taken from AQS indicates that the Area has attained the 8-hour ozone NAAQS.

B. Parkersburg Has Met All Applicable Requirements Under Section 110 and Part D of the CAA and Has a Fully Approved SIP Under Section 110(k) of the CAA

EPA has determined that Parkersburg has met all SIP requirements applicable for purposes of this redesignation under section 110 of the CAA (General SIP Requirements) and that it meets all applicable SIP requirements under Part D of Title I of the CAA, in accordance with section 107(d)(3)(E)(v). In addition, EPA has determined that the SIP is fully approved with respect to all requirements applicable for purposes of redesignation in accordance with section 107(d)(3)(E)(ii). In making these proposed determinations, EPA ascertained which requirements are applicable to Parkersburg and determined that the applicable portions of the SIP meeting these requirements are fully approved under section 110(k) of the CAA. We note that SIPs must be fully approved only with respect to applicable requirements.

The September 4, 1992 Calcagni memorandum (''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992) describes EPA's interpretation of section 107(d)(3)(E) with respect to the timing of applicable requirements. Under this interpretation, to qualify for redesignation, states requesting redesignation to attainment

must meet only the relevant CAA requirements that came due prior to the submittal of a complete redesignation request. See also Michael Shapiro memorandum, September 17, 1993, and 60 FR 12459, 12465–66 (March 7, 1995) (redesignation of Detroit-Ann Arbor). Applicable requirements of the CAA that come due subsequent to the area's submittal of a complete redesignation request remain applicable until a redesignation is approved, but are not required as a prerequisite to redesignation. Section 175A(c) of the CAA. *Sierra Club* v. *EPA,* 375 F.3d 537 (7th Cir. 2004). See also 68 FR at 25424, 25427 (May 12, 2003) (redesignation of St. Louis).

1. Section 110 General SIP Requirements

Section 110(a)(2) of Title I of the CAA delineates the general requirements for a SIP, which include enforceable emissions limitations and other control measures, means, or techniques, provisions for the establishment and operation of appropriate devices necessary to collect data on ambient air quality, and programs to enforce the limitations. The general SIP elements and requirements set forth in section 110(a)(2) include, but are not limited to, the following:

- Submittal of a SIP that has been adopted by the state after reasonable public notice and hearing;
- Provisions for establishment and operation of appropriate procedures needed to monitor ambient air quality;
- Implementation of a source permit program; provisions for the implementation of Part C requirement (Prevention of Significant Deterioration (PSD));
- Provisions for the implementation of Part D requirements for New Source Review (NSR) permit programs;
- Provisions for air pollution modeling; and
- Provisions for public and local agency participation in planning and emission control rule development.

Section 110(a)(2)(D) requires that SIPs contain certain measures to prevent sources in a state from significantly contributing to air quality problems in another state. To implement this provision, EPA has required certain states to establish programs to address transport of air pollutants in accordance with the NO_X SIP Call, October 27, 1998 (63 FR 57356), amendments to the NO_X SIP Call, May 14, 1999 (64 FR 26298) and March 2, 2000 (65 FR 11222), and the Clean Air Interstate Rule (CAIR), May 12, 2005 (70 FR 25162). However, the section 110(a)(2)(D) requirements for a state are not linked with a particular nonattainment area's designation and classification in that state. EPA believes that the requirements linked with a particular nonattainment area's designation and classifications are the relevant measures to evaluate in reviewing a redesignation request. The transport SIP submittal requirements, where applicable, continue to apply to a state regardless of the designation of any one particular area in the state.

Thus, we do not believe that these requirements are applicable requirements for purposes of redesignation. In addition, EPA believes that the other section 110 elements not connected with nonattainment plan submissions and not linked with an area's attainment status are not applicable requirements for purposes of redesignation. West Virginia and Ohio will still be subject to these requirements after the Area is redesignated. The section 110 and Part D requirements, which are linked with a particular area's designation and classification, are the relevant measures to evaluate in reviewing a redesignation request. This policy is consistent with EPA's existing policy on applicability of conformity (*i.e.,* for redesignations) and oxygenated fuels requirement. See Reading, Pennsylvania, proposed and final rulemakings 61 FR 53174–53176 (October 10, 1996), 62 FR 24826 (May 7, 1997); Cleveland-Akron-Lorain, Ohio, final rulemaking 61 FR 20458 (May 7, 1996); and Tampa, Florida, final rulemaking 60 FR 62748 (December 7, 1995). See also the discussion on this issue in the Cincinnati, Ohio redesignation 65 FR at 37890 (June 19, 2000), and in the Pittsburgh, Pennsylvania redesignation 66 FR at 53099 (October 19, 2001). Similarly, with respect to the NO_X SIP Call rules, EPA noted in its Phase 1 Final Rule to Implement the 8-hour Ozone NAAQS, that the NO_X SIP Call rules are not ''an 'applicable requirement' for purposes of section 110(1) because the NO_X rules apply regardless of an area's attainment or nonattainment status for the 8-hour (or the 1-hour) NAAQS.'' 69 FR 23951, 23983 (April 30, 2004).

EPA believes that section 110 elements not linked to the area's nonattainment status are not applicable for purposes of redesignation. Any section 110 requirements that are linked to the Part D requirements for 8-hour ozone nonattainment areas are not yet due, because, as we explain later in this notice, no Part D requirements applicable for purposes of redesignation under the 8-hour standard became due prior to submission of the redesignation request.

Because the West Virginia SIP satisfies all of the applicable general SIP elements and requirements set forth in section 110(a)(2), EPA concludes that West Virginia has satisfied the criterion of section 107(d)(3)(E) regarding section 110 of the Act.

2. Part D Nonattainment Area Requirements Under the 8-Hour Standard

The Area was designated a basic nonattainment area for the 8-hour ozone standard. Sections 172–176 of the CAA, found in subpart 1 of Part D, set forth the basic nonattainment requirements for all nonattainment areas. As discussed previously, there are no outstanding Part D submittals under the 1-hour standard for this Area.

Section 182 of the CAA, found in subpart 2 of Part D, establishes additional specific requirements depending on the area's nonattainment classification. The Area was classified as a subpart 1 nonattainment area; therefore, no subpart 2 requirements apply to the Area. With respect to the 8-hour standard, EPA proposes to determine that the West Virginia SIP meets all applicable SIP requirements under Part D of the CAA, because no 8-hour ozone standard Part D requirements applicable for purposes of redesignation became due prior to submission of the Area's redesignation request on September 8, 2006. Because the State submitted a complete redesignation request for Parkersburg prior to the deadline for any submissions required under the 8-hour standard, we have determined that the Part D requirements do not apply to Parkersburg for the purposes of redesignation.

In addition to the fact that Part D requirements applicable for purposes of redesignation did not become due prior to submission of the redesignation request, EPA believes it is reasonable to interpret the general conformity and NSR requirements as not requiring approval prior to redesignation.

With respect to section 176, Conformity Requirements, section 176(c) of the CAA requires states to establish criteria and procedures to ensure that federally supported or funded projects conform to the air quality planning goals in the applicable SIP. The requirement to determine conformity applies to transportation plans, programs, and projects developed, funded or approved under Title 23 U.S.C. and the Federal Transit Act (''transportation conformity'') as well as to all other Federally supported or funded projects (''general conformity''). State conformity revisions

must be consistent with Federal conformity regulations relating to consultation, enforcement and enforceability that the CAA required the EPA to promulgate.

EPA believes it is reasonable to interpret the conformity SIP requirements as not applying for purposes of evaluating the redesignation request under section 107(d) since state conformity rules are still required after redesignation and federal conformity rules apply where state rules have not been approved. See *Wall* v. *EPA,* 265 F. 3d 426, 438 (6th Cir. 2001), upholding this interpretation. See also 60 FR 62748 (December 7, 1995).

EPA has also determined that areas being redesignated need not comply with the requirement that a NSR program be approved prior to redesignation, provided that the area demonstrates maintenance of the standard without Part D NSR in effect, because PSD requirements will apply after redesignation. The rationale for this position is described in a memorandum from Mary Nichols, Assistant Administrator for Air and Radiation, dated October 14, 1994, entitled, ''Part D NSR Requirements or Areas Requesting Redesignation to Attainment.'' West Virginia has demonstrated that the Area will be able to maintain the standard without Part D NSR in effect in Parkersburg, and therefore, West Virginia need not have a fully approved Part D NSR program prior to approval of the redesignation request. West Virginia's SIP-approved PSD program will become effective in Parkersburg upon redesignation to attainment. See rulemakings for Detroit, Michigan (60 FR at 12467–68); Cleveland-Akron-Lorrain, Ohio (61 FR at 20458, 20469–70); Louisville, Kentucky (66 FR 53665, 53669 October 23, 2001); Grand Rapids, Michigan (61 FR at 31831, 31834–37, June 21, 1996).

3. Parkersburg Has a Fully Approved SIP for the Purposes of Redesignation

EPA has fully approved the West Virginia SIP for the purposes of this redesignation. EPA may rely on prior SIP approvals in approving a redesignation request. Calcagni Memo, p. 3; *Southwestern Pennsylvania Growth Alliance* v. *Browner,* 144 F. 3d 984, 989–90 (6th Cir. 1998), *Wall* v. *EPA,* 265 F.3d 426 (6th Cir. 2001), plus any additional measures it may approve in conjunction with a redesignation action. See 68 FR at 25425 (May 12, 2003) and citations therein. Parkersburg was a 1-hour maintenance area at the time of its designation as a basic 8-hour ozone nonattainment area on April 30, 2004. Because Parkersburg was a 1-hour maintenance area, all previous Part D SIP submittal requirements were fulfilled at the time Parkersburg was redesignated to attainment of the 1-hour ozone NAAQS or have been fulfilled with the September 8, 2006 submittal of the 8-hour maintenance plan. See rulemakings for Parkersburg (59 FR 29977, June 10, 1994) and (59 FR 45978, September 6, 1994). Because there are no outstanding SIP submission requirements applicable for the purposes of redesignation of Parkersburg, the applicable implementation plan satisfies all pertinent SIP requirements.

C. The Air Quality Improvement in the Area Is Due to Permanent and Enforceable Reductions in Emissions Resulting From Implementation of the SIP and Applicable Federal Air Pollution Control Regulations and Other Permanent and Enforceable Reductions

EPA believes that the State has demonstrated that the observed air quality improvement in the Area is due to permanent and enforceable reductions in emissions resulting from implementation of the SIP, Federal measures, and other state-adopted measures. Emissions reductions attributable to these rules in the Area are shown in Table 4.

TABLE 4.—PARKERSBURG TOTAL VOC AND NO_X EMISSIONS FOR 2002 AND 2004 (TPD)

Year	Point	Area	Nonroad	Mobile	Total*
Volatile Organic Compounds (VOC)					
Year 2002	1.8	7.6	2.8	4.8	17.0
Year 2004	2.1	7.8	2.8	4.0	16.7
Diff. (02–04)	+0.3	+0.2	0	−0.8	−0.3
Nitrogen Oxides (NO_X)					
Year 2002	2.6	0.7	4.9	6.1	14.3
Year 2004	2.6	0.7	6.2	5.7	15.2
Diff. (02–04)	0	0	+1.3	−0.4	+0.9
Marietta Total VOC and NO_X Emissions for 2002 and 2004 (tpd)					
Volatile Organic Compounds (VOC)					
Year 2002	2.1	3.0	1.3	4.4	10.8
Year 2004	2.1	2.9	1.2	3.6	9.8
Diff. (02–04)	0	−0.1	−0.1	−0.8	−1.0
Nitrogen Oxides (NO_X)					
Year 2002	94.6	0.2	5.3	5.7	105.8
Year 2004	71.9	0.2	5.0	4.9	82.0
Diff. (02–04)	−22.7	0	−0.3	−0.8	−23.8

* Emissions not exact due to rounding.

Between 2002 and 2004, VOC emissions in the Area were reduced by approximately 1.3 tpd, and NO_X emissions in the Area were reduced by 22.9 tpd. The reductions, and anticipated future reductions, are due to the following permanent and enforceable measures.

Programs Currently in Effect

(a) National Low Emission Vehicle (NLEV);

(b) Motor vehicle fleet turnover with new vehicles meeting the Tier 2 standards; and,

(c) Clean Diesel Program.

West Virginia has demonstrated that the implementation of permanent enforceable emissions controls have reduced local VOC and NO_X emissions. Reductions in VOC are attributable to mobile and nonroad source emission controls such as Federally mandated Tier 2 Vehicle and Gasoline Sulfur Program and the Clean Diesel Program.

Although there are no electric generating units (EGUs) in Wood County, West Virginia, the WVDEP, Division of Air Quality (DAQ) has identified permanent and enforceable reductions in NO_X emissions from EGUs in the Washington County, Ohio portion of the Area. In addition, the WVDEP has identified permanent and enforceable reductions in NO_X emissions from the implementation of the NO_X SIP call from EGUs and large industrial boilers located in counties adjacent to the Area, such as Pleasant County, West Virginia.

Additionally, WVDEP has identified, but not quantified, additional reductions in VOC emissions that will be achieved as a co-benefit of the reductions in the emission of hazardous air pollutants (HAPs) as a result of implementation of EPA's Maximum Achievable Control Technology (MACT) standards.

Other regulations, such as the non-road diesel, 69 FR 38958 (June 29, 2004), the heavy duty engine and vehicle standards, 66 FR 5002 (January 18, 2001) and the new Tier 2 tailpipe standards for automobiles, 65 FR 6698 (January 10, 2000), are also expected to greatly reduce emissions throughout the country and thereby reduce emissions impacting the Area monitors. The Tier 2 standards came into effect in 2004, and by 2030, EPA expects that the new Tier 2 standards will reduce NO_X emissions by about 74 percent nationally. EPA believes that permanent and enforceable emissions reductions contributed to the long-term improvement in ozone levels and are the cause of the Area achieving attainment of the 8-hour ozone standard.

D. Parkersburg Has a Fully Approved Maintenance Plan Pursuant to Section 175A of the CAA

In conjunction with its request to redesignate Parkersburg to attainment status, West Virginia submitted a SIP revision to provide for maintenance of the 8-hour ozone NAAQS in Parkersburg for at least 12 years after redesignation. West Virginia is requesting that EPA approve this SIP revision as meeting the requirements of CAA sections 175A(a) and 175A(b). Section 175A(a) was met with the September 8, 2006 submission of the maintenance plan, because it states that Parkersburg will maintain the 8-hour ozone NAAQS for at least 10 years after redesignation. Section 175A(b) was met with the September 8, 2006 submission of the maintenance plan, because it will replace the 1-hour ozone maintenance plan update requirement that was due 8 years after redesignation of Parkersburg to attainment.

Under 40 CFR 51.905(e), the EPA may approve a SIP revision requesting the removal of the obligation to implement contingency measures upon a violation of the 1-hour ozone NAAQS when the State submits and EPA approves an attainment demonstration for the 8-hour ozone NAAQS for an area *initially designated* nonattainment for the 8-hour NAAQS or a maintenance SIP for the 8-hour NAAQS for an area *initially designated* attainment for the 8-hour NAAQS. The rationale behind 40 CFR 51.905(e) is to ensure that Parkersburg maintains the applicable ozone standard (the 8-hour standard in areas where the 1-hour standard has been revoked). EPA believes this rationale analogously applies to areas that were not initially designated, but are *redesignated* as attainment with the 8-hour ozone NAAQS. Therefore, EPA intends to treat redesignated areas as though they had been initially designated attainment of the 8-hour ozone NAAQS, and accordingly proposes to relieve Parkersburg of its maintenance plan obligations with respect to the 1-hour standard. Once approved, the maintenance plan for the 8-hour ozone NAAQS will ensure that the SIP for Parkersburg meets the requirements of the CAA regarding maintenance of the applicable 8-hour ozone standard.

What Is Required in a Maintenance Plan?

Section 175A of the CAA sets forth the elements of a maintenance plan for areas seeking redesignation from nonattainment to attainment. Under section 175A(a), the plan must demonstrate continued attainment of the applicable NAAQS for at least 10 years after approval of a redesignation of an area to attainment. Section 175A(b) states that eight years after redesignation from nonattainment to attainment, the State must submit a revised maintenance plan demonstrating that attainment will continue to be maintained for the next 10-year period following the initial 10-year period. To address the possibility of future NAAQS violations, the maintenance plan must contain such contingency measures, with a schedule for implementation, as EPA deems necessary to assure prompt correction of any future 8-hour ozone violations. Section 175A of the CAA sets forth the elements of a maintenance plan for areas seeking redesignation from nonattainment to attainment. The Calcagni memorandum dated September 4, 1992, provides additional guidance on the content of a maintenance plan. An ozone maintenance plan should address the following provisions:

(a) An attainment emissions inventory;

(b) a maintenance demonstration;

(c) a monitoring network;

(d) verification of continued attainment; and

(e) a contingency plan.

Analysis of the Parkersburg Maintenance Plan

(a) *Attainment Inventory*—An attainment inventory includes the emissions during the time period associated with the monitoring data showing attainment. An attainment year of 2004 was used for Parkersburg since it is a reasonable year within the 3-year block of 2002–2004 and accounts for reductions attributable to implementation of the CAA requirements to date.

The WVDEP prepared comprehensive VOC and NO_X emissions inventories for Parkersburg, including point, area, mobile on-road, and mobile non-road sources for a base year of 2002.

To develop the NO_X and VOC base year emissions inventories, WVDEP used the following approaches and sources of data:

(i) *Point source emissions*—There are no EGUs in Parkersburg so documentation of procedures for developing ozone season day emissions is unnecessary. For the non-EGUs WVDEP used data supplied by facilities that is maintained in their i-STEPs database (a WVDEP maintained database that contains the states point source emission information).

(ii) *Area source emissions*—In order to calculate the area source emissions inventory the WVDEP took the annual values from the Visibility Improvement State and Tribal Association of the Southeast (VISTAS) base year inventory and derived the typical ozone summer weekday, using procedures outlined in the EPA's Emissions Modeling Clearinghouse (EMCH) Memorandum, ''Temporal Allocation of Annual Emissions Using EMCH Temporal

Profiles, April 29, 2002.'' This enabled WVDEP to arrive at the ''typical'' summer day emissions.

(iii) *On-road mobile source emissions*—VISTAS developed 2002 on-road mobile (highway) emissions inventory data based on vehicle miles traveled (VMT) updates provided by WVDEP. VISTAS also estimated future emissions based upon expected growth for the future years 2009 and 2018. However, federal Transportation Conformity requirements dictate that the WVDEP consult with the Metropolitan Planning Organization (MPO) responsible for transportation planning in developing SIP revisions which may establish MVEBs. This applies to the maintenance plan submitted by WVDEP on September 8, 2006. Therefore, the WVDEP has consulted with the Parkersburg MPO, the Wood-Washington-Wirt Interstate Planning Commission (WWW) to develop state MVEBs for the West Virginia portion of the Area. The WWW provided base year and projection emissions data consistent with their most recent available Travel Demand Model (TDM) results along with EPA's most recent emission factor model, MOBILE6.2. The WVDEP used these data to estimate highway emissions and, in consultation with the WWW, to develop highway emissions budgets for VOC and NO_X. The WWW must evaluate future Long Range Transportation Plans and Transportation Improvement Programs to ensure that the associated emissions are equal to or less then the final emissions budgets. The budgets are designed to facilitate a positive conformity determination while ensuring overall maintenance of the 8-hour NAAQS. It should be noted that the MVEBs and budgets only represent the Parkersburg, West Virginia (Wood County) portion of the Area.

(iv) *Mobile non-road emissions*—The 2002 mobile non-road emissions inventory was developed by WVDEP staff using the NONROAD2005b Model.

The 2004 attainment year VOC and NO_X emissions for the Area are summarized along with the 2009 and 2018 projected emissions in Table 5, which cover the demonstration of maintenance for the Area. EPA has concluded that West Virginia has adequately derived and documented the 2004 attainment year VOC and NO_X emissions for Parkersburg.

(b) *Maintenance Demonstration*—On September 8, 2006 the WVDEP submitted a SIP revision. The SIP submittal by WVDEP consists of the maintenance plan as required by section 175A of the CAA. The Parkersburg plan shows maintenance of the 8-hour ozone NAAQS by demonstrating that current and future emissions of VOC and NO_X remain at or below the attainment year 2004 emissions levels throughout Parkersburg through the year 2018. The Parkersburg maintenance demonstration need not be based on modeling. See *Wall* v. *EPA, Supra, Sierra Club* v. *EPA, Supra.* See also 66 FR at 53099–53100; 68 FR at 25418, 25430–32.

Table 5 shows the Area's VOC and NO_X emissions for 2004, 2009, and 2018. The WVDEP chose 2009 as an interim year in the 12-year maintenance demonstration period to demonstrate that the overall VOC and NO_X emissions are not projected to increase above the 2004 attainment level during the time of the 12-year maintenance period.

TABLE 5.—PARKERSBURG-MARIETTA, WV–OH NONATTAINMENT AREA SUMMARY OF EMISSIONS

[All emissions in tpd for an ozone season day]

	Emissions in tpd								
	2004			2009			2018		
	WV [1]	OH [2]	Total	WV [1]	OH [2]	Total	WV [1]	OH [2]	Total
Point:									
NO_X	2.6	71.9	74.5	2.6	15.1	17.7	2.8	22.0	24.8
VOC	2.1	2.1	4.2	1.4	2.3	3.7	1.7	2.7	4.4
Area:									
NO_X	0.7	0.2	0.9	0.7	0.2	0.9	0.8	0.3	1.1
VOC	7.8	2.9	10.7	7.2	2.8	10.0	8.0	2.9	10.9
Nonroad: [3]									
NO_X	6.2	5.0	11.2	4.4	4.2	8.6	3.8	3.6	7.4
VOC	2.8	1.2	4.0	2.4	1.0	3.4	2.0	0.8	2.8
MVEBs: [4]									
NO_X	5.7	4.9	10.6	4.1	3.6	7.7	2.0	1.8	3.8
VOC	4.0	3.4	7.4	3.0	2.6	5.6	1.9	1.7	3.6
Total: [5]									
NO_X	15.2	82.0	97.2	11.8	23.1	34.9	9.4	27.7	37.1
VOC	16.7	9.6	26.3	14.0	8.7	22.7	13.6	8.1	21.7

[1] WV emissions are total emissions for Wood County in West Virginia.
[2] OH emissions are total emissions for Washington County in Ohio, as provided by Ohio EPA.
[3] Nonroad includes NONROAD model results plus Commercial Marine Vessels, Railroad and Airports.
[4] MVEBs for 2004 are actual; budgets established for 2009 and 2018 include 15% reallocation from the safety margin.
[5] Sums may not total exactly due to rounding.

Additionally, the following mobile programs are either effective or due to become effective and will further contribute to the maintenance demonstration of the 8-hour ozone NAAQS:

• Heavy duty diesel on-road (2004/2007) and low-sulfur on-road (2006); 66 FR 5002 (January 18, 2001); and

• Non-road emissions standards (2008) and off-road diesel fuel (2007/2010); 69 FR 39858 (June 29, 2004).

In addition to the permanent and enforceable measures, CAIR, promulgated May 12, 2005 (70 FR 25162) should have positive impacts on West Virginia and Ohio's air quality. CAIR, which will be implemented in the eastern portion of the country in two phases (2009 and 2015), should reduce long range transport of ozone precursors, which will have a beneficial effect on air quality in the Area. West Virgina projected to achieve a 64 percent reduction and a 62 percent reduction in NO_X emissions by 2009 and 2018, respectively in the Area. The future year NO_X emissions decreases are largely attributable to the implementation of CAIR which West Virginia projects to result in a decrease of 83 percent and 74 percent for 2009 and 2018 from EGU sources located in Washington County, Ohio.

Currently, West Virginia is in the process of adopting rules to address CAIR through state rules 45CSR39, 45CSR40, and 45CSR41, which require annual and ozone season NO_X reductions from EGUs and ozone season NO_X reductions from non-EGUs. These rules were submitted to EPA as a SIP revision by September 11, 2006 as required in the May 12, 2005 (70 FR 25162) **Federal Register** publication.

Based upon the comparison of the projected emissions and the attainment year emissions, along with the additional measures, EPA concludes that WVDEP has successfully demonstrated that the 8-hour ozone standard should be maintained in the Area.

(c) *Monitoring Network*—The Area currently has two ozone monitors, one in Wood County, West Virginia and one in Washington County, Ohio. West Virginia will continue to operate its current air quality monitor (located in Wood County) in accordance with 40 CFR part 58.

(d) *Verification of Continued Attainment*—The State of West Virginia has the legal authority to implement and enforce specified measures necessary to attain and maintain the NAAQS. Additionally, Federal programs such as Tier 2/Low Sulfur Gasoline Rule, 2007 On-Road Diesel Engine Rule, and Federal Non-road Engine/Equipment Rules will continue to be implemented on a national level. These programs help provide the reductions necessary for the Area to maintain attainment.

In addition to maintaining the key elements of its regulatory program, the WVDEP proposes to fully update its point, area, and mobile emission inventories at 3-year intervals as required by the Consolidated Emissions Reporting Rule (CERR) to ensure that its growth projections relative to emissions in these areas are sufficiently accurate to assure ongoing attainment with the NAAQS. The WVDEP will review stationary source VOC and NO_X emissions by review of annual emissions statements and by update of its emissions inventories. The area source inventory will be updated using the same techniques as the 2002 ozone inventory. However, some source categories may be updated using historic activity levels determined from Bureau of Economic Analysis (BEA) data or West Virginia University/Regional Research Institute (WVU/RRI) population estimates. The mobile source inventory model will be updated by obtaining county-level VMT from the West Virginia Department of Transportation (WVDOT) for the subject year and calculating emissions using the latest approved MOBILE model. Alternatively, the motor vehicle emissions may be obtained in consultation with the MPO, the WWW, using methodology similar to that used for Transportation Conformity purposes.

The WVDEP shall also continue to operate the existing ozone monitoring stations in the areas pursuant to 40CFR58 throughout the maintenance period and submit quality-assured ozone data to EPA through AQS.

West Virginia also commits to submit a revision of the SIP eight years after final approval of the State's redesignation request to provide for maintenance of the NAAQS for a total of 20 years as required by the CAA.

(e) *The Maintenance Plan's Contingency Measures*—The contingency plan provisions are designed to promptly correct a violation of the NAAQS that occurs after redesignation. Section 175A of the Act requires that a maintenance plan include such contingency measures as EPA deems necessary to ensure that the State will promptly correct a violation of the NAAQS that occurs after redesignation. The maintenance plan should identify the events that would ''trigger'' the adoption and implementation of a contingency measure(s), the contingency measure(s) that would be adopted and implemented, and the schedule indicating the time frame by which the State would adopt and implement the measure(s).

The ability of Parkersburg to stay in compliance with the 8-hour ozone standard after redesignation depends upon VOC and NO_X emissions in Parkersburg remaining at or below 2004 levels. The State's maintenance plan projects VOC and NO_X emissions to decrease and stay below 2004 levels through the year 2018. The State's maintenance plan lays out two situations where the need to adopt and implement a contingency measure to further reduce emissions would be triggered. Those situations are as follows:

(i) If the triennial inventories indicate emissions growth above the 2004 maintenance base-year inventory or if a monitored air quality exceedance pattern indicates that an ozone NAAQS violation may be imminent—The maintenance plan states that an exceedance pattern would include, but is not limited to, the measurement of six exceedances or more occurring at the same monitor during a calendar year. The plan also states that comprehensive tracking inventories will also be developed every 3 years using current EPA-approved methods to ensure that its growth projections relative to emissions in Parkersburg are sufficiently accurate to assure ongoing attainment with the NAAQS. If the inventories indicate emissions growth above the 2004 maintenance base-year inventory or a monitored air quality exceedance pattern occurs, the following measure will be implemented:

• WVDEP will evaluate existing control measures to ascertain if additional regulatory revisions are necessary to maintain the ozone standard.

(ii) In the event that a violation of the 8-hour ozone standard occurs at any monitor in the Parkersburg-Marietta Area—The maintenance plan states that in the event that a violation of the ozone standard occurs at any monitor in the Parkersburg-Marietta Area, the State of West Virginia, will implement one or more of the following measures to assure continued attainment:

• Extend the applicability of 45CSR21 (VOC/RACT rule) to include source categories previously excluded (*e.g.*, waste water treatment facilities);

• Revised new source permitting requirements requiring more stringent emissions control technology and/or emissions offsets;

• NO_X RACT requirements;

• Regulations to establish plant-wide emissions caps (potentially with emissions trading provisions);

• Stage II Vapor Recovery regulations;

• Establish a Public Awareness/Ozone Action Day Program, a two pronged program focusing on increasing the public's understanding of air quality issues in the region and increasing support for actions to improve the air quality, resulting in reduced emissions

on days when the ozone levels are likely to be high.

• Initiate one or more of the following voluntary local control measures:

(1) Bicycle and Pedestrian Measures—A series of measures designed to promote bicycling and walking including both promotional activities and enhancing the environment for these activities;

(2) Reduce Engine Idling—Voluntary programs to restrict heavy duty diesel engine idling times for both trucks and school buses;

(3) Voluntary Partnership with Ground Freight Industry—A voluntary program using incentives to encourage the ground freight industry to reduce emissions;

(4) Increase Compliance with Open Burning Restrictions—Increase public awareness of the existing open burning restrictions and work with communities to increase compliance; and

(5) School Bus Engine Retrofit Program—Have existing school bus engines retrofitted to lower emissions.

The following schedule for adoption, implementation and compliance applies to the contingency measures concerning the option of implementing regulatory requirements.

• Confirmation of the monitored violation within 45 days of occurrence;

• Measure to be selected within 3 months after verification of a monitored ozone standard violation;

• Develop rule within 6 months of selection of measure;

• File rule with state secretary (process takes up to 42 days);

• Applicable regulation to be fully implemented within 6 months after adoption.

The following schedule for adoption, implementation and compliance applies to the voluntary contingency measures.

• Confirmation of the monitored violation within 45 days of occurrence;

• Measure to be selected within 3 months after verification of a monitored ozone standard violation;

• Initiation of program development with local governments within Parkersburg by the start of the following ozone season.

(f) *An Additional Provision of the Maintenance Plan*—The State's maintenance plan for Parkersburg has an additional provision. That provision states that based on the 2002 inventory data and calculation methodology, it is expected that area and mobile source emissions would not exhibit substantial increases between consecutive periodic year inventories. Therefore, if significant unanticipated emissions growth occurs, it is expected that new point sources would be the cause. West Virginia regulation 45CSR29 requires significant point source emitters in nearby counties, including Cabell, Wayne, Kanawha, Putnam and Wood to submit annual emission statements which contain emission totals for VOCs and NO_X. Any significant increases that occur can be identified from these reports without waiting for a periodic inventory. WVDEP believes this will give West Virginia the capability to identify needed regulations by source, source category and pollutant and to begin the rule promulgation process, if necessary, in an expeditious manner.

The maintenance plan adequately addresses the five basic components of a maintenance plan: attainment inventory, maintenance demonstration, monitoring network, verification of continued attainment, and a contingency plan. EPA believes that the maintenance plan SIP revision submitted by West Virginia for Parkersburg meets the requirements of section 175A of the Act.

VII. Are the Motor Vehicle Emissions Budgets Established and Identified in the Parkersburg Maintenance Plan Adequate and Approvable?

A. What Are the Motor Vehicle Emissions Budgets?

Under the CAA, States are required to submit, at various times, control strategy SIPs and maintenance plans in ozone areas. These control strategy SIPs (*i.e.*, RFP SIPs and attainment demonstration SIPs) and maintenance plans identify and establish MVEBs for certain criteria pollutants and/or their precursors to address pollution from on-road mobile sources. In the maintenance plan the MVEBs are termed ''on-road mobile source emissions budgets.'' Pursuant to 40 CFR part 93 and 51.112, MVEBs must be established in an ozone maintenance plan. An MVEB is the portion of the total allowable emissions that is allocated to highway and transit vehicle use and emissions. An MVEB serves as a ceiling on emissions from an area's planned transportation system. The MVEB concept is further explained in the preamble to the November 24, 1993, transportation conformity rule (58 FR 62188). The preamble also describes how to establish and revise the MVEBs in control strategy SIPs and maintenance plans.

Under section 176(c) of the CAA, new transportation projects, such as the construction of new highways, must ''conform'' to (*i.e.*, be consistent with) the part of the State's air quality plan that addresses pollution from cars and trucks. ''Conformity'' to the SIP means that transportation activities will not cause new air quality violations, worsen existing violations, or delay timely attainment of or reasonable progress towards the NAAQS. If a transportation plan does not ''conform,'' most new projects that would expand the capacity of roadways cannot go forward. Regulations at 40 CFR part 93 set forth EPA policy, criteria, and procedures for demonstrating and ensuring conformity of such transportation activities to a SIP.

When reviewing submitted ''control strategy'' SIPs or maintenance plans containing MVEBs, EPA must affirmatively find the MVEB budget contained therein ''adequate'' for use in determining transportation conformity. After EPA affirmatively finds the submitted MVEB is adequate for transportation conformity purposes, that MVEB can be used by State and Federal agencies in determining whether proposed transportation projects ''conform'' to the state implementation plan as required by section 176(c) of the CAA. EPA's substantive criteria for determining ''adequacy'' of a MVEB are set out in 40 CFR 93.118(e)(4).

EPA's process for determining ''adequacy'' consists of three basic steps: public notification of a SIP submission, a public comment period, and EPA's adequacy finding. This process for determining the adequacy of submitted SIP MVEBs was initially outlined in EPA's May 14, 1999 guidance, ''Conformity Guidance on Implementation of March 2, 1999, Conformity Court Decision.'' This guidance was finalized in the Transportation Conformity Rule Amendments for the ''New 8-Hour Ozone and PM2.5 National Ambient Air Quality Standards and Miscellaneous Revisions for Existing Areas; Transportation Conformity Rule Amendments—Response to Court Decision and Additional Rule Change'' on July 1, 2004 (69 FR 40004). EPA consults this guidance and follows this rulemaking in making its adequacy determinations.

The MVEBs for Parkersburg are listed in Table 1 of this document for 2009 and 2018. These are the projected emissions for the on-road mobile sources plus any portion of the safety margin allocated to the MVEBs. These emission budgets, when approved by EPA, must be used for transportation conformity determinations.

B. What Is a Safety Margin?

A ''safety margin'' is the difference between the attainment level of emissions (from all sources) and the projected level of emissions (from all sources) in the maintenance plan. The attainment level of emissions is the

level of emissions during one of the years in which the area met the NAAQS. The following example is for the 2018 safety margin: Parkersburg first attained the 8-hour ozone NAAQS during the 2002 to 2004 time period. The State used 2004 as the year to determine attainment levels of emissions for Parkersburg. The total emissions from point, area, mobile on-road, and mobile non-road sources in 2004 equaled 16.7 tpd of VOC and 15.2 tpd of NO_X. The WVDEP projected emissions out to the year 2018 and projected a total of 13.6 tpd of VOC and 9.4 tpd of NO_X from all sources in Parkersburg. The safety margin for 2018 would be the difference between these amounts, or 3.1 tpd of VOC and 5.8 tpd of NO_X. The emissions up to the level of the attainment year including the safety margins are projected to maintain the Area's air quality consistent with the 8-hour ozone NAAQS. The safety margin is the extra emissions reduction below the attainment levels that can be allocated for emissions by various sources as long as the total emission levels are maintained at or below the attainment levels.

Table 6 shows the safety margins for the 2009 and 2018 years.

TABLE 6.—2009 AND 2018 SAFETY MARGINS FOR PARKERSBURG

Inventory Year	VOC emissions (tpd)	NO_X emissions (tpd)
2004 Attainment	16.7	15.2
2009 Interim	14.0	11.8
2009 Safety Margin	2.7	3.4
2004 Attainment	16.7	15.2
2018 Final	13.6	9.4
2018 Safety Margin	3.1	5.8

The WVDEP allocated 0.39 tpd VOC and 0.54 tpd NO_X to the 2009 interim VOC projected on-road mobile source emissions projection and the 2009 interim NO_X projected on-road mobile source emissions projection to arrive at the 2009 MVEBs. For the 2018 MVEBs the WVDEP allocated 0.25 tpd VOC and 0.27 tpd NO_X from the 2018 safety margins to arrive at the 2018 MVEBs. Once allocated to the mobile source budgets these portions of the safety margins are no longer available, and may no longer be allocated to any other source category. Table 7 shows the final 2009 and 2018 MVEBS for Parkersburg.

TABLE 7.—2009 AND 2018 FINAL MVEBS FOR PARKERSBURG*

Inventory year	VOC emissions (tpd)	NO_X emissions (tpd)
2009 projected on-road mobile source projected emissions	2.6	3.6
2009 Safety Margin Allocated to MVEBs	0.4	0.5
2009 MVEBs	3.0	4.1
2018 projected on-road mobile source projected emissions	1.7	1.8
2018 Safety Margin Allocated to MVEBs	0.3	0.3
2018 MVEBs	2.0	2.1

* Numbers not exact due to rounding.

C. Why Are the MVEBs Approvable?

The 2009 and 2018 MVEBs for Parkersburg are approvable because the MVEBs for NO_X and VOC, including the allocated safety margins, continue to maintain the total emissions at or below the attainment year inventory levels as required by the transportation conformity regulations.

D. What Is the Adequacy and Approval Process for the MVEBs in the Parkersburg Maintenance Plan?

The MVEBs for the Parkersburg maintenance plan are being posted to EPA's conformity Web site concurrent with this proposal. The public comment period will end at the same time as the public comment period for this proposed rule. In this case, EPA is concurrently processing the action on the maintenance plan and the adequacy process for the MVEBs contained therein. In this proposed rule, EPA is proposing to find the MVEBs adequate and also proposing to approve the MVEBs as part of the maintenance plan. The MVEBs cannot be used for transportation conformity until the maintenance plan update and associated MVEBs are approved in a final **Federal Register** notice, or EPA otherwise finds the budgets adequate in a separate action following the comment period.

If EPA receives adverse written comments with respect to the proposed approval of the Parkersburg MVEBs, or any other aspect of our proposed approval of this updated maintenance plan, we will respond to the comments on the MVEBs in our final action or proceed with the adequacy process as a separate action. Our action on the Parkersburg MVEBs will also be announced on EPA's conformity Web site: *http://www.epa.gov/otaq/stateresources/transconf/index.htm,* (once there, click on the ''Conformity'' button, then look for ''Adequacy Review of SIP Submissions'').

VIII. Proposed Actions

EPA is proposing to determine that Parkersburg has attained the 8-hour ozone NAAQS. EPA is also proposing to approve the redesignation of the Parkersburg portion of the Area from nonattainment to attainment for the 8-hour ozone NAAQS. EPA has evaluated West Virginia's redesignation request and determined that it meets the redesignation criteria set forth in section 107(d)(3)(E) of the CAA. EPA believes that the redesignation request and monitoring data demonstrate that the Area has attained the 8-hour ozone standard. The final approval of this redesignation request would change the designation of Parkersburg from nonattainment to attainment for the 8-hour ozone standard. EPA is also proposing to approve the associated maintenance plan for Parkersburg, submitted on September 8, 2006, as a revision to the West Virginia SIP. EPA is proposing to approve the maintenance plan for Parkersburg because it meets the requirements of section 175A as described previously in this notice. EPA is also proposing to approve the MVEBs submitted by West Virginia for Parkersburg in conjunction with its redesignation request. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

IX. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)). This action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Redesignation of an area to attainment under section 107(d)(3)(e) of the Clean Air Act does not impose any new requirements on small entities. Redesignation is an action that affects the status of a geographical area and does not impose any new regulatory requirements on sources. Redesignation of an area to attainment under section 107(d)(3)(E) of the Clean Air Act does

not impose any new requirements on small entities. Redesignation is an action that affects the status of a geographical area and does not impose any new regulatory requirements on sources. Accordingly, the Administrator certifies that this proposed rule 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 this rule proposes to approve pre-existing requirements under state law and does 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). This proposed rule also does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (59 FR 22951, November 9, 2000), nor will it 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 proposes to affect the status of a geographical area, does not impose any new requirements on sources, or allow the state to avoid adopting or implementing other requirements, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is 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. Redesignation is an action that affects the status of a geographical area and does not impose any new requirements on sources. 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 proposed 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 rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This rule proposing to approve the redesignation of Parkersburg to attainment for the 8-hour ozone NAAQS, the associated maintenance plan, and the MVEBs identified in the maintenance plan, does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

This rule proposing to approve the redesignation of Parkersburg to attainment for the 8-hour ozone NAAQS, the associated maintenance plan, and the MVEBs identified in the maintenance plan, does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

40 CFR Part 81

Air pollution control, National Parks, Wilderness Areas.

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

Dated: January 4, 2007.

Donald S. Welsh,

Regional Administrator, Region III.

[FR Doc. E7–249 Filed 1–11–07; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 72, No. 8

Friday, January 12, 2007

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

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Trends in Use and Users in the Boundary Waters Canoe Area Wilderness, MN

AGENCY: Forest Service, USDA.

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments from all interested individuals and organizations on the new information collection entitled, Trends in Use and Users in the Boundary Waters Canoe Area Wilderness, Minnesota.

DATES: Comments must be received in writing on or before March 13, 2007 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to Alan E. Watson, Aldo Leopold Wilderness Research Institute, USDA Forest Service Rocky Mountain Research Station, 790 E. Beckwith Ave., Missoula, MT 59801.

Comments also may be submitted via facsimile to (406) 542–4196 or by e-mail to: *awatson@fs.fed.us.*

The public may inspect comments received at the Aldo Leopold Wilderness Research Institute, USDA Forest Service Rocky Mountain Station, 790 E. Beckwith Ave., Missoula, MT 59801 during normal business hours. Visitors are encouraged to call ahead to (406) 542–4197 to facilitate entry to the building.

FOR FURTHER INFORMATION CONTACT: Alan E. Watson, Aldo Leopold Wilderness Research Institute at (406) 542–4197. Individuals who use TDD may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Title: Trends in Use and Users in the Boundary Waters Canoe Area Wilderness, Minnesota.

OMB Number: 0596–NEW.

Type of Request: New.

Abstract: The Wilderness Act of 1964 directs the National Wilderness Preservation System (System) be managed to protect natural wilderness conditions and to provide outstanding opportunities for the public to find solitude or primitive and unconfined types of recreational experiences.

To meet the requirements of the Act and help the Forest Service enhance visitors' recreational experiences at the Boundary Waters Canoe Area Wilderness in Minnesota, agency scientists periodically monitor and report, to managers and the public, changes in visitor use and user characteristics over time. Forest Service personnel use the collected information to mitigate the impact of visitors' recreational activities on the natural resources of the National Wilderness Preservation System. The agency intends to record visitor responses in 2007 for comparison to similar surveys in 1969 and 1991, and expand the scope of the survey to include things that have potentially influenced visits since 1991. Potential influences include new recreation fees, widespread natural disturbances (e.g., fire and wind thrown trees) and changes in agency policies. The data from this information collection will be stored at the Aldo Leopold Wilderness Research Institute in Missoula, Montana. Scientists working at the Research Institute will conduct the data analysis.

The Forest Service will use information from this collection to:

(1) Understand changes in:

a. Individual visitor demographics, frequency of wilderness visits, and residence, and

b. changes in recreational visits such as group size, difficulty in finding campsites, evaluations of conditions encountered, etc. since previous studies;

(2) Gain an understanding of how the agency's management of the National Wilderness Preservation System influences a visitor's wilderness experience;

(3) Help understand how to educate visitors, so they may enjoy their wilderness experience without leaving permanent reminders of their visits, such as damaged vegetation, litter, and polluted lakes and streams; and

(4) Provide information that will assist in planning management direction for many other wilderness areas managed by the Forest Service.

Respondents will be visitors to the Boundary Waters Canoe Area Wilderness. Forest Service or university cooperator personnel will conduct face-to-face, on-site interviews with visitors as they enter the System and will send mail-back survey forms to visitors at their homes, using addresses that visitors voluntarily provide when interviewed.

Interview questions will cover number of visits, length of visits, and plans (if any) for future visits. Visitors will be asked:

- Number of times they have visited, length of visits, and plans (if any) for future visits;
- If they are part of a group, and if so, the size of the group;
- Whether they use equipment, such as stoves, or use wood for fires while visiting;
- Preferences for social conditions (i.e. acceptance of crowded conditions designed to limit negative effects to the natural resources); and
- Ideas for reducing the burden of information collected (i.e. suggestions for distribution of permits and collection of fees); and protecting resources.

Data collected in this information collection are not available from other sources.

The Boundary Waters Canoe Area Wilderness is one of four areas, in different regions of the country, where more than one study has occurred in the past. The studies have sought to understand how use and user characteristics are changing. Periodic evaluations of responses by visitors about conditions and experiences, contributes to a systematic effort to understand the effects of management policies and societal influences on wilderness protection.

Estimate of Annual Burden: 20 minutes for each respondent.

Type of Respondents: Visitors to the Boundary Waters Canoe Wilderness Area, Minnesota.

Estimated Annual Number of Respondents: 500.

Estimated Annual Number of Responses per Respondent: Once.

Estimated Total Annual Burden on Respondents: 167 hours.

Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the agency, including whether the information will have practical or scientific utility; (2) the accuracy of the agency's estimate of the burden of the 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 the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the request for Office of Management and Budget approval.

Dated: January 4, 2007.

Ann M. Bartuska,

Deputy Chief for Research & Development.

[FR Doc. E7–361 Filed 1–11–07; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Timber Purchaser Cost and Sales Data

AGENCY: Forest Service, USDA.

ACTION: Notice; Request for Comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments from all interested individuals and organizations on the extension of a currently approved information collection, Timber Purchaser Cost and Sales Data.

DATES: Comments must be received in writing on or before March 13, 2007 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to Forest Management, Attn: Lathrop Smith, Mail Stop 1103, Forest Service, USDA, 1400 Independence Avenue, SW., Washington, DC 20250–1103.

Comments also may be submitted via facsimile to (202) 205–1045 or by e-mail to: *cost_collecting@fs.fed.us*.

The public may inspect comments received at the Office of the Director, Forest Management Staff, Forest Service, USDA, Room 3 NW., Yates Building, 1400 Independence Avenue, SW., Washington, DC. Visitors are encouraged to call ahead to (202) 205–1496 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Lathrop Smith, Timber Staff, Forest Management at (202) 205–0858. Individuals who use TDD may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Title: Timber Purchaser Cost and Sales Data.

OMB Number: 0596–0017.

Expiration Date of Approval: June 30, 2007.

Type of Request: Extension of a currently approved collection.

Abstract: The Forest Service sells timber and other forest products on national forest lands to achieve policies set forth in the Multiple-Use Sustained Yield Act of 1960, and the Forest and Rangeland Renewable Resources Planning Act of 1974. Timber must not be sold for less than the appraised value (Pub. L. 94–588). The Forest Service may not sell timber below a minimum stumpage rate established by the Chief of the Forest Service, ensuring that timber sales recover some of the costs associated with preparation and administration of timber sales.

Forest Service timber appraisers develop advertised prices using transaction evidence or a residual value form of appraisal. The Forest Service collects and uses the following to develop transaction evidence and residual value appraisal systems: (1) Product value, (2) manufacturing cost, (3) falling and bucking costs, (4) skidding and loading costs, and (5) hauling costs.

In many areas, the Forest Service purchases lumber product values from the Western Wood Products Association. The Forest Service, via contracting officers, also collects data from timber purchasers and uses it to develop fair market average value and cost information for appraisals, as well as advertised prices for national forest timber. Forest Service staff at the Albuquerque Service Center analyzes the data. All data collected is subject to verification.

Standard timber sale contract forms FS–2400–6 and FS–2400–6T contain a provision requiring timber purchasers to furnish data to the Forest Service upon request. The Forest Service consulted with several timber industry groups during the development of this standard contract provision, including but not limited to: Western Wood Products Association, National Forest Products Association, Western Forest Industries Association, and Industrial Forestry Association.

States and other agencies also use the data in appraisals. Additionally, timber purchasers rely upon cost collection to help with independent appraisals of Federal timber and to estimate the cost of subcontracting aspects of Federal timber harvest activities.

The data is collected from various sources, ranging from paper to electronic media. The Forest Service does not provide forms for the collection of this data. Some firms mail the data to the Forest Service, others provide access to records and duplication equipment, and some firms provide on-site access to electronic data. Data gathered is not available from other sources.

Estimate of Annual Burden: 1 hour per request.

Type of Respondents: Timber sale purchasers.

Estimated Annual Number of Respondents: 20.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 20 hours.

Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the agency, including whether the information will have practical or scientific utility; (2) the accuracy of the agency's estimate of the burden of the 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 the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the request for Office of Management and Budget approval.

Dated: December 21, 2006.

Frederick Norbury,

Associate Deputy Chief.

[FR Doc. E7–366 Filed 1–11–07; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Newspaper To Be Used for Publication of Legal Notice of Appealable Decisions and Publication of Notice of Proposed Actions for Eastern Region: Illinois, Indiana and Ohio, Michigan, Minnesota, Missouri, New Hampshire and Maine, Pennsylvania, Vermont and New York, West Virginia, and Wisconsin

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: Deciding Officers in the Eastern Region will publish notice of decisions subject to administrative appeal under 36 CFR parts 215 and 217 in the legal notice section of the newspapers listed in the **SUPPLEMENTARY INFORMATION** section of this notice. As provided in 36 CFR part 215.5(a) and 36 CFR part 217.5(d), the public shall be advised through **Federal Register** notice, of the principal newspaper to be utilized for publishing legal notices of decisions. Newspaper publication of notice of decisions is in addition to direct notice of decisions to those who have requested notice in writing and to those known to be interested in or affected by a specific decision. In addition, the Responsible Official in the Eastern Region will also publish notice of proposed actions under 36 CFR 215 in the newspaper that are listed in the **SUPPLEMENTARY INFORMATION** section of this notice. As provided in 36 CFR part 215(a), the public shall be advised, through **Federal Register** notice, of the principal newspapers to be utilized for publishing notices on proposed actions.

DATES: Use of these newspapers for purposes of publishing legal notice of decisions subject to appeal under 36 CFR parts 215 and 217, and notices of proposed actions under 36 CFR part 215 shall begin on or after the date of this publication.

FOR FURTHER INFORMATION CONTACT: Patricia Rowell, Regional Appeals Assistant, Eastern Region, Gaslight Building, 7th Floor, 626 East Wisconsin Avenue, Milwaukee, Wisconsin, 53202 Phone: 414–297–3439.

SUPPLEMENTARY INFORMATION: Deciding Officers in the Eastern Region will give legal notice of decisions subject to appeal under 36 CFR part 217 and 36 CFR 215 in the following newspapers which are listed by Forest Service administrative unit. The timeframe of comment on a proposed action shall be based on the date of publication of the notice of the proposed action in the principal newspapers. The timeframe for appeals shall be based on the date of publication of the legal notice of the decision in the principal newspapers for both 36 CFR parts 215 and 217.

Where more than one newspaper is listed for any unit, the first newspaper listed is the principal newspaper that will be utilized for publishing the legal notices of decisions. Additional newspapers listed for a particular unit are those newspapers the Deciding Officer expects to use for purposes of providing additional notice. The timeframe for appeal shall be based on the date of publication of the legal notice of the decision in the principal newspaper. The following newspapers will be used to provide notice.

Eastern Region

Regional Forester Decisions

Affecting National Forest System lands in the states of Illinois, Indiana and Ohio, Michigan, Minnesota, Missouri, New Hampshire and Maine, Pennsylvania, Vermont and New York; West Virginia, Wisconsin and for any decision of Region-wide Impact.

Journal/Sentinel, published daily in Milwaukee, Milwaukee County, Wisconsin.

National Forests

Allegheny National Forest, Pennsylvania

Forest Supervisor Decisions

Warren Times Observer, Warren, Warren County, Pennsylvania

District Ranger Decisions

Bradford District: Bradford Era, Bradford, McKean County, Pennsylvania.

Marienville District: The Kane Republican, Kane, Pennsylvania.

Chequamegon/Nicolet National Forest, Wisconsin

Forest Supervisor Decisions

The Journal/Sentinel, published daily in Milwaukee, Milwaukee County, Wisconsin.

District Ranger Decisions

Eagle River/Florence District: The Daily News, published daily except Saturday, Rhinelander, Wisconsin.

Great Divide District: The Daily Press, published daily in Ashland County, Ashland, Wisconsin.

Medford/Park Falls District: The Star News published weekly in Medford, Taylor County, Wisconsin and *The Park Falls Herald,* published weekly in Park Falls, Price County, Wisconsin.

Washburn District: The Daily Press, published daily in Ashland County, Ashland, Wisconsin.

Lakewood/Laona District: The Daily News, published daily except Saturday, Rhinelander, Wisconsin.

Chippewa National Forest, Minnesota

Forest Supervisor Decisions

Bemidji Pioneer, published daily in Bemidji, Beltrami County, Minnesota.

District Ranger Decisions

Blackduck District: The American, published in Blackduck, Beltrami County, Minnesota.

Cass Lake District: The Cass Lake Times, published weekly in Cass Lake, Cass County, Minnesota.

Deer River and Marcell Districts: The Western Itasca Review, published weekly in Deer River, Itasca County, Minnesota.

Walker District: The Pilot/Independent, published weekly in Walker, Cass County, Minnesota.

Green Mountain National Forest, Vermont

Forest Supervisor Decisions

The Rutland Herald, published daily in Rutland, Rutland County, Vermont.

District Ranger Decisions

The Rutland Herald, published daily in Rutland, Rutland County, Vermont is the formal newspaper of record for all district ranger decisions. Other newspapers listed are optional.

Manchester District: The Rutland Herald, published daily in Rutland, Rutland County, Vermont; All others optional, The Bennington Banner, published daily in Bennington, Bennington County, Vermont *Manchester* Journal, published weekly in Bennington County, Vermont and *The Brattleboro Reformer,* published daily in Brattleboro, Windham County, Vermont.

Middlebury District: The Rutland Herald, published daily in Rutland, Rutland County, Vermont; All others optional, *The Addison County Independent,* published twice weekly in Middlebury, Addison County, Vermont.

Rochester District: The Rutland Herald, published daily in Rutland, Rutland County, Vermont; All others optional, *The Burlington Free Press,* published daily in Burlington, Chittenden County, Vermont; *The Valley Reporter,* published weekly in Washington County, Vermont and *The Randolph Herald,* published weekly in Orange County, Vermont.

Finger Lakes National Forest, New York

Forest Supervisor Decisions

The Ithaca Journal, published daily in Ithaca, Tompkins County, New York.

District Ranger Decisions

Hector District: The Ithaca Journal, published daily in Ithaca, Tompkins County, New York.

Hiawatha National Forest, Michigan

Forest Supervisor Decisions

The Daily Press, published daily in Escanaba, Delta County, Michigan.

District Ranger Decisions

Rapid River District: The Daily Press, published daily in Escanaba, Delta County, Michigan.

Manistique District: The Daily Press, published daily in Escanaba, Delta County, Michigan.

Munising District: The Mining Journal, published daily in Marquette, Marquette County, Michigan.

Sault Ste. Marie District: The Evening News, published daily in Sault Ste. Marie.

St. Ignace District: The Evening News, published daily in Sault Ste. Marie, Chippewa County, Michigan.

Hoosier National Forest, Indiana

Forest Supervisor Decisions

The Hoosier Times, published in Bloomington, Monroe County, and Bedford, Lawrence County, Indiana.

District Ranger Decisions

Brownstown District: The Hoosier Times, published in Bloomington, Monroe County, and Bedford, Lawrence County, Indiana.

Tell City District: The Perry County News, published in Tell City, Perry County, Indiana.

Huron-Manistee National Forest, Michigan

Forest Supervisor Decisions

Cadillac News, published daily in Cadillac, Wexford County, Michigan.

District Ranger Decisions

Baldwin District: Lake County Star, published weekly in Baldwin, Lake County, Michigan.

Cadillac District: Manistee News Advocate, published daily in Manistee, Manistee County, Michigan.

Harrisville District: Oscoda Press, published weekly in Oscoda, Iosco County, Michigan.

Manistee District: Manistee News Advocate, published daily in Manistee, Manistee County, Michigan.

Mio District: Oscoda County Herald, published weekly in Mio, Oscoda County, Michigan.

Tawas District: Oscoda Press, published weekly in Oscoda, Iosco County, Michigan.

White Cloud District: Lake County Star, published weekly in Baldwin, Lake County, Michigan.

Mark Twain National Forest, Missouri

Forest Supervisor Decisions

Rolla Daily News, published in Rolla Phelps County, Missouri.

District Ranger Decisions

Ava/Cassville District: Springfield News Leader, published daily in Springfield, Greene County, Missouri.

Cedar Creek District: Fulton Sun, published daily in Fulton, Callaway County, Missouri.

Doniphan District: Prospect News, published weekly in Doniphan, Ripley County, Missouri.

Eleven Point District: Prospect News, published weekly in Doniphan, Ripley County, Missouri.

Rolla District: Houston Herald, published weekly (Thursdays) in Houston, Texas County, Missouri.

Houston District: Houston Herald, published weekly (Thursdays) in Houston, Texas County, Missouri.

Poplar Bluff District: Daily American Republic, published daily in Poplar Bluff, Butler County, Missouri.

Potosi District: The Independent-Journal, published Thursday in Potosi, Washington County, Missouri.

Fredericktown District: The Democrat-News, published weekly in Fredericktown, Madison County, Missouri.

Salem District: The Salem News, published Tuesday and Thursday in Salem, Dent County, Missouri.

Willow Springs District: West Plains Daily Quill, published daily in West Plains, Howell County, Missouri.

Midewin Tall Grass Prairie, Wilmington, Illinois

Prairie Supervisor Decisions

The Herald News, published daily in Joliet, Illinois.

Monongahela National Forest, Elkins, West Virginia

Forest Supervisor Decisions

The Elkins Inter-Mountain, published daily in Elkins, Randolph County, WV.

District Ranger Decisions

Cheat-Potomac District: The Grant County Press, published weekly in Petersburg, Grant County, WV.

Gauley District: The Nicholas Chronicle, published weekly in Summersville, Nicholas County, WV.

Greenbrier District: The Pocahontas Times, published weekly in Marlinton, Pocahontas County, WV.

Marlinton-White Sulphur District: The Pocahontas Times, published weekly in Marlinton, Pocahontas County, WV.

Ottawa National Forest, Michigan

Forest Supervisor Decisions

The Ironwood Daily Globe, published in Ironwood, Gogebic County, Michigan and for those on the Iron River District, *The Reporter*, published in Iron River, Iron County, Michigan.

District Ranger Decisions

Bergland, Bessemer, Kenton, Ontonagon and Watersmeet Districts: The Ironwood Daily Globe, published in Ironwood, Gogebic County, Michigan.

Iron River District: The Reporter, published in Iron River, Michigan, Iron County, Michigan.

Shawnee National Forest, Illinois

Forest Supervisor Decisions

Southern Illinoisan, published daily in Carbondale, Jackson County, Illinois.

District Ranger Decisions

Hidden Springs, Mississippi Bluffs Districts: Southern Illinoisan, published daily in Carbondale, Jackson County, Illinois.

Superior National Forest, Minnesota

Forest Supervisor Decisions

Duluth News-Tribune, published daily in Duluth, St. Louis County, Minnesota.

District Ranger Decisions

Gunflint District: Cook County News-Herald, published weekly in Grand Marais, Cook County, Minnesota.

Kawishiwi District: Ely Echo, published weekly in Ely, St. Louis County, Minnesota.

LaCroix District: Mesabi Daily News, published daily in Virginia, St. Louis County, Minnesota.

Laurentian District: Mesabi Daily News, published daily in Virginia, St. Louis County, Minnesota.

Tofte District: Duluth News-Tribune, published daily in Duluth, St. Louis County, Minnesota.

Wayne National Forest, Ohio

Forest Supervisor Decisions

The Athens Messenger, published in Athens, Athens County, Ohio.

District Ranger Decisions

Athens District: Athens Messenger, (same for Marietta Unit), published in Athens, Athens County, Ohio.

Ironton District: The Ironton Tribune, published in Ironton, Lawrence County, Ohio.

White Mountain National Forest, New Hampshire and Maine

Forest Supervisor Decisions

The Union Leader, published daily in Manchester, County of Hillsborough, New Hampshire. If project will occur in Maine, also the *Lewiston Sun-Journal*, published daily in the Lewiston, County of Androscoggin, Maine.

Androscoggin District: The Union Leader, published daily in Manchester, County of Hillsborough, New Hampshire if project is in New Hampshire and the *Lewiston Sun-Journal*, published daily Lewiston, County of Androscoggin, Maine if the project is in Maine.

Pemigewasset District: The Union Leader, published daily in Manchester, County of Hillsborough, New Hampshire.

Saco District: The Union Leader, published daily in Manchester, County of Hillsborough, New Hampshire if project is in New Hampshire and the *Lewiston Sun-Journal*, published daily in Lewiston, County of Androscoggin, Maine if the project is in Maine.

Dated: January 3, 2007.

Randy Moore,

Regional Forester.

[FR Doc. 07–83 Filed 1–11–07; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Proposed New Fee Site; Federal Lands Recreation Enhancement Act, (Title VIII, Pub. L. 108–447)

AGENCY: Siuslaw National Forest, USDA Forest Service.

ACTION: Notice of proposed new fee site.

SUMMARY: The Siuslaw National Forest is planing to charge fees at a new recreation site that has recently been constructed. Fees are assessed based on the level of amenitites and services provided, cost of operation and maintenance and market assessment. Funds from fees will be used for the continued operation and maintenance of the site. Old Bark Road OHV Staging Area at the Oregon Dunes NRA will be available for day use staging by off highway vehicles (OHVs). A $5 per day fee will be charged for each highway vehicle using the site. National and regionally focused recreation passes such as the Interagency Annual Pass, Senior Pass or Access Pass and the Northwest Forest Pass will be valid for day use fees at the site. Northwest Forest Passes are $5 for a daily pass and $30 for an annual pass. The Interagency Annual Pass Costs $80.

DATES: New fees would began after June 2007 and are contingent upon completion of certain improvements.

ADDRESSES: Jose Linares, Forest Supervisor, Siuslaw National Forest, 4077 SW Research Way, Corvallis, OR 97333.

FOR FURTHER INFORMATION CONTACT: Mike Harvey, Recreation Fee Coordinator, 541–750–7046. Information about proposed fee changes can also be found on the Siuslaw National Forest Web site: *http//www.fs.fed.us/r6/Siuslaw/recreation/index.html*.

SUPPLEMENTARY INFORMATION: The Federal Recreation Lands Enhancement Act (Title VII, P.L. 108–447) directed the Secretary of Agriculture to publish a six month advance notice in **Federal Register** whenever new recreation fees are established. Once public involvement is complete, these new fees will be reviewed by a Recreation Resource Advisory Committee prior to a final decision and implementation.

Dated: January 8, 2007.

Jose L. Linaes,

Forest Supervisor.

[FR Doc. 07–92 Filed 1–11–07; 8:45 am]

BILLING CODE 3410–11–M

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletion

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletion from Procurement List.

SUMMARY: The Committee is proposing to add to the Procurement List products and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and to delete products previously furnished by such agencies.

DATES: *Comments Must Be Received On Or Before:* February 11, 2007.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, VA 22202–3259.

For Further Information Or To Submit Comments Contact: Sheryl D. Kennerly, Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *CMTEFedReg@jwod.gov.*

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 proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice for each product or service will be required to procure the products and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

Regulatory Flexibility Act Certification

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. If approved, 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 products and services to the Government.

2. If approved, the action will result in authorizing small entities to furnish the products 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 products 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.

End of Certification

The following products and services are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Products

Hydramax Hydration System

NSN: 8465–00–NIB–0080—Replacement Reservoir, Alpha and Mustang

NSN: 8465–00–NIB–0139—Mustang, Black

NSN: 8465–00–NIB–0151—Mustang, Universal Camouflage
NSN: 8465–00–NIB–0152—Mustang, Desert Camouflage
NSN: 8465–00–NIB–0154—Alpha, High Visibility Orange
NSN: 8465–00–NIB–0155—Alpha, Universal Camouflage
Coverage: B-list—for the broad Government requirement as specified by the General Services Administration
NPA: The Lighthouse for the Blind, Inc. (Seattle Lighthouse), Seattle, WA
Contracting Activity: GSA, Southwest Supply Center, Fort Worth, TX

Spices, Dry, Group II

NSN: 8950–01–E60–9152—Ground Ginger
NSN: 8950–01–E60–9155—Cayenne Pepper
NSN: 8950–01–E61–0099—Taco Mix Seasoning
NSN: 8950–01–E61–0100—Taco Mix Seasoning (Group II)
NSN: 8950–01–E61–0101—Taco Mix Seasoning (Group II)
NSN: 8950–01–E61–0102—Taco Mix Seasoning (Group II)
NSN: 8950–01–E61–0103—Cayenne Pepper
NSN: 8950–01–E61–0104—Ginger Ground
NSN: 8950–01–E61–0105—Ginger Ground
NSN: 8950–01–E61–0106—Cayenne Pepper
NSN: 8950–01–E61–0107—Cayenne Pepper
NSN: 8950–01–E61–0108—Red Pepper
Coverage: C-List for the requirements of Defense Supply Center Philadelphia (DSCP).
NPA: Continuing Developmental Services, Inc., Fairport, NY
Contracting Activity: Defense Supply Center Philadelphia, Philadelphia, PA

Services

Service Type/Location: Administrative Services,
Calexico Border Station, 11150 Birch Street, Calexico, CA.
NPA: ARC-Imperial Valley, El Centro, CA
Contracting Activity: Department of Homeland Security, Customs and Border Protection, Washington, DC.

Service Type/Location: Custodial Services, Federal Building, 555 Independence, Cape Girardeau, MO.
NPA: Cape Girardeau Community Sheltered Workshop, Inc., Cape Girardeau, MO
Contracting Activity: GSA, PBS—Region 6, Kansas City, MO.

Service Type/Location: Custodial Services, Kastenmeir U.S. Courthouse, (120 Henry Street), Madison, WI.
NPA: Madison Area Rehabilitation Centers, Inc., Madison, WI
Contracting Activity: GSA, Public Buildings Service, Region 5, Chicago, IL.

Service Type/Location: Custodial Services, U.S. DOI—Bureau of Land Mgmt., (Eight Recreation Areas/Campgrounds), Bessemer Bend Rec Site, Golden Eye Rec Site, Government Bridge Site, Lodgepole Campground, MuddyMountain Educational Kiosk, Poison Spider OHV Rec Site, Rim Campground, Trappers Route #1 Rec Site, Casper, WY.
NPA: Northwest Community Action Programs of Wyoming, Inc., Casper, WY
Contracting Activity: U.S. DOI—Bureau of Land Mgmt, Denver, CO.

Deletions

Regulatory Flexibility Act Certification

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. If approved, the action may result in additional reporting, recordkeeping or other compliance requirements for small entities.
2. If approved, the action may result in authorizing small entities to furnish the products 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 products proposed for deletion from the Procurement List.

End of Certification

The following product is proposed for deletion from the Procurement List:

Products

Holder, Card Label

NSN: 9905–00–045–3624—Holder, Card Label
NSN: 9905–00–045–3626—Holder, Card Label
NSN: 9905–00–782–3768—Holder, Card Label
NPA: UNKNOWN
Contracting Activity: GSA, Southwest Supply Center, Fort Worth, TX.

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. E7–328 Filed 1–11–07; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Addition And Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Addition to and deletions from Procurement List.

SUMMARY: This action adds to the Procurement List products to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes from the Procurement List products previously furnished by such agencies.

DATES: *Effective Date:* February 11, 2007.

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 OR TO SUBMIT COMMENTS CONTACT: Sheryl D. Kennerly, Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *CMTEFedReg@jwod.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On November 2, 2006, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (71 FR 64682) of proposed addition to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and impact of the additions on the current or most recent contractors, the Committee has determined that the products listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

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 products to the Government.
2. The action will result in authorizing small entities to furnish the products 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 products proposed for addition to the Procurement List.

End of Certification

Accordingly, the following product is added to the Procurement List:

Products

Pan, Drip Oil

NSN: 4910–01–211–2195—Pan, Drip Oil
NPA: Central Association for the Blind & Visually Impaired, Utica, NY
Contracting Activity: Defense Supply Center Columbus, Columbus, OH
Coverage: C-List for the requirements of Defense Supply Center Columbus (DSCC)

Deletions

On October 27, 2006 & November 3, 2006 the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (71 FR 62992, 64682) of proposed deletions to the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

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 may result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the products 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 products deleted from the Procurement List.

End of Certification

Accordingly, the following products are deleted from the Procurement List:

Products

Envelope, Crystal Clear Vinyl

NSN: 7510–00–NIB–0004—Envelope, Crystal Clear Vinyl
NSN: 7510–00–NIB–0006—Envelope, Crystal Clear Vinyl
NPA: The Oklahoma League for the Blind, Oklahoma City, OK
NPA: Winston-Salem Industries for the Blind, Winston-Salem, NC
Contracting Activity: Federal Bureau of Investigation, Dept of Justice, Washington, DC

Clean-N-Disinfect Maximum Heavy-Duty Cleaner & Wax Stripper

NSN: 7930–01–513–8005—Maximum Heavy-Duty Cleaner & Wax Stripper
NPA: Lighthouse for the Blind, St. Louis, MO
Contracting Activity: Office Supplies & Paper Products Acquisition Ctr, New York, NY

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. E7–329 Filed 1–11–07; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Correction of Notice of Proposed Additions & Deletions; Correction of Notice of Proposed Additions

In the document appearing on page 75496, FR Doc E6–21358, Procurement List Proposed Additions and Deletions, in the issue of December 15, 2006, the Committee published additions and deletions with a comment period to end date of January 21, 2007. The Committee is making a correction to the comment date. The new deadline for the submission of comments is January 14, 2007.

In the document appearing on page 76966, FR Doc E6–21940, Procurement List Proposed Additions, in the issue of December 22, 2006, Committee published additions and deletions with a comment period to end date of January 28, 2007. The Committee is making a correction to the comment date. The new deadline for the submission of comments is January 21, 2007.

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. E7–326 Filed 1–11–07; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Correction of Notice of Additions & Deletions

In the document appearing on page 75497, FR Doc E6–21360, Procurement List Additions and Deletions, in the issue of December 15, 2006 the Committee published additions and deletions with a comment period to end date of January 21, 2007. The Committee is making a correction to the comment date. The new deadline for the submission of comments is January 14, 2007.

In the document appearing on page 76967, FR Doc E6–21976, Procurement List Additions & Deletions, in the issue of December 22, 2006, Committee published additions and deletions with a comment period to end date of January 28, 2007. The Committee is making a correction to the comment date. The new deadline for the submission of comments is January 21, 2007.

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. E7–327 Filed 1–11–07; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Secrecy and License To Export

ACTION: Proposed collection; comment request.

SUMMARY: The United States Patent and Trademark Office (USPTO), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the extension of a currently approved collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before March 13, 2007.

ADDRESSES: You may submit comments by any of the following methods:

- *E-mail: Susan.Brown@uspto.gov.* Include ''0651–0034 comment'' in the subject line of the message.
- *Fax:* 571–273–0112, marked to the attention of Susan Brown.
- *Mail:* Susan K. Brown, Records Officer, Office of the Chief Information Officer, Architecture, Engineering and Technical Services, Data Architecture and Services Division, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.
- *Federal e-Rulemaking Portal: http//www.regulations.gov*

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to the attention of Robert A. Clarke, Deputy Director, Office of Patent Legal Administration, U.S. Patent and Trademark Office (USPTO), P.O. Box 1450, Alexandria, VA 22313–1450; by telephone 571–272–7735; or by e-mail at *robert.clarke@uspto.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

In the interest of national security, patent laws and rules place certain limitations on the disclosure of information contained in patents and patent applications and on the filing of applications for patents in foreign countries. When an invention is determined to be detrimental to national security, the Commissioner for Patents at the United States Patent and Trademark Office (USPTO) must issue a secrecy order and withhold the grant of a patent for such period as the national interest requires. It a secrecy order is applied to an international application, the application will not be forwarded to

the International Bureau as long as the secrecy order is in effect. The USPTO collects information to determine whether the patent laws and rules have been complied with, and to grant or revoke licenses to file abroad when appropriate. This collection of information is required by 35 U.S.C. 181–188 and administered through 37 CFR Ch. 1, Part 5, 5.1–5.33.

There are no forms associated with this collection of information.

II. Method of Collection

By mail, facsimile, or hand delivery to the USPTO when the applicant or agent files a patent application with the USPTO, submits subsequent papers during the prosecution of the application to the USPTO, or submits a request for a foreign filing license for a patent application to be filed abroad before the filing of a United States patent application.

III. Data

OMB Number: 0651–0034.

Form Number(s): None.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for profit; not-for-profit institutions.

Estimated Number of Respondents: 1,669 responses per year.

Estimated Time per Response: The USPTO estimates that it will take between 30 minutes to 4 hours to gather, prepare and submit this information, depending upon the complexity of the situation.

Estimated Total Annual Respondent Burden Hours: 1,310 hours per year.

Estimated Total Annual Respondent Cost Burden: $398,240. Using the professional hourly rate of $304 for associate attorneys in private firms, the USPTO estimates $398,240 per year for salary costs associated with respondents.

Item	Estimated time for response	Estimated annual responses	Estimated annual burden hours
Petition for rescission of secrecy order	3 hours	6	18
Petition to disclose or modification of secrecy order	2 hours	3	6
Petition for general and group permits	1 hour	1	1
Petition for expedited handling of license (no corresponding appliction)	30 minutes	1,402	701
Petition for expedited handling of license (corresponding U.S. application)	30 minutes	126	63
Petition for changing the scope of a license	30 minutes	1	1
Petition for retroactive license	4 hours	130	520
Totals		1,669	1,310

Estimated Total Annual Non-Hour Respondent Cost Burden: $331,865. There are no capital start-up or maintenance costs associated with this information collection. There are, however, filing fees and postage costs.

This collection has a total of $331,800 in associated filing fees, as shown in the accompanying table:

Item	Responses (a)	Filing fee ($) (b)	Total filing fee cost burden (c) (a × b)
Petition for rescission of secrecy order	6	$0	$0.00
Petition to disclose or modification of secrecyorder	3	0	0.00
Petition for general and group permits	1	0	0.00
Petition for expedited handling of license (no corresponding application)	1,402	200.00	280,400.00
Petition for expedited handling of license (corresponding U.S. application)	126	200.00	25,200.00
Petition for changing the scope of a license	1	200.00	200.00
Petition for retroactive license	130	200.00	26,000.00
Totals	1,669		331,800.00

The USPTO estimates that 90 percent (90%) of the petitions in this collection are submitted to the USPTO by facsimile or hand carried because of the quick turnaround required. For the 10 percent (10%) of the public that chooses to submit the petitions in this collection to the USPTO by mail through the United States Postal Service, the USPTO estimates that the average first class postage cost for a mailed submission will be 39 cents. Therefore, the USPTO estimates that up to 167 submissions per year may be mailed to the USPTO at an average first class postage cost of 39 cents, for a total postage cost of $65.

The USPTO estimates that the total non-hour respondent cost burden for this collection in the form of postage costs and filing fees amounts to $331,865.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, e.g., the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they will also become a matter of public record.

Dated: January 4, 2007.

Susan K. Brown,

Records Officer, USPTO, Office of the Chief Information Officer, Architecture, Engineering and Technical Services, Data Architecture and Services Division.

[FR Doc. 07–91 Filed 1–11–07; 8:45 am]

BILLING CODE 3510–16–M

COURT SERVICES AND OFFENDER SUPERVISION AGENCY FOR THE DISTRICT OF COLUMBIA

Privacy Act of 1974; Notice of Amended Systems

Pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a), the Court Services and Offender Supervision Agency for the District of Columbia (CSOSA) gives notice of proposed amendments to previously published systems of records on the Budget System (CSOSA–5), the Supervision Offender Case File (CSOSA–9), the Supervision & Management Automated Record Tracking (CSOSA–11), and the Office of Professional Responsibility Record (CSOSA–17).

The systems of records are proposed to be amended to note access by an expert, consultant, or contractor of CSOSA in the performance of a Federal duty to which the information is relevant. Such access may include the use of off-site contract computer servers for maintaining certain treatment information under CSOSA–9.

Accordingly, a new routine use is proposed to be added to CSOSA–5, CSOSA–9, CSOSA–11, and CSOSA–17, and the Storage and Safeguards data elements of CSOSA–9 are proposed to be revised to reflect this access.

In accordance with Title 5 U.S.C. 552a(e)(4) and (11), the public is given a 30-day period in which to comment on this notice; and the Office of Management and Budget (OMB), which has oversight responsibilities under the Act, requires a 40-day period in which to conclude its review of the system. Therefore, please submit any comments to Renee Barley, FOIA Officer, Office of the General Counsel, Court Services and Offender Supervision Agency for the District of Columbia, 633 Indiana Avenue, NW., Washington, DC 20004 by February 12, 2007. The amended system of records will be effective, as proposed, on February 26, 2007 unless CSOSA determines, upon review of the comments received, that changes should be made. In that event, CSOSA will publish a revised notice in the **Federal Register**.

In accordance with Privacy Act requirements, CSOSA has provided a report on the amended systems to OMB and Congress.

The specific amendments are given below.

1. In CSOSA–5 add a new paragraph G to data element ''Routine Uses of Records Maintained in the System, Including Categories of Users and the Purposes of such Users''.

CSOSA–5

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

* * * * *

G. To an expert, consultant, or contractor of CSOSA in the performance of a Federal duty to which the information is relevant.

* * * * *

2. In CSOSA–9 make the following changes:

a. Redesignate paragraphs G, H, and I in data element ''Routine Uses of Records Maintained in the System, Including Categories of Users and the Purposes of such Users'' as paragraphs H, I, and J, and add a new paragraph G;

b. Revise data element ''Storage''; and

c. Revise data element ''Safeguards.''

CSOSA–9

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

* * * * *

G. To an expert, consultant, or contractor of CSOSA in the performance of a Federal duty to which the information is relevant.

* * * * *

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

GPS data and treatment assessment information are hosted on servers that are managed by contract companies. Other information is stored manually in file folders or electronically on computers.

* * * * *

SAFEGUARDS:

The servers maintaining GPS data and treatment assessment information are located in a locked room; access to the servers is restricted, and end users must have a valid ID and password to access the data. Other information is maintained manually in file cabinets which are kept in locked offices.

* * * * *

3. In CSOSA–11 redesignate paragraph I of data element ''Routine Uses of Records Maintained in the System, Including Categories of Users and the Purposes of such Users'' as paragraph J, and add a new paragraph I.

CSOSA–11

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

* * * * *

I. To an expert, consultant, or contractor of CSOSA in the performance of a Federal duty to which the information is relevant.

* * * * *

4. In CSOSA–17 redesignate paragraph H of data element ''Routine Uses of Records Maintained in the System, Including Categories of Users and the Purposes of such Users'' as I and add a new paragraph H.

CSOSA–17

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

* * * * *

H. To an expert, consultant, or contractor of CSOSA in the performance of a Federal duty to which the information is relevant.

* * * * *

Dated: January 5, 2007.

Paul A. Quander, Jr.,

Director, Court Services and Offender Supervision Agency.

[FR Doc. E7–299 Filed 1–11–07; 8:45 am]

BILLING CODE 3129–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting of the Board of Regents of the Uniformed Services University of the Health Sciences

AGENCY: Uniformed Services University of the Health Sciences (USU).

ACTION: Quarterly meeting notice.

SUMMARY: The actions that will take place include the approval of minutes from the Board of Regents Meeting held November 13, 2006; acceptance of administrative reports; approval of faculty appointments and promotions; and the awarding of post-baccalaureate masters and doctoral degrees in the biomedical sciences and public health. The President, USU; Dean, USU School of Medicine; and Acting Dean, USU Graduate School of Nursing will also present reports. These actions are necessary for the University to remain an accredited medical school and to pursue our mission, which is to provide trained health care personnel to the uniformed services.

DATES: February 5, 2007, from 8 a.m. to 2 p.m.

ADDRESSES: Uniformed Services University of the Health Sciences, Board of Regents Conference Room (D3001), 4301 Jones Bridge Road, Bethesda, MD 20814–4799.

FOR FURTHER INFORMATION CONTACT: Janet S. Taylor, Designated Federal Official, Board of Regents, 301.295.3066.

Dated: January 8, 2007.

C.R. Choate,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–104 Filed 1–11–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Department of the Army

Army Science Board; Notice of Open Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following Committee Meeting:

Name of Committee: Army Science Board (ASB).

Date(s) of Meeting: 17–18 January 2007.

Time(s) of Meeting: 0700–1700, 17 January 2007; 0700–1700, 18 January 2007.

Place: Hampton Roads Convention Center, Hampton, VA.

1. *Agenda:* The FY07 study panels of the Army Science Board (ASB) are holding a Plenary Meeting on 17–18 January 2007. The meetings will be held at the Hampton Roads Convention Center, Hampton, VA. The plenary will begin at 0700 hrs on the 17th and will end at approximately 1700 hrs on the 18th. For further information on the FY07 ASB Plenary Meeting, please contact COL Heather Ierardi @ (703) 604–7474 or e-mail @ *heather.ierardi@hqda.army.mil.*

Wayne Joyner,

Program Support Specialist, Army Science Board.

[FR Doc. 07–93 Filed 1–11–07; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Corps of Engineers, Department of the Army

Notice of Availability for the Final Environmental Impact Statement for the San Juan Creek Watershed/ Western San Mateo Creek Watershed Special Area Management Plan (SAMP), Orange County, CA

AGENCY: Department of Defense, Department of the Army, Corps of Engineers, Los Angeles District Regulatory Branch.

ACTION: Notice of Availability for a Final EIS.

SUMMARY: The U.S. Army Corps of Engineers, Regulatory Branch has completed a Final EIS for the San Juan Creek Watershed/Western San Mateo Creek Watershed Special Area Management Plan (SAMP). The San Juan Creek Watershed/Western San Mateo Creek Watershed SAMP establishes three alternative permitting procedures that balance aquatic resource protection and reasonable economic development for the San Juan Creek Watershed and western San Mateo Creek Watershed.

DATES: The Final EIS will be available to the public for 30 days from January 12, 2007 to February 12, 2007. After the 30 day availability period, a Record of Decision will be issued.

FOR FURTHER INFORMATION CONTACT: Mr. Jae Chung, Project Manager, Regulatory Branch, U.S. Army Corps of Engineers, P.O. Box 532711, Los Angeles, California, 90053–2325, (213) 452–3292, *yong.j.chung@usace.army.mil.*

SUPPLEMENTARY INFORMATION: A previous Notice of Availability for this Final EIS was published on December 28, 2006. Because there were portions of the Final EIS not provided to other federal agencies in advance of the **Federal Register** notice, the Notice of Availability is re-issued with a new public review period that ends on February 12, 2007.

Under Section 404 of the Clean Water Act, the Corps is authorized to issue permits for activities that discharge dredged and/or fill materials into waters of the U.S., including wetlands, for roads, developments, utilities, and other activities. For the San Juan Creek and western San Mateo Creek Watersheds, the Corps is proposing a watershed-based SAMP to balance aquatic resource protection and reasonable economic development. The SAMP is an improvement over the current incremental case-by-case approach, which does a less effective job of taking a watershed perspective of aquatic resources and considering the needs of future permit applicants. The SAMP involves characterizing aquatic resource conditions and processes through the watershed, establishing alternative permitting procedures more appropriate for the given aquatic resources in the watershed, and developing a coordinated aquatic resources management framework.

The Draft EIS was made available to the public on November 21, 2005. The Corps accepted written comments until January 16, 2006, and accepted oral comments in a public hearing dated December 6, 2006. The Corps received ten written comments throughout the comment period and two oral comments at the public hearing.

The Final EIS is available to the public at the reference desks at the following local libraries: Mission Viejo Library, 100 Civic Center, Mission Viejo, CA 92691; San Clemente Library, 242 Avenida Del Mar, San Clemente, CA 92672; Laguna Hills Library, 25555 Alicia Parkway, Laguna Hills, CA 92653; Laguna Niguel Library, 30341 Crown Valley Parkway, Laguna Niguel, CA 92656; San Juan Capistrano Library, 31495 El Camino Real, San Juan Capistrano, CA 92675; Rancho Santa Margarita Library, 30902 La Promesa, Rancho Santa Margarita, CA 92688; and Dana Point Library, 33841 Niguel Road, Laguna Niguel, CA 92656. Information on obtaining electronic copies of the Final EIS is available by phoning or mailing the contact person or by visiting *http://www.spl.usace.army.mil/samp/sanjuancreeksamp.htm.*

David J. Castanon,

Chief, Regulatory Branch.

[FR Doc. E7–228 Filed 1–11–07; 8:45 am]

BILLING CODE 3710–KF–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: U.S. Department of Energy.

ACTION: Notice and request for comments.

SUMMARY: The Department of Energy (DOE), pursuant to the Paperwork Reduction Act of 1995), intends to propose an information collection request package with the Office of Management and Budget (OMB) concerning the Weatherization Assistance Program Evaluation which is needed to gather information in order to fund the weatherization of approximately 100,000 low-income homes each year. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record. Information about the operation of the program, energy used before and after weatherization, energy used by control group low-income homes, the effectiveness of specific energy conservation measures, customer satisfaction with the program, and non-energy benefits is needed for a

comprehensive and rigorous evaluation of the program.

DATES: Comments regarding this proposed information collection must be received on or before March 13, 2007. If you anticipate difficulty in submitting comments within that period, contact the person listed below as soon as possible.

ADDRESSES: Written comments may be sent to: Jeffrey Martus, Records Management Division, IM–11/ Germantown Building, Office of the Chief Information Officer, U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874–1290 or by fax at 301–903–9061 or by e-mail at *jeffrey.martus@hq.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Jeffrey Martus at the address listed above in **ADDRESSES**.

SUPPLEMENTARY INFORMATION: This package contains: (1) *OMB No.:* 1910–XXXX; (2) *Package Title:* The Weatherization Assistance Program Evaluation; (3) *Type of Review:* New Collection; (4) *Purpose:* This collection of information is necessary for a complete evaluation of the program in order to fund to the weatherization of approximately 100,000 low-income homes each year; (5) *Respondents:* There are 1700 to 2000 respondents; (6) *Estimated Number of Burden Hours:* 73,000.

Statutory Authority: Department of Energy Organization Act, Public Law 95–91, of August 4, 1977.

Issued in Washington, DC.

Sharon A. Evelin,

Acting Director, Records Management Division, Office of the Chief Information Officer.

[FR Doc. E7–307 Filed 1–11–07; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–123–000]

Central Kentucky Transmission Company; Notice of Revenue Crediting Report

January 4, 2007.

Take notice that on December 29, 2006, Central Kentucky Transmission Company (Central Kentucky) pursuant to section 19.6 of the General Terms and Condition tendered for filing a report showing that it did not collect any penalties for the 2005–2006 contract year.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time January 11, 2007.

Magalie R. Salas,

Secretary.

[FR Doc. E7–274 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12667–002]

City of Hamilton, OH; Notice Dismissing Request for Rehearing as Moot

January 5, 2007.

On August 10, 2006, the Director, Division of Hydropower Licensing, Office of Energy Project, issued a letter order rejecting as patently deficient an application for license that the City of Hamilton, Ohio (Hamilton) filed on May 12, 2006, proposing to develop a hydroelectric project at the U.S. Army Corps of Engineers' Captain Anthony Meldahl Lock and Dam on the Ohio River in Bracken County, Kentucky. On September 11, 2006, Hamilton sought rehearing of the rejection.

Hamilton filed a second license application for the proposed site on October 6, 2006. The new application was accepted for processing on December 13, 2006. Hamilton's request for rehearing is therefore dismissed as moot.

This notice constitutes final agency action. Requests for rehearing by the Commission of this dismissal must be filed within 30 days of the date of issuance of this notice, pursuant to 18 CFR 385.713.

Magalie R. Salas,

Secretary.

[FR Doc. E7–284 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP95–408–067]

Columbia Gas Transmission Corporation; Notice of Compliance Filing

January 5, 2007.

Take notice that on December 29, 2006, Columbia Gas Transmission Corporation (Columbia) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following revised tariff sheets with a proposed effective date of February 1, 2007:

Eighty-first Revised Sheet No. 25
Eighty-first Revised Sheet No. 26
Eightieth Revised Sheet No. 27
Sixty-eighth Revised Sheet No. 28
Tenth Revised Sheet No. 28B
Twenty-second Revised Sheet No. 29

Eighth Revised Sheet No. 29A
Thirty-fifth Revised Sheet No. 30A

Columbia states that this filing is being submitted pursuant to an order issued September 15, 1999 by the Commission approving an uncontested settlement that resolves environmental cost recovery issues in the above referenced proceeding. Columbia Gas Transmission Corporation, 88 FERC ¶ 61,217 (1999). The settlement established environmental cost recovery through unit components of base rates, all as more fully set forth in the settlement agreement filed April 5, 1999.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing 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. Such protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E7–290 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–125–000]

Columbia Gulf Transmission Company; Notice of Proposed Changes in FERC Gas Tariff

January 4, 2007.

Take notice that on December 29, 2006, Columbia Gulf Transmission Company (Columbia Gulf) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets, with a proposed effective date of February 1, 2007:

Ninth Revised Sheet No. 125
First Revised Sheet No. 289
Original Sheet No. 290

Columbia Gulf states that it is making this filing to prescribe the treatment of operational purchases and sales of natural gas by Columbia Gulf.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E7–276 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–124–000]

Crossroads Pipeline Company; Notice of Revenue Crediting Report

January 4, 2007.

Take notice that on December 29, 2006, Crossroads Pipeline Company (Crossroads) pursuant to section 19.6 of the General Terms and Condition tendered for filing a report showing that it did not collect any penalties for the 2005–2006 contract year.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a

document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time January 11, 2007.

Magalie R. Salas,

Secretary.

[FR Doc. E7–275 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP06–595–003]

Discovery Gas Transmission LLC; Notice of Negotiated Rate Filing

January 5, 2007.

Take notice that on December 29, 2006, Discovery Gas Transmission LLC (Discovery) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, Fourth Revised Sheet No. 22, to become effective January 1, 2007.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E7–288 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP06–426–002]

Discovery Gas Transmission LLC; Notice Of Compliance Filing

January 5, 2006.

Take notice that on December 29, 2006, Discovery Gas Transmission LLC (Discovery) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the following tariff sheets, to be effective December 1, 2006:

Sixth Revised Sheet No. 101
First Revised Sheet No. 188
Second Revised Sheet No. 199

Discovery also filed the following alternate tariff sheet, to be effective upon Commission approval:

Alternate First Revised Sheet No. 188

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing 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. Such protests must be filed on or before the date as indicated below. Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible online at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Protest Date: 5 p.m. Eastern Time on January 23, 2007.

Magalie R. Salas,

Secretary.

[FR Doc. E7–292 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL07–27–000]

East Texas Electric Cooperative, Inc., Tex-La Electric Cooperative of Texas, Inc., Deep East Texas Electric Cooperative, Inc.; Notice of Filing

January 4, 2007.

Take notice that on December 22, 2006, East Texas Electric Cooperative, Inc., Tex-La Electric Cooperative of Texas, Inc. and Deep East Texas Electric Cooperative, Inc. filed a petition for approval of transmission revenue requirements for inclusion in the open access transmission tariff of the Southwest Power Pool, Inc., pursuant to Rule 207(a)(5) of the Rules of Practice and Procedure of the Federal Energy Regulatory Commission, 18 CFR 385.207(a)(5).

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission,

888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on January 11, 2007.

Magalie R. Salas,

Secretary.

[FR Doc. E7–271 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–122–000]

Florida Gas Transmission Company, LLC; Notice of Proposed Changes in FERC Gas Tariff

January 4, 2007.

Take notice that on December 29, 2006, Florida Gas Transmission Company, LLC (FGT) submitted for filing pursuant to section 19.1 of the General Terms and Conditions of its FERC Gas Tariff, Fourth Revised Volume No. 1, schedules detailing certain information related to its Cash-Out Mechanism, Fuel Resolution Mechanism and Balancing Tools charges for the accounting months October 2005 through September 2006. No tariff changes are proposed.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E7–273 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99–518–098]

Gas Transmission Northwest Corporation; Notice of Negotiated Rate

January 5, 2007.

Take notice that on December 29, 2006, Gas Transmission Northwest Corporation (GTN) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1–A, Forty-First Revised Sheet No. 15, to become effective January 1, 2007.

GTN states that this sheet is being filed to update GTN's reporting of negotiated rate transactions that it has entered into.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible online at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E7–280 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP06–407–003]

Gas Transmission Northwest Corporation; Notice of Motion to Place Suspended Rates and Tariff Sheets into Effect

January 5, 2007.

Take notice that on December 29, 2006, Gas Transmission Northwest Corporation (GTN) moved to place the rates and tariff sheets suspended in the Commission's July 31, 2006 ''Order Accepting and Suspending Tariff Sheets Subject to Refund and Conditions, Establishing Hearing Procedures, and Establishing a Technical Conference'' into effect on January 1, 2007. In addition, GTN submitted for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1–A, the following tariff sheets to become effective January 1, 2007:

Third Substitute Ninth Revised Sheet No. 4
Substitute Fourth Revised Sheet No. 5
Substitute Fourth Revised Sheet No. 12

GTN states that these substitute tariff sheets reflect (1) Tariff modifications which were made subsequent to GTN's original filing and (2) the removal of the costs of facilities that will not be in service by the end of the test period, as required by the July 31, 2006 Order. Suspended sheets that were modified subsequent to GTN's original filing are referenced in Appendix A of GTN's motion filing. Sheets that will become effective without change are referenced in Appendix C of GTN's motion filing. GTN moved to place the sheets in both Appendix A and C into effect on January 1, 2007.

GTN further states that a copy of this filing has been served on GTN's jurisdictional customers and interested state regulatory agencies.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing 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. Such protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,
Secretary.
[FR Doc. E7–287 Filed 1–11–07; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2306–098]

Great Bay Hydro Corporation; Notice Dismissing Rehearing Requests as Moot

January 5, 2007.

On August 29, 2006, the license for the Great Bay Hydro Corporation's (Great Bay) 4.80-megawatt Clyde River Hydroelectric Project No. 2306 was amended to authorize the licensee to remove from the project boundary certain impoundments, structures, and lands and to convey in fee a portion of the lands to the Vermont Agency of Natural Resources (ANR), as well as to convey to the Vermont ANR a conservation easement on certain lands remaining within the project boundary.[1]

On September 28, 2006, Great Bay and Vermont ANR filed timely requests for rehearing and or clarification of the August 29 order. However, upon consideration of the record in the proceeding, the August 29 order was rescinded and the proceeding was remanded to Commission staff for further action.[2] Accordingly, the requests for rehearing filed on September 28, 2006, by Great Bay Hydro Corporation and by Vermont Agency of Natural Resources are dismissed as moot.

Magalie R. Salas,
Secretary.
[FR Doc. E7–286 Filed 1–11–07; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP07–51–000]

Gulfstream Natural Gas System, L.L.C.; Notice of Application

January 5, 2007.

On December 22, 2006, in Docket No. CP07–51–000, Gulfstream Natural Gas System, L.L.C. (Gulfstream), pursuant to section 7(c) of the Natural Gas Act, as amended, and section 157 Subpart A of the Federal Energy Regulatory Commission's (Commission) regulations, filed for authorization to install, construct, own, operate and maintain certain pipeline facilities, consisting primarily of the installation of approximately 17.74 miles of 20-inch diameter pipeline and additional compression totaling 45,000 horsepower to be installed at Stations 410 and 420, as more fully described in the application (Phase IV Project). Gulfstream further requests that the Commission grant a preliminary determination on the non-environmental aspects of this Application by May 31, 2007, with a final order granting the requested authorizations and related approvals by September 1, 2007. Gulfstream states that issuing orders by these dates will help to ensure that the Phase IV facilities are available to meet the timing needs of the Phase IV shipper and to give the Phase IV shipper and Gulfstream the economic assurance needed to go forward with their respective projects.

Questions concerning the application should be directed to: P. Martin Teague, Associate General Counsel at Gulfstream Natural Gas System, L.L.C., 5400 Westheimer Court, P.O. Box 1642, Houston, Texas 77251–1642, or by calling (713) 627–5242.

On November 21, 2006, the Commission staff granted Gulfstreams' request to utilize the Pre-Filing process and assigned Docket No. PF06–29–000 to staff activities involving the Phase IV Project. As of the filing of this application on December 29, 2006, the Pre-Filing Process for this project has ended. From this time forward, Gulfstreams' proceedings will be conducted in Docket No. CP07–51–000.

Pursuant to Section 157.9 of the Commission rules, 18 CFR 157.9 and to ensure compliance with the Energy Policy Act of 2005, upon completion of the Commission staff's environmental review for Gulfstreams' proposal, the environmental document will be placed into the record on the Commission's eLibrary system. The action of the document's placement in the record alerts the other agencies of the requirement to complete necessary reviews and authorizations within 90 days of the date of the Commission staff's environmental document.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A

[1] See 116 FERC ¶ 62,169 (2006).
[2] See 117 FERC ¶ 61,329 (2006).

person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding. However, a person does not have to intervene in order to have comments considered.

The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link at *http://www.ferc.gov.* The Commission strongly encourages intervenors to file electronically. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on January 31, 2007.

Magalie R. Salas,

Secretary.

[FR Doc. E7–282 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP07–57–000, CP97–238–012, RP04–360–009]

Maritimes & Northeast Pipeline L.L.C., Portland Natural Gas Transmission System; Notice of Filing

January 5, 2007.

Take notice that on December 18, 2006, Maritimes & Northeast Pipeline L.L.C. and Portland Natural Gas Transmission System (Settling Parties) submitted a Settlement Agreement for Commission approval. The principal effect of the Settlement Agreement is to modify certain agreements between the Settling Parties relating to their ownership of certain jointly-owned facilities approved by the Commission in a November 4, 1997 order.[1]

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on January 16, 2007.

Magalie R. Salas,

Secretary.

[FR Doc. E7–283 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

[1] Maritimes & Northeast Pipeline, L.L.C. and Portland Natural Gas Transmission System, 80 FERC ¶ 61,136, order on reh'g and approving agreements, 81 FERC ¶ 61,166 (1997).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99–176–121]

Natural Gas Pipeline Company of America; Notice Of Negotiated Rate

January 5, 2007.

Take notice that on December 28, 2006, Natural Gas Pipeline Company of America (Natural) tendered for filing Amendment No. 1 dated December 8, 2006 to Transportation Rate Schedule FTS Agreement dated September 26, 2005, to be effective January 1, 2007.

Natural states that the purpose of this filing is to implement an amendment to an existing negotiated rate agreement entered into by Natural and Nicor Gas Company under Natural's Rate Schedule FTS and Section 49 of the General Terms and Conditions of its Tariff.

Natural states that copies of the filing are being mailed to all parties set out on the Commission's official service list in Docket No. RP99–176.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the

''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E7–291 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP06–72–004]

Northern Border Pipeline Company; Notice of Compliance Filing

January 5, 2006.

Take notice that on December 28, 2006, Northern Border Pipeline Company (Northern Border) tendered for filing to become part of its FERC Gas Tariff, First Revised Volume No. 1, the following tariff sheets to be effective January 1, 2007:

Ninth Revised Sheet No. 201
First Revised Sheet No. 300H.04
First Revised Sheet No. 300I

On September 18, 2006, Northern Border filed a Stipulation and Agreement (Stipulation) in Northern Border's rate case proceeding at Docket No. RP06–72–000. In an order dated November 21, 2006 (117 FERC ¶ 61,217), the Commission approved the Stipulation. As provided for in Articles XII and XIII of the Stipulation, Northern Border is filing compliance tariff sheets that are necessary after the issuance of the Commission's Order approving the Stipulation to implement the tariff revisions shown in Appendix B of the Stipulation.

Northern Border has served a copy of this filing upon all parties of record in this proceeding.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing 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. Such protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible online at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E7–289 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP06–45–003]

Northwest Pipeline Corporation; Notice of Compliance Filing

January 5, 2007.

Take notice that on December 29, 2006, Northwest Pipeline Corporation tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, the following tariff sheets, to be effective January 15, 2007:

Substitute Thirty-Second Revised Sheet No. 5,
Substitute Seventh Revised Sheet No. 5–C,
Substitute Second Revised Sheet No. 5–D.

Northwest states that the purpose of this filing is to reflect the same rates in its Docket No. CP06–45 filing as those filed in Northwest's motion rates that were filed on December 22, 2006 in Docket No. RP06–416–001.

Northwest Pipeline Corporation states that copies of the filing were served on parties on the official service list in the above-captioned proceeding.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing 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. Such protests must be filed on or before the date as indicated below. Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Protest Date: 5 p.m. Eastern Time on January 23, 2007.

Magalie R. Salas,

Secretary.

[FR Doc. E7–281 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL07–26–000]

City of Pasadena, California; Notice of Filing

January 4, 2007.

Take notice that on December 22, 2006, City of Pasadena, California filed its second annual revisions to its Transmission Revenue Balancing Account Adjustment, to become effective January 1, 2007.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of

the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. eastern Time on January 22, 2007.

Magalie R. Salas,

Secretary.

[FR Doc. E7–278 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–126–000]

Sea Robin Pipeline Company, LLC; Notice of Flowthrough Crediting Mechanism

January 4, 2007.

Take notice that on December 29, 2006, Sea Robin Pipeline Company, LLC (Sea Robin) submitted its Annual Flowthrough Crediting Mechanism Filing. Sea Robin states that this filing was made pursuant to section 22 of the General Terms and Conditions of Sea Robin's FERC Gas Tariff, which requires the crediting of certain amounts received as a result of resolving monthly imbalances between its gas and liquefiables shippers and under its operational balancing agreements as described in Section 6 of its Tariff, and to accumulate amounts received as a result of imposing scheduling penalties as described in section 7 of its Tariff.

Sea Robin reports that it received $210,294.06 in excess of amounts paid to shippers for the twelve months ended October 31, 2006. In accordance with section 22.2 of its Tariff, this excess amount will be credited to shippers, based upon shippers transportation volumes for the twelve months ended October 31, 2006.

Sea Robin further states that copies of this filing are being served on all jurisdictional customers, applicable state regulatory agencies and parties to this proceeding.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time January 11, 2007.

Magalie R. Salas,

Secretary.

[FR Doc. E7–277 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–120–000]

Stingray Pipeline Company, L.L.C.; Notice of Proposed Changes in FERC Gas Tariff

January 3, 2007.

Take notice that on December 22, 2006, Stingray Pipeline Company, L.L.C. (Stingray) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, the following tariff sheets, to become effective January 21, 2007:

Tenth Revised Sheet No. 2
Original Sheet No. 205
Original Sheet No. 206
Original Sheet No. 207
Original Sheet No. 208
Sheet Nos. 209–299 (reserved for future use)

Stingray states it is filing these tariff sheets to reflect currently effective service and discount rate agreements which do not conform with its current form of service agreement. Stingray requests that the Commission accept these non-conforming agreements for filing and grant any and all waivers necessary to allow these agreements to be effective as of their respective effective dates and to remain in effect in accordance with their respective terms.

Stingray states that copies of its filing have been mailed to all affected customers of Stingray and any interested State commissions. However, due to the voluminous nature of this filing, Stingray is not providing copies of the appendices or filed agreements or red-lines of such agreements as part of each service copy. Stingray states that it will provide copies of such appendices and agreements to any affected customer or interested State commission who requests such copies.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of

intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E7–272 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–127–000]

Texas Eastern Transmission; LP Notice of Proposed Changes in FERC Gas Tariff

January 4, 2007.

Take notice that on December 29, 2006, Texas Eastern Transmission, LP (Texas Eastern) tendered for filing as part of its FERC Gas Tariff, Seventh Revised Volume No. 1 and First Revised Volume No. 2, revised tariff sheets, as listed on Appendix B to the filing, to become effective February 1, 2007.

Texas Eastern states that these revised tariff sheets are filed pursuant to Section 15.1, Electric Power Cost (EPC) Adjustment, of the General Terms and Conditions of Texas Eastern's FERC Gas Tariff, Seventh Revised Volume No. 1. Texas Eastern states that Section 15.1 provides that Texas Eastern shall file, to be effective each February 1, revised rates for each applicable zone and rate schedule, based upon the projected annual EPC required for the operation of transmission compressor stations with electric motor prime movers. The revised tariff sheets also reflect the EPC Surcharge, which is designed to clear the balance in the Deferred EPC Account.

Texas Eastern states that all costs of electric power compression required for the incremental services under the Freehold Project and the M–1 Expansion Project are appropriately assigned to the incremental projects as required by the Commission orders certificating those projects. In addition, Texas Eastern states that it has based its EPC allocation to the TIME Project on the methodology set forth in the Commission-approved joint settlement in Docket Nos. RP03–542, *et al.*

Texas Eastern states that generally, the revised tariff sheets reflect an increase in Texas Eastern's EPC Adjustment. For example, the proposed rate changes to the primary firm capacity reservation charges, usage rates and 100% load factor average costs for full Access Area Boundary service from the Access Area Zone, East Louisiana, to the three market area zones are as follows:

Zone	Reservation	Usage	100% load factor
Market 1	$0.035/Dth	$0.0012/Dth	0.0024/Dth
Market 2	0.104/Dth	0.0040/Dth	0.0074/Dth
Market 3	0.152/Dth	0.0056/Dth	0.0106/Dth

Texas Eastern states that copies of its filing have been served upon all affected customers of Texas Eastern and interested State commissions.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

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Magalie R. Salas,

Secretary.

[FR Doc. E7–270 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Comined Notice of Filings #1

January 3, 2007.

Docket Numbers: EC07–41–000.

Applicants: Scottish Power plc; PPM Enrgy, Inc.; Big Horn Wind Project LLC; Casselman Windpower LLC; Colorado Green Holdings LLC; Eastern Desert Power LLC; Elk River Wind LLC; Flat Rock Windpower LLC; Flat Rock Windpower II LLC; Flying Cloud Power Partners, LLC; Klamath Generation LLC;

Klondike Wind Power LLC; Klondike Wind Power II LLC; Klondike Wind Power III LLC; Leaning Juniper Wind Power LLC; MinnDakota Wind LLC; Moraine Wind LLC; Mountain View Power Partners III, LLC; Phoenix Wind Power LLC; Shiloh I Wind Project, LLC; Trimont Wind I LLC; Twin Buttes Wind LLC; Iberdrola, S.A.

Description: Joint application of Scottish Power plc et al for authorization for indirect disposition of jurisdictional facilities and requests for waiver of filing requirements and expedited consideration.

Filed Date: 12/22/2006.

Accession Number: 20061227–0070.

Comment Date: 5 p.m. Eastern Time on Friday, January 12, 2007.

Docket Numbers: EC07–42–000.

Applicants: BBPOP Wind Equity LLC; Babcock & Brown Wind Partners U.S. LLC; B&B Wind Portfolio I LLC; Mendota Hills, LLC; Allegheny Ridge Wind Farm, LLC; North Allegheny Wind, LLC; Argonne Wind LLC; GSG, LLC.

Description: BBPOP Wind Equity LLC et al submits an application for authorization of indirect disposal of jurisdictional facilities pursuant to Section 203 of the FPA.

Filed Date: 12/22/2006.

Accession Number: 20061227–0071.

Comment Date: 5 p.m. Eastern Time on Friday, January 12, 2007.

Docket Numbers: EC07–43–000.

Applicants: LSP Energy Limited Partnership; Complete Energy Holdings, LLC.

Description: LSP Energy Limited Partnership and Complete Energy Holdings, LLC submit a joint application for authorization of the disposition of jurisdictional facilities.

Filed Date: 12/22/2006.

Accession Number: 20061228–0100.

Comment Date: 5 p.m. Eastern Time on Friday, January 12, 2007.

Docket Numbers: EC07–44–000.

Applicants: Entegra Power Group LLC; Gila River Power, L.P.; Union Power Partners, L.P.

Description: Entegra Power Group LLC et al, submit an application for order amending blanket authorization for certain future transfers and acquisitions of equity interests under Section 203 of the Federal Power Act.

Filed Date: 12/28/2006.

Accession Number: 20070103–0125.

Comment Date: 5 p.m. Eastern Time on Thursday, January 18, 2007.

Take notice that the Commission received the following electric rate filings

Docket Numbers: ER96–719–015; EL05–59–003.

Applicants: MidAmerican Energy Company.

Description: MidAmerican Energy Company submits a refund report.

Filed Date: 12/22/2006.

Accession Number: 20061222–5024.

Comment Date: 5 p.m. Eastern Time on Friday, January 12, 2007.

Docket Numbers: ER00–1053–019.

Applicants: Maine Public Service Company.

Description: Maine Public Service Co. submits a revised Open Access Transmission Tariff pages and a Settlement Agreement regarding its Formula Rate and its 2006 Informational Filing.

Filed Date: 12/22/2006.

Accession Number: 20061226–0202.

Comment Date: 5 p.m. Eastern Time on Friday, January 12, 2007.

Docket Numbers: ER03–345–008.

Applicants: New England Power Pool Participants Committee

Description: ISO New England, Inc. submits its Semi-Annual Status Report on load response programs in accordance with FERC's 2/25/03 Order.

Filed Date: 12/29/2006.

Accession Number: 20070103–0128.

Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Docket Numbers: ER05–1178–007; ER05–1191–007.

Applicants: Gila River Power, L.P.; Union Power Partners, L.P.

Description: Gila River Power, LP and Union Power Partners L.P. submit a notice of non-material change in status relating to their upstream ownership structure pursuant to Section 35.27(c) of FERC's Rules and Regs.

Filed Date: 12/29/2006.

Accession Number: 20070103–0132.

Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Docket Numbers: ER06–185–006.

Applicants: New York Independent System Operator, Inc.

Description: New York Independent System Operator, Inc. submits worksheets that detail the results of its Real-Time guarantee payment impact test for the period from 5/1/05 to 4/7/06 pursuant to FERC's 11/3/06 Order.

Filed Date: 12/29/2006.

Accession Number: 20070103–0131.

Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Docket Numbers: ER06–451–017.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits materials demonstrating its readiness to deploy its Energy Imbalance Services market, to become effective 2/1/07.

Filed Date: 12/22/2006.

Accession Number: 20070103–0134.

Comment Date: 5 p.m. Eastern Time on Monday, January 8, 2007.

Docket Numbers: ER07–314–001.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc submits a supplement to their filing of revised Network Integration Transmission Service Agreement.

Filed Date: 12/27/2006.

Accession Number: 20061228–0193.

Comment Date: 5 p.m. Eastern Time on Wednesday, January 17, 2007.

Docket Numbers: ER07–379–000.

Applicants: Southern California Edison Company.

Description: Southern California Edison Co submits a Small Generator Interconnection Agreement and a Service Agreement for Wholesale Distribution Service with MM Tulare Energy LLC.

Filed Date: 12/28/2006.

Accession Number: 20061229–0076.

Comment Date: 5 p.m. Eastern Time on Thursday, January 18, 2007.

Docket Numbers: ER07–380–000; ER06–319–004; ER06–1136–001; ER06–1550–001.

Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection, LLC submits revisions to Schedule 2 of the PJM Open Access Transmission Tariff.

Filed Date: 12/28/2006.

Accession Number: 20070103–0120.

Comment Date: 5 p.m. Eastern Time on Thursday, January 18, 2007.

Docket Numbers: ER07–381–000.

Applicants: Electric Energy, Inc.

Description: Electric Energy, Inc submits modification 18 to a Power Contract dated 9/2/87 with the United States Department of Energy designated as Contract # DE-AC05–760R01312 (Rate Schedule FERC 10).

Filed Date: 12/28/2006.

Accession Number: 20070103–0121.

Comment Date: 5 p.m. Eastern Time on Thursday, January 18, 2007.

Docket Numbers: ER07–382–000.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool Inc submits a Revised Agreement for Wholesale Distribution Service Charges between Kansas Electric Power Cooperative Inc and the Empire District Electric Company.

Filed Date: 12/28/2006.

Accession Number: 20070103–0122.

Comment Date: 5 p.m. Eastern Time on Thursday, January 18, 2007.

Docket Numbers: ER07–383–000.

Applicants: PacifiCorp.

Description: PacifiCorp submits proposed revisions to its Large Generator Interconnection Agreement designated as Exhibit A—First Rev Sheet 428 to FERC Electric Tariff, Substitute 6th Rev Volume 11 to become effective 12/29/06.

Filed Date: 12/28/2006.

Accession Number: 20070103–0123.

Comment Date: 5 p.m. Eastern Time on Thursday, January 18, 2007.

Docket Numbers: ER07–384–000.

Applicants: Midwest ISO.

Description: Midwest Independent Transmission System Operator, Inc submits proposed revisions to Schedules 10, 16 and 17 of their Open Access Transmission and Energy Markets Tariff.

Filed Date: 12/28/2006.

Accession Number: 20070103–0124.

Comment Date: 5 p.m. Eastern Time on Thursday, January 18, 2007.

Docket Numbers: ER07–386–000.

Applicants: San Diego Gas & Electric Company.

Description: San Diego Gas & Electric submits a change in rates for the Transmission Revenue Balancing Account Adjustment and its Transmission Owner Tariff, to become effective 1/2/06.

Filed Date: 12/29/2006.

Accession Number: 20070103–0080.

Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Docket Numbers: ER07–387–000.

Applicants: New England Power Pool Participants Committee

Description: The New England Power Pool Participants Committee submits a transmittal letter along with counterpart signature pages of the New England Power Pool Agreement executed with Conectiv Energy Supply Inc et al.

Filed Date: 12/29/2006.

Accession Number: 20070103–0133.

Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Docket Numbers: ER07–388–000.

Applicants: New York Independent System Operator, Inc.; New York State Electric & Gas Corporation.

Description: New York Independent System Operator Inc et al. submit an executed Standard Large Generator Interconnection Agreement for the Munnsville Wind Farm Project.

Filed Date: 12/29/2006.

Accession Number: 20070103–0129.

Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Docket Numbers: ER07–390–000.

Applicants: Nevada Solar One, LLC.

Description: Nevada Solar One, LLC submits an application for order granting market-based rate authority, waiving regulations and granting blanket approvals, the proposed market-based rate tariff.

Filed Date: 12/29/2006.

Accession Number: 20070103–0130.

Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Docket Numbers: ER07–391–000.

Applicants: Dynegy Midwest Generation, Inc.

Description: Dynegy Midwest Generation Inc submits an Amended and Restated Black Start Service Agreement dated as of 12/27/06 by and between Illinois Power Company dba AmerenIP.

Filed Date: 12/29/2006.

Accession Number: 20070103–0135.

Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Docket Numbers: ER07–393–000.

Applicants: MidAmerican Energy Company.

Description: MidAmerican Energy Company submits its First Revised Sheet 10 to their FERC Electric Rate Schedule 72, Contract for Firm Transmission Service, with Western Area Power Administration.

Filed Date: 12/29/2006.

Accession Number: 20070103–0137.

Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Docket Numbers: ER07–394–000.

Applicants: MidAmerican Energy Company.

Description: MidAmerican Energy Company submits its First Revised Sheets 11, 12, 15–18 and Original Sheet 12a to Original Service Agreement 260 with Eldridge Electric and Water Utilities.

Filed Date: 12/29/2006.

Accession Number: 20070103–0138.

Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Docket Numbers: ER07–395–000.

Applicants: ALLETE, Inc.

Description: ALLETE, Inc submits two service agreements establishing the rates, terms and conditions pursuant to which the transmission function of MP Transmission.

Filed Date: 12/29/2006.

Accession Number: 20070103–0139.

Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Docket Numbers: ER07–396–000.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc submits revised pages to its Open Access Transmission Tariff.

Filed Date: 12/29/2006.

Accession Number: 20070103–0140.

Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Docket Numbers: ER07–397–000.

Applicants: ISO New England Inc.; New England Power Pool Participants Committee.

Description: ISO New England, Inc and New England Power Pool Participants Committee submit revised tariff sheets reflecting proposed amendments to Schedule 2—Reactive Supply & Voltage control from Generation Resources Service.

Filed Date: 12/29/2006.

Accession Number: 20070103–0141.

Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Take notice that the Commission received the following electric securities filings

Docket Numbers: ES07–14–000.

Applicants: International Transmission Company.

Description: International Transmission Company submit an application pursuant to Section 204 for Authority to Issue Securities

Filed Date: 12/29/2006.

Accession Number: 20061229–5049.

Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Docket Numbers: ES07–15–000.

Applicants: Michigan Electric Transmission Company, LLC.

Description: Michigan Electric Transmission Company, LLC submits an Application under Section 204 for Authority to Issue Securities.

Filed Date: 12/29/2006.

Accession Number: 20061229–5051.

Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified *Comment Date*. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. 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. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access

who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

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Magalie Salas,

Secretary.

[FR Doc. E7–269 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings # 1

January 5, 2007.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG07–25–000.
Applicants: Fenton Power Partners I, LLC.
Description: Fenton Power Partners I, LLC submits a notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 12/22/2006.
Accession Number: 20070104–0522.
Comment Date: 5 p.m. Eastern Time on Friday, January 12, 2007.

Docket Numbers: EG07–26–000.
Applicants: Buena Vista Energy, LLC.
Description: Buena Vista Energy, LLC submits a notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 12/27/2006.
Accession Number: 20070104–0521.
Comment Date: 5 p.m. Eastern Time on Wednesday, January 17, 2007.

Docket Numbers: EG07–27–000.
Applicants: Grays Harbor Energy LLC.
Description: Grays Harbor Energy LLC submits a Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 12/28/2006.
Accession Number: 20070104–0520.
Comment Date: 5 p.m. Eastern Time on Thursday, January 18, 2007.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER04–691–081.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: Midwest Independent Transmission System Operator, Inc submits proposed revisions to its Open Access Transmission and Energy Markets Tariff.
Filed Date: 12/26/2006.
Accession Number: 20070103–0184.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 16, 2007.

Docket Numbers: ER06–1420–003.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: Midwest Independent Transmission System Operator submits proposed revisions to the Midwest Contingency Reserve Sharing Group Agreement.
Filed Date: 12/26/2006.
Accession Number: 20070103–0185.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 16, 2007.

Docket Numbers: ER07–139–001.
Applicants: Oklahoma Gas and Electric Company.
Description: Oklahoma Gas and Electric Co submits a notice of withdrawal of amendment to rate schedule and request to terminate proceeding of the 11/1/06 filing.
Filed Date: 12/29/2006.
Accession Number: 20070104–0066.
Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Docket Numbers: ER07–366–000.
Applicants: Duke Energy Carolinas, LLC; Duke Power Company
Description: Duke Energy Carolinas, LLC files specific rates to be charged under its Power Supply Agreements pursuant to the Commission's 10/31/06 order.
Filed Date: 12/22/2006.
Accession Number: 20070103–0150.
Comment Date: 5 p.m. Eastern Time on Friday, January 12, 2007.

Docket Numbers: ER07–385–000; ER06–451–002.
Applicants: American Electric Power Service Corporation; Southwestern Electric Power Company; Public Service Company of Oklahoma.
Description: Public Service Company of Oklahoma and Southwestern Electric Power Co submits revisions to its Open Access Transmission Tariff, Third Revised Volume 6 in compliance with FERC's 7/20/06 Order.
Filed Date: 12/26/2006.
Accession Number: 20070103–0079.
Comment Date: 5 p.m. Eastern Time on Wednesday, January 10, 2007.

Docket Numbers: ER07–389–000.
Applicants: Power Provider, LLC.
Description: Power Provider, LLC submits a notice of cancellation of its FERC Electric Tariff 1.
Filed Date: 12/29/2006.
Accession Number: 20070104–0524.
Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Docket Numbers: ER07–392–000.
Applicants: MidAmerican Energy Company.
Description: Mid American Energy Co submits its First Revised Network Integration Transmission Service Agreement and First Revised Network Operating Agreement with Montezuma Municipal Light and Power.
Filed Date: 12/29/2006.
Accession Number: 20070104–0523.
Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Docket Numbers: ER07–398–000.
Applicants: Entergy Services Inc.
Description: Entergy Arkansas, Inc submits its revised Network Integration Transmission Service Agreements with the Cities of Prescott and West Memphis, Arkansas.
Filed Date: 12/29/2006.
Accession Number: 20070103–0187.
Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Docket Numbers: ER07–399–000.
Applicants: Entergy Services Inc.
Description: Entergy Services Inc agent for Entergy Arkansas, Inc submits revised rate schedule sheets to its Power Coordination, Interchange and Transmission Service Agreements with Cit of Hope, Arkansas and Cities of Campbell and Thayer, Missouri.
Filed Date: 12/29/2006.
Accession Number: 20070103–0186.
Comment Date: 5 p.m. Eastern Time on Friday, January 19, 2007.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and § 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. 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. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

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Magalie R. Salas,

Secretary.

[FR Doc. E7–279 Filed 1–11–07; 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

January 5, 2007.

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:* 12753–000.

c. *Date filed:* December 7, 2006.

d. *Applicant:* AquaEnergy Group Ltd.

e. *Name of Project:* Humboldt County Offshore Wave Energy Project.

f. *Location:* The project would be located in the Pacific Ocean off the coast of Humboldt County, California.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contacts:* Ms. Alla Weinstein, President, AquaEnergy Group, Ltd., P.O. Box 1267, Mercer Island, WA 98040, phone: (425) 430–7924, fax: (425) 988–1977, or e-mail address: *allawa@aeg-ltd.com*.

i. *FERC Contact:* Chris Yeakel, (202) 502–8132.

j. *Deadline for filing comments, protests, and motions to intervene:* 60 days from the issuance date of this notice.

The Commission's Rules of Practice and Procedure require all intervenors 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 intervenor 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) 200–300 wave-energy conversion buoys with a generating capacity of 200 kilowatts to 1 megawatt each consisting of; (2) integrated generators; (3) anchoring devices; and (4) interconnection transmission lines. The anticipated annual generation of the project will be approximately 175 gigawatt-hours.

l. *Locations of Applications:* A copy of the application is available for inspection and reproduction at the Commission in the Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov*. For TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Competing 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.

o. *Competing Development Application*—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.

p. *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.

q. *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.

r. *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.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; See 18 C.F.R. 385.2001 (a)(1)(iii) and the instructions on the Commission's Web site under ''e-filing'' link. The Commission strongly encourages electronic filing.

s. *Filing and Service of Responsive Documents*—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'',''COMPETING APPLICATION'' OR ''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, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

t. *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.

Magalie R. Salas,

Secretary.

[FR Doc. E7–285 Filed 1–11–07; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2006–0852; FRL–8106–1]

Agency Information Collection Activities; Proposed Collection; Comment Request; Chemical-Specific Rules, TSCA Section 8(a); EPA ICR No. 1198.08, OMB Control No. 2070–0067

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit a request to renew an existing approved Information Collection Request (ICR) to the Office of Management and Budget (OMB). This ICR, entitled: ''Chemical-Specific Rules, TSCA Section 8(a)'' and identified by EPA ICR No. 1198.08 and OMB Control No. 2070–0067, is scheduled to expire on October 31, 2007. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection.

DATES: Comments must be received on or before March 13, 2007.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2006–0852, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Hand Delivery*: OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID number EPA–HQ–OPPT–2006–0852. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2006–0852. EPA's policy is that all comments received will be included in the public docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket's index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov*, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

For technical information contact: Gerry Brown, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8086; fax number: (202) 564–4765; e-mail address: *brown.gerry@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. What Information is EPA Particularly Interested in?

Pursuant to section 3506(c)(2)(A) of the PRA, EPA specifically solicits comments and information to enable it 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 estimates 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.

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. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What Should I Consider when 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 and provide specific examples.

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. Offer alternative ways to improve the collection activity.

7. Make sure to submit your comments by the deadline identified under **DATES**.

8. To ensure proper receipt by EPA, be sure to identify the docket ID 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.

III. What Information Collection Activity or ICR Does this Action Apply to?

Affected entities: Entities potentially affected by this action are companies that manufacture, process, or import or propose to manufacture, process, or import chemical substances and mixtures.

Title: Chemical-Specific Rules, TSCA Section 8(a).

ICR numbers: EPA ICR No. 1198.08, OMB Control No. 2070–0067.

ICR status: This ICR is currently scheduled to expire on October 31, 2007. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: TSCA section 8(a) authorizes the Administrator of EPA to promulgate rules that require persons who manufacture, import, or process chemical substances and mixtures or who propose to manufacture, import, or process chemical substances and mixtures, to maintain such records and submit such reports to EPA as may be reasonably required. Any chemical covered by TSCA for which EPA or another Federal Agency has a reasonable need for information and which cannot be satisfied via other sources is a proper potential subject for a chemical-specific TSCA section 8(a) rulemaking. Information that may be collected under TSCA section 8(a) includes, but is not limited to, chemical names, categories of use, production volume, byproducts of chemical production, existing data on deaths and environmental effects, exposure data, and disposal information. Generally, EPA uses chemical-specific information under TSCA section 8(a) to evaluate the potential for adverse human health and environmental effects caused by the manufacture, importation, processing, use or disposal of identified chemical substances and mixtures. Additionally, EPA may use TSCA section 8(a) information to assess the need or set priorities for testing and/or further regulatory action. To the extent that reported information is not considered confidential, environmental groups, environmental justice advocates, state and local government entities and other members of the public will also have access to this information for their own use.

Responses to the collection of information are mandatory (see 40 CFR part 704). Respondents may claim all or part of a notice confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14 and 40 CFR part 2.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 68.8 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal Agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

The ICR provides a detailed explanation of this estimate, which is only briefly summarized here:

Estimated total number of potential respondents: 4.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 1.

Estimated total annual burden hours: 275 hours.

Estimated total annual costs: $14,080. This includes an estimated burden cost of $14,080 and an estimated cost of $0 for capital investment or maintenance and operational costs.

IV. Are There Changes in the Estimates from the Last Approval?

There is no change in the total estimated respondent burden compared with that identified in the last ICR approved by OMB.

V. What is the Next Step in the Process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR

1320.12. EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

List of Subjects

Environmental protection, Reporting and recordkeeping requirements.

Dated: January 3, 2007.

James B. Gulliford,

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

[FR Doc. E7–341 Filed 1–11–07; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OA–2005–0004; FRL–8268–3]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Focus Groups as Used by EPA for Economics Projects; EPA ICR No. 2205.01

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA)(44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request for a new collection. The ICR, which is abstracted below, describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before February 12, 2007.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OA–2005–0004, to (1) EPA online using *www.regulations.gov* (our preferred method), by e-mail *oei.docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Office of Environmental Information, Mail Code 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Nathalie Simon, Office of Policy, Economics and Innovation, Mail Code 1809T, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: 202–566–2347; fax 202–566–2363; e-mail address: *simon.nathalie@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On November 4, 2005 (70 FR 67163), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received one comment during the comment period, which is addressed in the ICR. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–OA–2005–0004, which is available for online viewing at *www.regulations.gov,* or in person viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is 202–566–1744, and the telephone number for the Office of Environmental Information (OEI) Docket is 202–566–1752.

Use EPA's electronic docket and comment system at *www.regulations.gov,* to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *www.regulations.gov* as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *www.regulations.gov.*

Title: Focus Groups as Used by EPA for Economics Projects

ICR numbers: EPA ICR No. 2205.01

ICR Status: This ICR is for a new information collection activity. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: The Environmental Protection Agency (EPA) is seeking approval for a generic information collection request (ICR) for the conduct of focus groups and protocol interviews (hereafter jointly referred to as focus groups) related to economics projects. Over the next three years, the Agency anticipates embarking on a number of survey development efforts associated with a variety of economics projects including those related to valuation of ecosystems, children's health risks, improvements to coastal waters, and invasive species to name a few. Focus groups are an important part of any survey development process, allowing for researchers to directly gauge what specific issues are important to the public and providing a means for explicitly testing draft survey materials. Through these focus groups, the Agency will be able to gain a more in-depth understanding of the public's attitudes, beliefs, motivations and feelings regarding specific issues and will provide valuable information regarding the quality of draft survey instruments.

The information collected in the focus groups will be used to develop and improve economics-related surveys. To the extent that these surveys are ultimately successfully administered, they will serve to expand the Agencies understanding of benefits and costs of a variety of actions and could provide the means to quantitatively assess the effects of others. Participation in the focus groups will be voluntary and the identity of the participants will be kept confidential.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average about 2.5 hours per response (and 1,510 hours per year). Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and

maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Individuals or Households.

Estimated Number of Respondents: 626 per year.

Frequency of Response: one-time.

Estimated Total Annual Hour Burden: 1,510.

Estimated Total Annual Cost: $2,363,493, includes $0 annualized capital or O&M costs.

Dated: January 4, 2007.

Richard T. Westlund,

Acting Director, Collection Strategies Division.

[FR Doc. E7–357 Filed 1–11–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6683–1]

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 7, 2006 (71 FR 17845).

Draft EISs

EIS No. 20060292, ERP No. D–SFW–K99035–CA, Orange County Southern Subregion Habitat Conservation Plan (HCP), Implementation, Application for and Incidental Take Permit, Orange County, CA.

Summary: EPA expressed environmental concerns about air quality impacts and water-related issues.

Rating EC2.

EIS No. 20060423, ERP No. D–MMS–L02033–AK, Chukchi Sea Planning Area Oil and Gas Lease Sale 193 and Seismic Surveying Activities, Offshore Marine Environment, Chukchi Sea Coastal Plain, and the North Slope Borough of Alaska.

Summary: EPA expressed concerns about environmental justice issues due to adverse effects from multiple, overlapping and fast-tracked development planning processes on local residents and tribes, and requested additional information on human health impacts due to increased oil and gas development. EPA also requested further evaluation of oil spill risk to biological and subsistence resources.

Rating EC2.

EIS No. 20060444, ERP No. D–COE–K36055–CA, San Luis Rey Flood Control Project, Operation and Maintenance of the Vegetation and Sediment Management, from College Blvd to the Pacific Ocean, San Diego County, CA.

Summary: EPA expressed environmental concerns about the potential impacts to waters of the U.S., including wetlands and riparian habitat. EPA recommended evaluation of alternatives that do not propose fill in waters of the U.S., and requested additional analysis to demonstrate compliance with the Clean Water Act Section 404(b)(1) Guidelines.

Rating EC2.

EIS No. 20060480, ERP No. D–BIA–C60006–NY, Oneida Nation of New York Conveyance of Lands into Trust, Proposes to Transfer 17,370 Acre of Fee Land into Federal Trust Status, Oneida, Madison and New York Counties, NY.

Summary: EPA expressed environmental concerns about potential impacts in alternative B associated with the phased acquisition of an additional 17,630 acres.

Rating EC2.

Final EISs

EIS No. 20060482, ERP No. F–FRC–L05234–WA, Priest Rapids Hydroelectric Project, FERC Project #2114–116 Relicensing Application for New License, Columbia River, Grant, Yakima, Kittitas, Douglas, Benton, and Chelan Counties, WA.

Summary: EPA continues to have concerns about the proposed project's potential impacts to water quality due to total dissolved gas and temperature exceedances, and recommended that accountability measures be incorporated into the Clean Water Act Section 401 certification requirements and monitoring plan.

EIS No. 20060485, ERP No. F–NOA–A91072–00, PROGRAMMATIC—Codified Regulations at 50 CFR 300 Subparts A and G Implementing Conservation and Management Measures Adopted by the Commission for the Conservation of Antarctic Marine Living Resources.

Summary: EPA does not object to the proposed action as described in the FEIS.

EIS No. 20060492, ERP No. F–BIA–L61230–OR, Coyote Business Park, Confederated Tribes of the Umatilla Indian Reservation, Proposes to Develop, Build and Manage a Light Industrial Commercial Business Park, Umatilla County, OR.

Summary: EPA's previous concerns have been addressed; therefore, EPA does not object to the proposed action.

Dated: January 9, 2007.

Robert W. Hargrove,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. E7–345 Filed 1–11–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6682–9]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7167 or *http://www.epa.gov/compliance/nepa/.*

Weekly receipt of Environmental Impact Statements Filed 1/1/2007 through 1/5/2007 pursuant to 40 CFR 1506.9.

EIS No. 20070000, Final EIS, AFS, ID, Clearwater National Forest, Proposes to Approve Plans-of-Operation for Small-Scale Suction Dredging in Lolo Creek and Moose Creek, Clearwater National Forest, North Fork Ranger District, Clearwater and Idaho Counties, ID, Wait Period Ends: 2/12/2007, Contact: Vern Bretz, 208–476–8322.

EIS No. 20070001, Draft EIS, AFS, CA, Turntable Bay Marina Master Development Plan, To Build and Operate a Resort Marina, Special-Use-Permit, Shasta-Trinity National Forest, Shasta Lake at Turntable Bay, Shasta and Trinity Counties, CA, Comment Period Ends: 2/26/2007, Contact: R. Phipps, 530–226–2421.

EIS No. 20070002, Final EIS, FHW, MN, I–94/TH–10 Interregional Connection from St. Cloud to Becker Transportation Improvements, Funding and U.S. Army COE Section 404 Permit, Sherurne, Stearns, and Wright Counties, MN, Wait Period Ends: 2/12/2007, Contact: Cheryl Martin, 651–291–6120.

EIS No. 20070003, Draft EIS, AFS, AK, Tongass Land and Resource Management Plan, Plan Amendment, Implementation, Tongass National Forest, AK, Comment Period Ends: 4/10/2007, Contact: Lee Kramer, 907–586–8811, Ext 225.

EIS No. 20070004, Final EIS, NOA, AK, Alaska Groundfish Harvest Specifications Project, Establish Harvest Strategy for the Bering Sea and Aleutian Islands (BSAI) and Gulf of Alaska (GOA) Groundfish Fisheries, AK, Wait Period Ends: 2/12/2007, Contact: Ben Muse, 907–586–7234.

EIS No. 20070005, Final EIS, IBR, AZ, Welton-Mohawk Title Transfer Project, Transfer of the Facilities, Works, and Lands of the Welton Mohawk Division of the Gila Project, Welton-Mohawk Irrigation and Drainage District, Yuma County, AZ, Wait Period Ends: 2/12/2007, Contact: Renee Kolvet, 702–293–8443.

EIS No. 20070006, Draft Supplement, DOE, PA, Gilberton Coal-to-Clean Fuels and Power Project, Construction and Operation a New Demonstration Plant, Updated Information to Correct Information regarding Carbon Dioxide (CO_2) Emissions, Schuylkill County, PA, Comment Period Ends: 2/27/2007. Contact: Janice L. Bell, 1–866–576–8240.

Amended Notices

EIS No. 20060406, Draft EIS, BLM, AK, Bay Resource Management Plan, Implementation, Located within the Bristol Bay and Goodnews Bay Areas, AK, Comment Period Ends: 2/5/2007. Contact: Mark Fullmer, 907–267–1246.

Revision of FR Notice Published 10/13/2006: Extending Comment Period from 1/11/2007 to 2/5/2007.

Dated: January 9, 2007.

Robert W. Hargrove,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. E7–347 Filed 1–11–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2006–0913; FRL–8105–3]

Notice of Filing of a Pesticide Petition for a Time-Extension of the Exemption from the Requirement of a Tolerance for Residues of Bacillus thuringiensis VIP3A913 Protein and the Genetic Material Necessary for Its Production on Cotton Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the 3 year extension until May 1, 2010, of the current exemption from the requirement of a tolerance for the biopesticide, Bacillus thuringiensis VIP3A913 protein and the genetic material necessary for its production, in or on the commodity cotton.

DATES: Comments must be received on or before February 12, 2007.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2006–0913 and pesticide petition number (PP) 3G6547, by one of the following methods:

• Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The telephone number for the Docket Facility is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2006–0913. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The Federal regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Leonard Cole, Biopesticides and Pollution Prevention Division, (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5412; e-mail: *cole.leonard@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

• Crop production (NAICS code 111).

• Animal production (NAICS code 112).
• Food manufacturing (NAICS code 311).
• Pesticide manufacturing (NAICS code 32532).

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes 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 docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. What Action is the Agency Taking?

EPA is printing a summary of each pesticide petition received under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, proposing the establishment or amendment of regulations in 40 CFR part 180 for residues of pesticide chemicals in or on various food commodities. EPA has determined that this pesticide petition contains data or information regarding the elements set forth in FFDCA 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 pesticide petition. Additional data may be needed before EPA rules on this pesticide petition.

Pursuant to 40 CFR 180.7(f), a summary of the petition included in this notice, prepared by the petitioner along with a description of the analytical method available for the detection and measurement of the pesticide chemical residues is available on EPA's Electronic Docket at *http://www.regulations.gov*. To locate this information on the home page of EPA's Electronic Docket, select ''Quick Search'' and type the OPP docket ID number. Once the search has located the docket, clicking on the ''Docket ID'' will bring up a list of all documents in the docket for the pesticide including the petition summary.

Exemption from Tolerance

(PP) *3G6547.* Syngenta Seeds, Inc., 3054 Cornwallis Road, Research Triangle Park, NC 27709-2257, proposes a time-extension for 3 years until May 1, 2010, for the current exemption from the requirement of a tolerance for residues of the biopesticide, Bacillus thuringiensis VIP3A913 protein and the genetic material necessary for its production, in or on the commodity cotton. Because this petition is a request for an exemption from the requirement of a tolerance without numerical limitations, no analytical method is required.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 21, 2006.

Janet L. Andersen

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. E7–253 Filed 1–11–07; 8:45 am]

BILLING CODE 6560–50–S

FARM CREDIT SYSTEM INSURANCE CORPORATION

Adjusting Civil Money Penalties for Inflation

AGENCY: Farm Credit System Insurance Corporation.

ACTION: Notice.

SUMMARY: This notice assesses the need for cost-of-living adjustments to the civil money penalties (CMPs) that the Farm Credit System Insurance Corporation (FCSIC) may impose under the Farm Credit Act of 1971, as amended. The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, requires all Federal agencies with statutory authority to impose CMPs, to regularly evaluate those CMPs and to adjust them periodically for inflation, so they continue to maintain their deterrent value. Consequently, FCSIC is issuing this notice concerning any required adjustments to the CMPs.

FOR FURTHER INFORMATION CONTACT: Alan Glenn, Director of Risk Management, Farm Credit System Insurance Corporation, McLean, VA 22102, (703) 883–4384, TTY (703) 883–4390; or Jane M. Virga, Senior Counsel, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TTY (703) 883–4020.

SUPPLEMENTARY INFORMATION:

Background

A. Statutes Concerning Inflation Adjustment of Civil Money Penalties

The Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIA Act),[1] as amended by the Debt Collection Improvement Act of 1996 (DCIA),[2] provides for the regular evaluation of CMPs and requires FCSIC, and every Federal agency with authority to impose CMPs,[3] to ensure that CMPs continue to

[1] Pub. L. 101–410, 104 Stat. 890 (October 5, 1990), codified at 28 U.S.C. 2461 note.

[2] Pub. L. 104–134, title III, section 31001(s), 110 Stat. 1321–373 (April 26, 1996), codified at 28 U.S.C. 2461 note.

[3] Under the amended FCPIA Act, a CMP is defined as any penalty, fine, or other sanction that: (1) Either is for a specific monetary amount as provided by Federal law or has a maximum amount

maintain their deterrent values. An agency must enact regulations that adjust its CMPs pursuant to the inflation adjustment formula of the FCPIA Act. The amended FCPIA Act specifies that inflation-adjusted CMPs will apply only to violations that occur after the effective date of the adjustment.

The inflation adjustment is based on the percentage increase in the Consumer Price Index (CPI) for all consumers (CPI–U).[4] Specifically, the term cost-of-living adjustment is defined as the percentage (if any) for each civil monetary penalty by which the Consumer Price Index for the month of June of the calendar year preceding the adjustment, exceeds the Consumer Price Index for the month of June of the calendar year in which the amount of such civil monetary penalty was last set or adjusted pursuant to law. Furthermore, any increase to a CMP that is adjusted for inflation must be rounded using a method prescribed by the FCPIA Act. Agencies do not have discretion in choosing whether to adjust a CMP, by how much to adjust a CMP, or the methods used to determine the adjustment.

B. CMPs Imposed Pursuant to Section 5.65 of the Farm Credit Act

First, section 5.65(c) of the Farm Credit Act, as amended (Act) provides that any insured Farm Credit System bank that willfully fails or refuses to file any certified statement or pay any premium required under this part shall be subject to a penalty of not more than $100 for each day that such violations continue, which penalty the Corporation may recover for its use. 12 U.S.C. 2277a-14(c). Second, section 5.65(d) of the Act provides that, except with the prior written consent of the Farm Credit Administration, it shall be unlawful for any person convicted of any criminal offense involving dishonesty or a breach of trust to serve as a director, officer, or employee of any System institution. 12 U.S.C. 2277a-14(d). For each willful violation of section 5.65(d), the institution involved shall be subject to a penalty of not more than $100 for each day during which the violation continues, which the Corporation may recover for its use.

As adjusted for inflation pursuant to the requirements of the DCIA, the current regulation at 12 CFR 1411.1, which was promulgated in 2001, provides that FCSIC can impose a maximum penalty of $117 per day for a violation under section 5.65(c) and (d) of the Act.

1. Mathematical Calculation

The adjustment calculation will be based on the percentage by which the CPI for June 2006 exceeds the CPI for June 2001.

According to the Bureau of Labor Statistics, the CPI for June 2001 was 178, and the CPI for June 2006 was 202.9, resulting in a percentage change of 14.0 percent.

2. Penalty Amounts Remain the Same in § 1411.1

The maximum CMP in 12 CFR 1411.1 for a violation of section 5.65(c) or (d) of the Act is currently $117. Multiplying $117 by 14 percent results in $16.38. When that number is rounded as required by the FCPIA Act,[5] the inflation-adjusted maximum remains the same.

Dated: January 9, 2007.

Roland Smith,

Secretary, Farm Credit System Insurance Corporation Board.

[FR Doc. E7–359 Filed 1–11–07; 8:45 am]

BILLING CODE 6710–01–P

provided for by Federal law; (2) is assessed or enforced by an agency pursuant to Federal law; and (3) is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts. All three requirements must be met for a fine to be defined as a CMP.

[4] The CPI is published by the Department of Labor, Bureau of Labor Statistics, and is available at its Web site: *ftp://ftp.bls.gov/pub/special.requests/cpi/cpiai.txt.*

[5] Any increase must be rounded to the nearest multiple of $100 in the case of penalties greater than $100 but less than or equal to $1,000. Therefore, $16.38 is rounded to the nearest multiple of $100, which is $0.

FEDERAL HOUSING FINANCE BOARD

[No. 2007–N–02]

Notice of Annual Adjustment of the Cap on Average Total Assets That Defines Community Financial Institutions; Notice of Annual Adjustment of the Limits on Annual Compensation for Federal Home Loan Bank Directors

AGENCY: Federal Housing Finance Board.

ACTION: Notice.

SUMMARY: The Federal Housing Finance Board (Finance Board) has adjusted the cap on average total assets that defines a ''Community Financial Institution'' and the limits on annual compensation for Federal Home Loan Bank (Bank) directors based on the annual percentage increase in the Consumer Price Index for all urban consumers (CPI–U) as published by the Department of Labor (DOL). These changes took effect on January 1, 2007.

FOR FURTHER INFORMATION CONTACT: Patricia L. Sweeney, Office of Supervision, by telephone at 202–408–2872, by electronic mail at *sweeneyp@fhfb.gov,* or by regular mail at the Federal Housing Finance Board, 1625 Eye Street, NW., Washington DC 20006–4001.

SUPPLEMENTARY INFORMATION:

A. Statutory and Regulatory Background

Section 2(13) of the Federal Home Loan Bank Act (Bank Act) and § 925.1 of the Finance Board regulations define a member that is a ''Community Financial Institution'' (CFI) by the member's total asset size. See 12 U.S.C. 1422(13)(A) and 12 CFR 925.1. The Bank Act requires the Finance Board annually to adjust the CFI asset cap to reflect any percentage increase in the preceding year's CPI–U as published by the DOL. See 12 U.S.C. 1422(13)(B).

Section 7(i)(2)(B) of the Bank Act and § 918.3(a)(1) of the Finance Board regulations require the Finance Board to make similar annual adjustments to the annual compensation limits for members of the boards of directors of the Banks. See 12 U.S.C. 1427(i)(2) and 12 CFR 918.3(a).

Effective January 1, 2007, the CPI adjustment provisions in the Affordable Housing Program (AHP) regulation were removed. See 71 FR 59262 (Oct. 6, 2006) (12 CFR 951.3(a)(1)(iii) and 951.3(a)(2) (removed)). The revised provisions of the AHP regulation are located at 12 CFR 951.2(b)(2)(i) and (b)(3). As a result, this notice does not include any CPI adjustments under the AHP regulation.

B. Calculating the Annual Adjustments

The annual adjustments to the CFI asset cap and Bank director compensation limits reflect the percentage by which the CPI–U published for November of the preceding calendar year exceeds the CPI–U published for November of the year before the preceding calendar year (if at all). Thus, the adjustments that took effect on January 1, 2007, were based on the percentage increase in the CPI–U from November 2005 to November 2006. The Finance Board uses November data to provide notice of the changes to the annual limits before the January 1st effective date. This practice is consistent with that of other federal agencies.

The DOL encourages use of CPI–U data that has not been seasonally adjusted in ''escalation agreements'' because seasonal factors are updated annually and seasonally adjusted data are subject to revision for up to 5 years following the original release.

Unadjusted data are not routinely subject to revision, and previously published unadjusted data are only corrected when significant calculation errors are discovered. Accordingly, the Finance Board is using data that has not been seasonally adjusted.

The unadjusted CPI–U increased 2 percent between November 2005 and November 2006. Based on this change, the Finance Board made the following adjustments, which took effect on January 1, 2007:

CFI Asset Cap: The CFI Asset Cap, which was $587 million for 2006, is $599 million in 2007. The Finance Board arrived at the adjusted limit of $599 million by rounding to the nearest million.

Annual Compensation Limits: The annual compensation limits for members of the Bank boards of directors is as follows in 2007: for a Chairperson—$29,944; for a Vice-Chairperson—$23,955; for any other member of a Bank's board of directors—$17,967. The Finance Board arrived at the adjusted annual compensation limits by rounding to the nearest dollar.

Date: January 9, 2007.

By the Federal Housing Finance Board.

Ronald A. Rosenfeld,

Chairman.

[FR Doc. E7–369 Filed 1–11–07; 8:45 am]

BILLING CODE 6725–01–P

FEDERAL HOUSING FINANCE BOARD

[No. 2007–N–01]

Federal Home Loan Bank Members Selected for Community Support Review

AGENCY: Federal Housing Finance Board.

ACTION: Notice.

SUMMARY: The Federal Housing Finance Board (Finance Board) is announcing the Federal Home Loan Bank (Bank) members it has selected for the 2006–07 fourth quarter review cycle under the Finance Board's community support requirements regulation. This notice also prescribes the deadline by which Bank members selected for review must submit Community Support Statements to the Finance Board.

DATES: Bank members selected for this review cycle must submit completed Community Support Statements to the Finance Board on or before February 26, 2007.

ADDRESSES: Submit completed Community Support Statements to the Finance Board either by regular mail at the Federal Housing Finance Board, Office of Supervision, Community Investment and Affordable Housing, 1625 Eye Street NW., Washington, DC 20006, or by electronic mail at *FITZGERALDE@FHFB.GOV*.

FOR FURTHER INFORMATION CONTACT: Emma J. Fitzgerald, Program Analyst, Office of Supervision, Community Investment and Affordable Housing, by telephone at 202–408–2874, by electronic mail at *FITZGERALDE@FHFB.GOV*, or by regular mail at the Federal Housing Finance Board, 1625 Eye Street NW., Washington, DC 20006.

SUPPLEMENTARY INFORMATION:

I. Selection for Community Support Review

Section 10(g)(1) of the Federal Home Loan Bank Act (Bank Act) requires the Finance Board to promulgate regulations establishing standards of community investment or service Bank members must meet in order to maintain access to long-term advances. *See* 12 U.S.C. 1430(g)(1). The regulations promulgated by the Finance Board must take into account factors such as the Bank member's performance under the Community Reinvestment Act of 1977 (CRA), 12 U.S.C. 2901 *et seq.*, and record of lending to first-time homebuyers. *See* 12 U.S.C. 1430(g)(2). Pursuant to section 10(g) of the Bank Act, the Finance Board has promulgated a community support requirements regulation that establishes standards a Bank member must meet in order to maintain access to long-term advances, and review criteria the Finance Board must apply in evaluating a member's community support performance. *See* 12 CFR part 944. The regulation includes standards and criteria for the 2 statutory factors—CRA performance and record of lending to first-time homebuyers. 12 CFR 944.3. Only members subject to the CRA must meet the CRA standard. 12 CFR 944.3(b). All members, including those not subject to CRA, must meet the first-time homebuyer standard. 12 CFR 944.3(c).

Under the rule, the Finance Board selects approximately one-eighth of the members in each Bank district for community support review each calendar quarter. 12 CFR 944.2(a). The Finance Board will not review an institution's community support performance until it has been a Bank member for at least 1 year. Selection for review is not, nor should it be construed as, any indication of either the financial condition or the community support performance of the member.

Each Bank member selected for review must complete a Community Support Statement and submit it to the Finance Board by the February 26, 2007 deadline prescribed in this notice. 12 CFR 944.2(b)(1)(ii) and (c). On or before January 26, 2007, each Bank will notify the members in its district that have been selected for this review cycle that they must complete and submit a Community Support Statement to the Finance Board by the deadline. 12 CFR 944.2(b)(2)(i). The member's Bank will provide a blank Community Support Statement Form, which also is available on the Finance Board's Web site: *www.fhfb.gov*. Upon request, the member's Bank also will provide assistance in completing the Community Support Statement.

The Finance Board has selected the following members for the 2006–07 fourth quarter community support review cycle:

Federal Home Loan Bank of Boston—District 1

Union Savings Bank	Danbury	Connecticut
Jewett City Savings Bank	Jewett City	Connecticut
The First National Bank of Litchfield	Litchfield	Connecticut
Naugatuck Valley Savings and Loan	Naugatuck	Connecticut
New Alliance Bank	New Haven	Connecticut
Newtown Savings Bank	Newtown	Connecticut
Fairfield County Bank-Corp	Ridgefield	Connecticut
Patriot National Bank	Stamford	Connecticut
First County Bank	Stamford	Connecticut
Dutch Point Credit Union, Inc	Wethersfield	Connecticut
Windsor Locks Federal Credit Union	Windsor Locks	Connecticut
Northeast Bank	Auburn	Maine
Bangor Federal Credit Union	Bangor	Maine

Bangor Savings Bank	Bangor	Maine
Bar Harbor Savings & Loan Association	Bar Harbor	Maine
First Citizens Bank	Presque Isle	Maine
York County Federal Credit Union	Sanford	Maine
North Abington Co-operative Bank	Abington	Massachusetts
South Adams Savings Bank	Adams	Massachusetts
Athol Credit Union	Athol	Massachusetts
Barre Savings Bank	Barre	Massachusetts
Crescent Credit Union	Brockton	Massachusetts
Brookline Bank	Brookline	Massachusetts
North Cambridge Co-operative Bank	Cambridge	Massachusetts
Cambridge Trust Company	Cambridge	Massachusetts
Canton Co-Operative Bank	Canton	Massachusetts
Dedham Institution for Savings	Dedham	Massachusetts
Meetinghouse Cooperative Bank	Dorchester	Massachusetts
The Edgartown National Bank	Edgartown	Massachusetts
Fidelity Co-Operative	Fitchburg	Massachusetts
Fitchburg Savings Bank, FSB	Fitchburg	Massachusetts
Greenfield Co-operative Bank	Greenfield	Massachusetts
Haverhill Bank	Haverhill	Massachusetts
Ipswich Co-operative Bank	Ipswich	Massachusetts
Leominster Credit Union	Leominster	Massachusetts
The Lowell Co-operative Bank	Lowell	Massachusetts
Marlborough Savings Bank	Marlborough	Massachusetts
The Milford National Bank & Trust Company	Milford	Massachusetts
Natick Federal Savings Bank	Natick	Massachusetts
Institution for Savings in Newburyport & its Vicinity	Newburyport	Massachusetts
River Bank North	Andover	Massachusetts
South Coastal Bank	Rockland	Massachusetts
Rockland Federal Credit Union	Rockland	Massachusetts
The Cooperative Bank	Roslindale	Massachusetts
Salem Five Cents Savings Bank	Salem	Massachusetts
Taupa Lithuanian Federal Credit Union	South Boston	Massachusetts
Southbridge Credit Union	Southbridge	Massachusetts
Stoneham Savings Bank	Stoneham	Massachusetts
Country Bank for Savings	Ware	Massachusetts
Wellesley Co-operative Bank	Wellesley	Massachusetts
South Shore Co-operative Bank	Weymouth	Massachusetts
Winchester Co-Operative Bank	Winchester	Massachusetts
Bay State Savings Bank	Worcester	Massachusetts
Cape Cod Co-Operative Bank	Yarmouth Port	Massachusetts
Centrix Bank & Trust	Bedford	New Hampshire
Northway Bank	Berlin	New Hampshire
Lancaster National Bank	Lancaster	New Hampshire
Profile Bank	Rochester	New Hampshire
Holy Rosary Regional Credit Union	Rochester	New Hampshire
Bank of Newport	Newport	Rhode Island
Citizens Bank of Rhode Island	Providence	Rhode Island
Greenwood Credit Union	Warwick	Rhode Island
The Brattleboro Savings & Loan Association FA	Brattleboro	Vermont
LyndonBank	Lyndonville	Vermont
First Community Bank	Woodstock	Vermont

Federal Home Loan Bank of New York—District 2

Cape Savings Bank	Cape May Court House	New Jersey
United Roosevelt Savings Bank	Carteret	New Jersey
Commerce Bank, N.A.	Cherry Hill	New Jersey
Unity Bank	Clinton	New Jersey
1st Constitution Bank	Cranbury	New Jersey
Delanco Federal Savings Bank	Delanco	New Jersey
Pinnacle Federal Credit Union	Edison	New Jersey
Columbia Bank	Fair Lawn	New Jersey
Haven Savings Bank	Hoboken	New Jersey
Manasquan Savings Bank	Manasquan	New Jersey
Susquehanna Patriot Bank	Marlton	New Jersey
1st Bank of Sea Isle City	Sea Isle City	New Jersey
Somerset Valley Bank	Somerville	New Jersey
Union Center National Bank	Union	New Jersey
Wawel Savings Bank	Wallington	New Jersey
Crest Savings Bank	Wildwood	New Jersey
The Bridgehampton National Bank	Bridgehampton	New York
Atlas Savings and Loan Association	Brooklyn	New York
Visions Federal Credit Union	Endicott	New York
Bank of Smithtown	Hauppauga	New York
Tompkins Trust Company	Ithaca	New York

The First National Bank of Jeffersonville	Jeffersonville	New York
The National Union Bank of Kinderhook	Kinderhook	New York
Mid-Hudson Valley Federal Credit Union	Kingston	New York
Medina Savings and Loan Association	Medina	New York
Emigrant Savings Bank	New York	New York
Israel Discount Bank of New York	New York	New York
NBT Bank, N.A	Norwich	New York
First Tier Bank & Trust	Olean	New York
The Oneida Savings Bank	Oneida	New York
Wilber National Bank	Oneonta	New York
Suffolk County National Bank	Riverhead	New York
Saratoga National Bank & Trust Company	Saratoga Springs	New York
Sawyer Savings Bank	Saugerties	New York
Tioga State Bank	Spencer	New York
Adirondack Bank	Utica	New York
Walden Federal Savings and Loan Association	Walden	New York
Fourth Federal Savings Bank	White Plains	New York
First Central Savings Bank	Whitestone	New York
City and Suburban Federal Savings Bank	Yonkers	New York
Banco Bilbao Vizcaya Argentaria Puerto Rico	Hato Rey	Puerto Rico
Westernbank Puerto Rico	Mayaguez	Puerto Rico

Federal Home Loan Bank of Pittsburgh—District 3

Christiana Bank & Trust Company	Greenville	Delaware
ING Bank, fsb	Wilmington	Delaware
The First National Bank of Wyoming	Wyoming	Delaware
Commerce Bank/Pennsylvania, N.A	Cherry Hill	New Jersey
American Bank	Allentown	Pennsylvania
Iron Workers Bank	Aston	Pennsylvania
Brentwood Bank	Bethel Park	Pennsylvania
National Penn Bank	Boyertown	Pennsylvania
Union Building & Loan Savings Bank	Bridgewater	Pennsylvania
Community Bank & Trust Co	Clarks Summit	Pennsylvania
Clearfield Bank & Trust Company	Clearfield	Pennsylvania
Vartan National Bank	Harrisburg	Pennsylvania
The Dime Bank	Honesdale	Pennsylvania
Indiana First Bank	Indiana	Pennsylvania
Jim Thorpe National Bank	Jim Thorpe	Pennsylvania
Manor National Bank	Manor	Pennsylvania
Province Bank FSB	Marietta	Pennsylvania
The First National Bank of Marysville	Marysville	Pennsylvania
Standard Bank, PaSB	Monroeville	Pennsylvania
SB1 Federal Credit Union	Philadelphia	Pennsylvania
American Heritage Federal Credit Union	Philadelphia	Pennsylvania
The Philadelphia Trust Company	Philadelphia	Pennsylvania
New Century Bank	Phoenixville	Pennsylvania
Allegheny Valley Bank	Pittsburgh	Pennsylvania
PNC Bank, National Association	Pittsburgh	Pennsylvania
GUARD Security Bank	Plains	Pennsylvania
Somerset Trust Company	Somerset	Pennsylvania
Univest National Bank and Trust Company	Souderton	Pennsylvania
Omega Bank N/A	State College	Pennsylvania
Compass Federal Savings Bank	Wilmerding	Pennsylvania
Sovereign Bank FSB	Wyomissing	Pennsylvania
Hancock County Savings Bank FSB	Chester	West Virginia
Citizens National Bank	Elkins	West Virginia
The Monongahela Valley Bank, Inc	Fairmont	West Virginia
Fayette County National Bank	Fayetteville	West Virginia
Rock Branch Community Bank	Nitro	West Virginia
The Bank of Romney	Romney	West Virginia
Traders Bank	Spencer	West Virginia
Progressive Bank, N.A	Wheeling	West Virginia

Federal Home Loan Bank of Atlanta—District 4

First Educators Credit Union	Birmingham	Alabama
America's First Federal Credit Union	Birmingham	Alabama
First Bank of Boaz	Boaz	Alabama
Town-Country National Bank	Camden	Alabama
Coosa Pines Federal Credit Union	Childersburg	Alabama
Escambia County Bank	Flomaton	Alabama
First Gulf Bank, N.A	Foley	Alabama
First Federal Bank	Fort Payne	Alabama
Traders & Farmers Bank	Haleyville	Alabama
City Bank of Hartford	Hartford	Alabama

First National Bank of Jasper	Jasper	Alabama
Pinnacle Bank	Jasper	Alabama
Marion Bank and Trust Company	Marion	Alabama
Bank of Pine Hill	Pine Hill	Alabama
Alabama Credit Union	Tuscaloosa	Alabama
First Federal Bank, A Federal Savings Bank	Tuscaloosa	Alabama
Alabama Exchange Bank	Tuskegee	Alabama
AmeriFirst Bank	Union Springs	Alabama
Small Town Bank	Wedowee	Alabama
Bank of York	York	Alabama
Independence Federal Savings Bank	Washington	D.C.
Department of Veterans Affairs FCU	Washington	D.C.
Community National Bank of Bartow	Bartow	Florida
First Southern Bank	Boca Raton	Florida
Platinum Bank	Brandon	Florida
R–G Crown Bank	Casselberry	Florida
First National Bank of Nassau County	Fernandian Beach	Florida
Harbor Federal Savings Bank	Fort Pierce	Florida
Citizens Bank & Trust	Frostproof	Florida
Homosassa Springs Bank	Homosassa Springs	Florida
Columbia Bank	Lake City	Florida
Metro Bank of Dade County	Miami	Florida
City National Bank of Florida	Miami	Florida
Pacific National Bank	Miami	Florida
Northern Trust, N.A	Miami	Florida
Interamerican Bank, a Federal Savings Bank	Miami	Florida
Intercredit Bank, N.A	Miami	Florida
Farmers and Merchants Bank	Monticello	Florida
The First National Bank of Mount Dora	Mount Dora	Florida
First Commercial Bank of Florida	Orlando	Florida
Fairwinds Credit Union	Orlando	Florida
GulfStream Community Bank	Port Richey	Florida
First Peoples Bank	Port St. Lucie	Florida
Community Educators' Credit Union of Brevard	Rockledge	Florida
Public Bank	St. Cloud	Florida
Cornerstone Community Bank	St. Petersburg	Florida
First Community Bank of America	St. Petersburg	Florida
Valrico State Bank	Valrico	Florida
Grand Bank & Trust of Florida	West Palm Beach	Florida
Fidelity Federal Bank & Trust	West Palm Beach	Florida
The Perkins State Bank	Williston	Florida
Albany Bank and Trust	Albany	Georgia
North Atlanta National Bank	Alpharetta	Georgia
Bank of North Georgia	Alpharetta	Georgia
ebank	Atlanta	Georgia
United Americas Bank, N.A	Atlanta	Georgia
SunTrust Bank	Atlanta	Georgia
First Port City Bank	Bainbridge	Georgia
Peoples State Bank and Trust	Baxley	Georgia
Bank of Early	Blakely	Georgia
The Coastal Bank of Georgia	Brunswick	Georgia
West Georgia National Bank	Carrollton	Georgia
Unity National Bank	Cartersville	Georgia
Tippins Bank and Trust Company	Claxton	Georgia
The Citizens Bank of Forsyth County	Cumming	Georgia
First Bank of Dalton	Dalton	Georgia
Alliance National Bank	Dalton	Georgia
Decatur First Bank	Decatur	Georgia
The Peachtree Bank	Duluth	Georgia
The Bank of Edison	Edison	Georgia
Talbot State Bank	Fayetteville	Georgia
Community Banking Company of Fitzgerald	Fitzgerald	Georgia
Colony Bank of Fitzgerald	Fitzgerald	Georgia
Farmers State Bank	Lumpkin	Georgia
Southern National Bank	Marietta	Georgia
The Security State Bank	McRae	Georgia
First Bank of Coastal Georgia	Pembroke	Georgia
First Peoples Bank	Pine Mountain	Georgia
Colony Bank Quitman, FSB	Quitman	Georgia
Citizens Bank of Washington County	Sandersville	Georgia
Bank of Hancock County	Sparta	Georgia
Thomas County Federal S&L Association	Thomasville	Georgia
Stephens Federal Bank	Toccoa	Georgia
Bank of Dade	Trenton	Georgia
Commercial Banking Company	Valdosta	Georgia
Altamaha Bank and Trust Company	Vidalia	Georgia

Darby Bank and Trust Company	Vidalia	Georgia
Vidalia Federal Savings Bank	Vidalia	Georgia
Bank of Dooly	Vienna	Georgia
The Peoples Bank	Willacoohee	Georgia
The Peoples Bank	Winder	Georgia
Harford Bank	Aberdeen	Maryland
Fairmount Federal Savings Bank	Baltimore	Maryland
Rosedale Federal Savings & Loan Association	Baltimore	Maryland
Arundel Federal Savings Bank	Baltimore	Maryland
Chesapeake Bank of Maryland	Baltimore	Maryland
Golden Prague Federal Savings and Loan Association	Baltimore	Maryland
Madison Square Federal Savings Bank	Baltimore	Maryland
Municipal Employees Credit Union of Baltimore	Baltimore	Maryland
Hopkins Federal Savings Bank	Baltimore	Maryland
Marriott Employees Federal Credit Union	Bethesda	Maryland
Chevy Chase Bank, F.S.B	Bethesda	Maryland
U.S. Postal Service Federal Credit Union	Clinton	Maryland
Suburban Federal Savings Bank	Crofton	Maryland
The Bank of Delmarva, N.A	Delmar	Maryland
The Patapsco Bank	Dundalk	Maryland
Farmers and Mechanics Bank	Frederick	Maryland
OBA Federal Savings Bank	Germantown	Maryland
Library of Congress Federal Credit Union	Hyattsville	Maryland
Senator Bank	Timonium	Maryland
Community Bank of Tri-County	Waldorf	Maryland
Woodsboro Bank	Woodsboro	Maryland
The Bank of Asheville	Asheville	North Carolina
Asheville Savings Bank	Asheville	North Carolina
Crescent State Bank	Cary	North Carolina
Charlotte Metro Credit Union	Charlotte	North Carolina
First Trust Bank	Charlotte	North Carolina
Cherryville Federal S&L Association	Cherryville	North Carolina
First Federal Bank	Dunn	North Carolina
Mutual Community Savings Bank, Inc. SSB	Durham	North Carolina
North Carolina Community Federal Credit	Goldsboro	North Carolina
First Federal Savings Bank	Lincolnton	North Carolina
Mooresville Savings Bank, SSB	Mooresville	North Carolina
Lumbee Guarantee Bank	Pembroke	North Carolina
Paragon Commercial Bank	Raleigh	North Carolina
North Carolina Local Government Employees	Raleigh	North Carolina
Roanoke Valley Savings Bank, SSB	Roanoke Rapids	North Carolina
Roxboro Savings Bank, SSB	Roxboro	North Carolina
First South Bank	Washington	North Carolina
WNC Community Credit Union	Waynesville	North Carolina
Truliant Federal Credit Union	Winston-Salem	North Carolina
Abbeville Savings and Loan Association	Abbeville	South Carolina
Sentry Bank and Trust	Cheraw	South Carolina
The Conway National Bank	Conway	South Carolina
Sharonview Federal Credit Union	Fort Mill	South Carolina
First Piedmont F&SL Association of Gaffney	Gaffney	South Carolina
S.C. Telco Federal Credit Union	Greenville	South Carolina
Citizens Building and Loan Association	Greer	South Carolina
Mutual Savings Bank	Hartsville	South Carolina
The Commercial Bank	Honea Path	South Carolina
Founders Federal Credit Union	Lancaster	South Carolina
First Community Bank, N.A	Lexington	South Carolina
Pee Dee Federal Savings Bank	Marion	South Carolina
Coastal Federal Bank	Myrtle Beach	South Carolina
South Carolina Federal Credit Union	North Charleston	South Carolina
First Savers Bank	Pawleys Island	South Carolina
Family Trust Federal Credit Union	Rock Hill	South Carolina
Seneca National Bank	Seneca	South Carolina
Oconee Federal Savings and Loan Association	Seneca	South Carolina
Community First Bank	Walhalla	South Carolina
First Federal of South Carolina, FSB	Walterboro	South Carolina
Bank of Walterboro	Walterboro	South Carolina
Citizens Bank and Trust Company	Blackstone	Virginia
First Community Bank, N.A	Bluefield	Virginia
Alliance Bank Corporation	Chantilly	Virginia
Monarch Bank	Chesapeake	Virginia
Acacia Federal Savings Bank	Falls Church	Virginia
Virginia Savings Bank, F.S.B	Front Royal	Virginia
Virginia Community Bank	Louisa	Virginia
First Federal Savings and Loan Association	Martinsville	Virginia
Cardinal Bank	McLean	Virginia
Capital One, F.S.B	McLean	Virginia

Community Bankers' Bank	Midlothian	Virginia
TowneBank	Portsmouth	Virginia
Millennium Bank, N.A	Reston	Virginia
Partners Financial Federal Credit Union	Richmond	Virginia
Shenandoah Life Insurance Company	Roanoke	Virginia
Franklin Security Bank, FSB	Virginia Beach	Virginia
Shenandoah Valley National Bank	Winchester	Virginia
Fort Belvoir Federal Credit Union	Woodbridge	Virginia

Federal Home Loan Bank of Cincinnati—District 5

Home FS&LA of Ashland	Ashland	Kentucky
Fort Campbell Federal Credit Union	Clarksville	Kentucky
Kentucky Federal Savings and Loan Association	Covington	Kentucky
Greensburg Deposit Bank and Trust Company	Greensburg	Kentucky
The Casey County Bank	Liberty	Kentucky
Independence Bank	Livermore	Kentucky
Laurel National Bank	London	Kentucky
Louisville Community Development Bank	Louisville	Kentucky
Home Savings Bank, fsb	Ludlow	Kentucky
First Guaranty Bank	Martin	Kentucky
Bank of Maysville	Maysville	Kentucky
Hart County Bank and Trust Company	Munfordville	Kentucky
The Farmers Bank	Nicholasville	Kentucky
First Security Bank of Owensboro, Inc	Owensboro	Kentucky
Owingsville Banking Company	Owingsville	Kentucky
Family Bank, FSB	Paintsville	Kentucky
Community Trust Bank, Inc	Pikeville	Kentucky
Madison Bank	Richmond	Kentucky
Cumberland Security Bank, Inc	Somerset	Kentucky
Citizens National Bank of Somerset	Somerset	Kentucky
Commercial Bank	West Liberty	Kentucky
The Antwerp Exchange Bank Company	Antwerp	Ohio
Hocking Valley Bank	Athens	Ohio
Rockhold, Brown & Company Bank	Bainbridge	Ohio
Citizens Federal Savings and Loan Association of Bellefontaine	Bellefontaine	Ohio
The Citizens Bank Company	Beverly	Ohio
Mercer Savings Bank	Celina	Ohio
The Cheviot Savings Bank	Cheviot	Ohio
Cincinnati Federal Savings and Loan Association	Cincinnati	Ohio
Kemba Credit Union, Inc	Cincinnati	Ohio
Cincinnati Police Federal Credit Union	Cincinnati	Ohio
The North Side Bank and Trust Company	Cincinnati	Ohio
National City Bank	Cleveland	Ohio
Ohio Savings Bank	Cleveland	Ohio
Commerce National Bank	Columbus	Ohio
The Home Loan Savings Bank	Coshocton	Ohio
The Covington Savings and Loan Association	Covington	Ohio
The Citizens Bank of DeGraff	De Graff	Ohio
Midwest Community FCU	Defiance	Ohio
First Place Bank	Elyria	Ohio
First National Bank of Germantown	Germantown	Ohio
Indian Village Community Bank	Gnadenhutten	Ohio
Chaco Credit Union, Inc	Hamilton	Ohio
The Hicksville Bank	Hicksville	Ohio
The Citizens Bank of Higginsport	Higginsport	Ohio
Salt Creek Valley Bank	Laurelville	Ohio
The Delaware County Bank & Trust Company	Lewis Center	Ohio
The Home Builders Association	Lynchburg	Ohio
The Bank of Magnolia Company	Magnolia	Ohio
The Citizens Savings Bank	Martins Ferry	Ohio
Peoples Building, Loan and Savings Company	Mason	Ohio
Western Reserve Bank	Medina	Ohio
Bramble Savings Bank	Milford	Ohio
The Commercial & Savings Bank of Millersburg	Millersburg	Ohio
The First National Bank of Nelsonville	Nelsonville	Ohio
Peoples National Bank	New Lexington	Ohio
The First National Bank of Pandora	Pandora	Ohio
Century Bank	Parma	Ohio
Farmers Bank and Savings Company	Pomeroy	Ohio
The St. Henry Bank	St. Henry	Ohio
The Arlington Bank	Upper Arlington	Ohio
The Commercial Savings Bank	Upper Sandusky	Ohio
The First Citizens NB of Upper Sandusky	Upper Sandusky	Ohio
The Versailles Savings and Loan Company	Versailles	Ohio
First National Bank of Waverly	Waverly	Ohio

Spring Valley Bank	Wyoming	Ohio
The Home Savings and Loan Company of Youngstown Ohio	Youngstown,	Ohio
Century National Bank	Zanesville	Ohio
Athens Federal Community Bank	Athens	Tennessee
Benton Banking Company	Benton	Tennessee
People's Bank and Trust Co. of Pickett County	Byrdstown	Tennessee
Bank of Camden	Camden	Tennessee
Legends Bank	Clarksville	Tennessee
Bank Tennessee	Collierville	Tennessee
Greenfield Banking Company	Greenfield	Tennessee
First Peoples Bank of Tennessee	Jefferson City	Tennessee
Lawrenceburg FS&LA	Lawrenceburg	Tennessee
Community Bank	Lexington	Tennessee
Union Bank & Trust Company	Livingston	Tennessee
City of Memphis Credit Union	Memphis	Tennessee
Farmers State Bank	Mountain City	Tennessee
Cumberland Bank	Nashville	Tennessee
The Tennessee Credit Union	Nashville	Tennessee
Citizens Savings Bank & Trust Company	Nashville	Tennessee
The First National Bank of Oneida	Oneida	Tennessee
First Trust & Savings Bank	Oneida	Tennessee
Citizens B&TC of Grainger County	Rutledge	Tennessee
The Bank of Waynesboro	Waynesboro	Tennessee

Federal Home Loan Bank of Indianapolis—District 6

Knisely Bank	Butler	Indiana
The Elberfeld State Bank	Elberfeld	Indiana
FORUM Credit Union	Fishers	Indiana
Mutual Savings Bank	Franklin	Indiana
First FS & LA of Hammond	Hammond	Indiana
MainSource Bank	Hobart	Indiana
First Indiana Bank	Indianapolis	Indiana
Central Indiana School Educators Credit Union	Indianapolis	Indiana
The Lafayette Life Insurance Company	Lafayette	Indiana
Farmers State Bank	LaGrange	Indiana
Linden State Bank	Linden	Indiana
MFB Financial	Mishawaka	Indiana
St. Joseph Capital Bank	Mishawaka	Indiana
West End Bank, S.B.	Richmond	Indiana
Scott County State Bank	Scottsburg	Indiana
Communitywide Federal Credit Union	South Bend	Indiana
Indiana State University Federal Credit Union	Terre Haute	Indiana
Steel Parts Federal Credit Union	Tipton	Indiana
Purdue Employees Federal Credit Union	West Lafayette	Indiana
United Communities National Bank	Winchester	Indiana
TLC Community Credit Union	Adrian	Michigan
Community Bank of Dearborn	Allen Park	Michigan
Sunrise Family Credit Union	Bay City	Michigan
Brighton Commerce Bank	Brighton	Michigan
Macomb Community Bank	Clinton Township	Michigan
DFCU Financial Federal Credit Union	Dearborn	Michigan
First Independence National Bank	Detroit	Michigan
Communicating Arts Credit Union	Detroit	Michigan
Michigan State University FCU	East Lansing	Michigan
Northern Michigan Bank & Trust	Escanaba	Michigan
Citizens Bank	Flint	Michigan
Grand Haven Bank	Grand Haven	Michigan
Lake Michigan Credit Union	Grand Rapids	Michigan
Mercantile Bank of West Michigan	Grand Rapids	Michigan
Northpointe Bank	Grand Rapids	Michigan
Greenville Community Bank	Greenville	Michigan
Mainstreet Savings Bank, FSB	Hastings	Michigan
The Bank of Holland	Holland	Michigan
Honor State Bank	Honor	Michigan
Ionia County National Bank of Ionia	Ionia	Michigan
First National Bank of Iron Mountain	Iron Mountain	Michigan
Mayville State Bank	Mayville	Michigan
Wolverine Bank, FSB	Midland	Michigan
Dow Chemical Employee Credit Union	Midland	Michigan
Northland Area Federal Credit Union	Oscoda	Michigan
The Port Austin State Bank	Port Austin	Michigan
Portage Commerce Bank	Portage	Michigan
Central Savings Bank	Sault Ste. Marie	Michigan
Sturgis Bank & Trust Company	Sturgis	Michigan
First Savings Bank, FSB	Three Rivers	Michigan

Howmet Credit Union	Whitehall	Michigan

Federal Home Loan Bank of Chicago—District 7

Citizens National Bank of Albion	Albion	Illinois
Farmers State Bank of Western Illinois	Alpha	Illinois
Anna National Bank	Anna	Illinois
Apple River State Bank	Apple River	Illinois
Arcola Homestead Savings Bank	Arcola	Illinois
The First National Bank of Arcola	Arcola	Illinois
The First National Bank of Arenzville	Arenzville	Illinois
Ben Franklin Bank of Illinois	Arlington Heights	Illinois
State Bank of Ashland	Ashland	Illinois
Farmers State Bank of Astoria	Astoria	Illinois
The Atlanta National Bank	Atlanta	Illinois
Better Banks	Bartonville	Illinois
Scott State Bank	Bethany	Illinois
First State Bank of Bloomington	Bloomington	Illinois
Midland Federal Savings and Loan Association	Bridgeview	Illinois
Farmers and Merchants State Bank of Bushnell	Bushnell	Illinois
Byron Bank	Byron	Illinois
First State Bank of Campbell Hill	Campbell Hill	Illinois
Carrollton Bank	Carrollton	Illinois
Main Street Bank & Trust	Champaign	Illinois
State Bank of Cherry	Cherry	Illinois
Bank of Chestnut	Chestnut	Illinois
Seaway National Bank	Chicago	Illinois
Second Federal Savings and Loan Association of Chicago	Chicago	Illinois
American Metro Bank	Chicago	Illinois
Hoyne Savings Bank	Chicago	Illinois
Chicago Patrolmens Federal Credit Union	Chicago	Illinois
Loomis Federal Savings & Loan Association	Chicago	Illinois
Royal Savings Bank	Chicago	Illinois
Illinois Service FS&LA	Chicago	Illinois
North Side Federal Savings and Loan Association of Chicago.	Chicago	Illinois
Central Federal Savings and Loan Association	Cicero	Illinois
Mid America Bank, fsb	Clarendon Hills	Illinois
Central State Bank	Clayton	Illinois
DeWitt Savings Bank	Clinton	Illinois
First Federal Bank	Colchester	Illinois
First Collinsville Bank	Collinsville	Illinois
First United Bank	Crete	Illinois
Crystal Lake Bank & Trust Company, N.A	Crystal Lake	Illinois
Soy Capital Bank & Trust Company	Decatur	Illinois
Castle Bank, N.A	DeKalb	Illinois
Downers Grove National Bank	Downers Grove	Illinois
Erie State Bank	Erie	Illinois
Community First Bank	Fairview Heights	Illinois
Bank of Farmington	Farmington	Illinois
Heritage Bank	Frankfort	Illinois
Community State Bank	Galva	Illinois
Gifford State Bank	Gifford	Illinois
Harvard Savings Bank	Harvard	Illinois
Mutual Bank	Harvey	Illinois
Premier Bank of Jacksonville	Jacksonville	Illinois
Joy State Bank	Joy	Illinois
First Trust Bank	Kankakee	Illinois
First National Bank of LaGrange	LaGrange	Illinois
Cambridge Bank	Lake Zurich	Illinois
Exchange State Bank	Lanark	Illinois
Lemont National Bank	Lemont	Illinois
State Bank of Lincoln	Lincoln	Illinois
Prairie State Bank	Marengo	Illinois
A.J. Smith Federal Savings Bank	Midlothian	Illinois
Southeast National Bank	Moline	Illinois
Security Savings Bank	Monmouth	Illinois
Farmers State Bank and Trust Company	Mt. Sterling	Illinois
The First National Bank	Mulberry Grove	Illinois
First County Bank	New Baden	Illinois
Warren-Boynton State Bank	New Berlin	Illinois
Peoples State Bank of Newton	Newton	Illinois
Old Exchange National Bank	Okawville	Illinois
First Personal Bank	Orland Park	Illinois
Ottawa Savings Bank	Ottawa	Illinois
State Bank of Paw Paw	Paw Paw	Illinois
Farmers-Merchants National Bank of Paxton	Paxton	Illinois

Morton Community	Pekin	Illinois
The Heights Bank	Peoria Heights	Illinois
Town & Country Bank of Quincy	Quincy	Illinois
Community State Bank of Rock Falls	Rock Falls	Illinois
Alpine Bank of Illinois	Rockford	Illinois
MB Financial Bank, NA	Rosemont	Illinois
Rushville State Bank	Rushville	Illinois
AmericaUnited Bank and Trust Company USA	Schaumburg	Illinois
American Chartered Bank	Schaumburg	Illinois
State Bank of Speer	Speer	Illinois
Illini Bank	Springfield	Illinois
Tuscola National Bank	Tuscola	Illinois
Baxter Credit Union	Vernon Hills	Illinois
Petefish, Skiles and Company Bank	Virginia	Illinois
Bank of Warrensburg	Warrensburg	Illinois
First DuPage Bank	Westmont	Illinois
Community Bank	Winslow	Illinois
State Bank	Wonder Lake	Illinois
Portage County Bank	Almond	Wisconsin
Pioneer Bank	Auburndale	Wisconsin
First Bank of Baldwin	Baldwin	Wisconsin
Black River Country Bank	Black River Falls	Wisconsin
Dairyman's State Bank	Clintonville	Wisconsin
Farmers & Merchants Union Bank	Columbus	Wisconsin
Wisconsin Community Bank	Cottage Grove	Wisconsin
Cumberland Federal Bank, FSB	Cumberland	Wisconsin
Town Bank	Delafield	Wisconsin
Cornerstone Community Bank	Grafton	Wisconsin
Bay Bank	Green Bay	Wisconsin
Highland State Bank	Highland	Wisconsin
The Park Bank	Holmen	Wisconsin
Security State Bank	Iron River	Wisconsin
East Wisconsin Savings Bank, S.A	Kaukauna	Wisconsin
Greenwood's State Bank	Lake Mills	Wisconsin
First Bank & Trust	Menomonie	Wisconsin
Bank of Milton	Milton	Wisconsin
Bank Mutual	Milwaukee	Wisconsin
Universal Savings Bank	Milwaukee	Wisconsin
Milwaukee Western Bank	Milwaukee	Wisconsin
First National Bank—Fox Valley	Neenah	Wisconsin
Clare Bank, N.A	Platteville	Wisconsin
Mound City Bank	Platteville	Wisconsin
First National Bank of Platteville	Platteville	Wisconsin
First National Bank of River Falls	River Falls	Wisconsin
Intercity State Bank	Schofield	Wisconsin
Community Bank & Trust	Sheboygan	Wisconsin
Bank of Sun Prairie	Sun Prairie	Wisconsin
Walworth State Bank	Walworth	Wisconsin
First Federal Savings Bank of Wisconsin	Waukesha	Wisconsin
The State Bank of Viroqua	Westby	Wisconsin
Wood County National Bank	Wisconsin Rapids	Wisconsin
River Cities Bank	Wisconsin Rapids	Wisconsin
KeySavings Bank	Wisconsin Rapids	Wisconsin

Federal Home Loan Bank of Des Moines—District 8

Landmands National Bank	Audubon	Iowa
Community Bank of Boone	Boone	Iowa
Iowa Savings Bank	Carroll	Iowa
Commercial Savings Bank	Carroll	Iowa
Page County State Bank	Clarinda	Iowa
Linn County State Bank	Coggon	Iowa
Farmers Savings Bank	Colesburg	Iowa
Okey Vernon First National Bank	Corning	Iowa
Corydon State Bank	Corydon	Iowa
Fortress Bank of Cresco	Cresco	Iowa
Alliant Credit Union	Dubuque	Iowa
First National Bank in Fairfield	Fairfield	Iowa
Farmers Savings Bank	Fostoria	Iowa
Grinnell Mutual Reinsurance Company	Grinnell	Iowa
Security State Bank	Hubbard	Iowa
First State Bank of Mapleton	Mapleton	Iowa
Maxwell State Bank	Maxwell	Iowa
Bridge Community Bank	Mount Vernon	Iowa
State Bank and Trust Company	Nevada	Iowa
New Vienna Savings Bank	New Vienna	Iowa

First Newton National Bank	Newton	Iowa
First State Bank	Nora Springs	Iowa
Farmers State Bank	Northwood	Iowa
The First National Bank, Oelwein	Oelwein	Iowa
City State Bank	Ogden	Iowa
American State Bank	Osceola	Iowa
Panora State Bank	Panora	Iowa
Marion County State Bank	Pella	Iowa
Savings Bank	Primghar	Iowa
Readlyn Savings Bank	Readlyn	Iowa
Premier Bank	Rock Valley	Iowa
Home State Bank	Royal	Iowa
Iowa State Bank	Sac City	Iowa
Sanborn Savings Bank	Sanborn	Iowa
The State Bank	Spirit Lake	Iowa
Meta Bank	Storm Lake	Iowa
The State Bank of Toledo	Toledo	Iowa
Farmers Savings Bank	Walford	Iowa
Iowa State Bank	Wapello	Iowa
Farmers State Bank	Waterloo	Iowa
Security State Bank	Waverly	Iowa
State Bank of Waverly	Waverly	Iowa
First State Bank	Webster City	Iowa
Freedom Financial Bank	West Des Moines	Iowa
Union State Bank	Winterset	Iowa
Farmers & Merchants State Bank	Winterset	Iowa
First State Bank of Alexandria	Alexandria	Minnesota
Altura State Bank	Altura	Minnesota
American National Bank of Minnesota	Baxter	Minnesota
First State Bank and Trust	Bayport	Minnesota
First National Bank Bemidji	Bemidji	Minnesota
State Bank of Bricelyn	Bricelyn	Minnesota
Farmers and Merchants State Bank	Clarkfield	Minnesota
The First National Bank of Coleraine	Coleraine	Minnesota
Farmers State Bank of Dent	Dent	Minnesota
Northwestern Bank N.A.	Dilworth	Minnesota
Western National Bank	Duluth	Minnesota
Fidelity Bank	Edina	Minnesota
State Bank of Fairmont	Fairmont	Minnesota
Franklin State Bank	Franklin	Minnesota
Commerce Bank	Geneva	Minnesota
First National Bank	Gilbert	Minnesota
Yellow Medicine County Bank	Granite Falls	Minnesota
Marshall Bank National Association	Hallock	Minnesota
Merchant Bank, National Association	Hampton	Minnesota
1st American State Bank of Minnesota	Hancock	Minnesota
First Southeast Bank	Harmony	Minnesota
Farmers State Bank of Hartland	Hartland	Minnesota
Exchange State Bank	Hills	Minnesota
CornerStone State Bank	La Sueur	Minnesota
First Community Bank Lester Prairie	Lester Prairie	Minnesota
Center National Bank	Litchfield	Minnesota
Northern Star Bank	Mankato	Minnesota
First National Bank of Montgomery	Montgomery	Minnesota
United Farmers & Merchants State Bank	Morris	Minnesota
Lakewood Bank N.A	Nisswa	Minnesota
Citizens State Bank Norwood Young America	Norwood Young America	Minnesota
Washington County Bank, N.A	Oakdale	Minnesota
Odin State Bank	Odin	Minnesota
First State Bank Southwest	Pipestone	Minnesota
PrinsBank	Prinsburg	Minnesota
Randall State Bank	Randall	Minnesota
First Security Bank—Storden	Reinville	Minnesota
Woodland Bank	Remer	Minnesota
Home Federal Savings Bank	Rochester	Minnesota
North Star Bank	Roseville	Minnesota
Unity Bank East	Rush City	Minnesota
First Community Bank	Savage	Minnesota
First Community Bank Silver Lake	Silver Lake	Minnesota
Park Midway Bank	St. Paul	Minnesota
Integrity Plus Bank	Wabasso	Minnesota
Citizens State Bank of Waverly	Waverly	Minnesota
Flagship Bank Minnesota	Wayzata	Minnesota
Wells Federal Bank	Wells	Minnesota
St. Paul Postal Employees Credit Union	Woodbury	Minnesota
Worthington Federal Savings Bank f.s.b	Worthington	Minnesota

First Missouri National Bank	Brookfield	Missouri
BC National Banks	Butler	Missouri
Community First Bank	Butler	Missouri
Carroll County Trust Company	Carrollton	Missouri
Chillicothe State Bank	Chillicothe	Missouri
Investors National Bank	Chillicothe	Missouri
Concordia Bank	Concordia	Missouri
First State Community Bank	Farmington	Missouri
Ozarks Federal Savings and Loan Association	Farmington	Missouri
The Callaway Bank	Fulton	Missouri
Northland National Bank	Gladstone	Missouri
Bank Northwest	Hamilton	Missouri
HNB National Bank	Hannibal	Missouri
Eagle Bank & Trust Company of Missouri	Hillsboro	Missouri
Bank of Iberia	Iberia	Missouri
Generations Bank	Kansas City	Missouri
Kennett National Bank	Kennett	Missouri
Lamar Bank & Trust Company	Lamar	Missouri
Central Bank	Lebanon	Missouri
Summit Lee's Bank of Kansas City	Lee's Summit	Missouri
Linn State Bank	Linn	Missouri
First National Bank	Malden	Missouri
Wood & Huston Bank	Marshall	Missouri
Community Bank of Marshall	Marshall	Missouri
The First National Bank of Audrain County	Mexico	Missouri
Peoples Bank of the Ozarks	Nixa	Missouri
First Midwest Bank of Ozark	Piedmont	Missouri
Peoples Savings Bank of Rhineland	Rhineland	Missouri
The State Bank	Richmond	Missouri
Town & Country Bank	Salem	Missouri
Farmers State Bank, S/B	Schell City	Missouri
Third National Bank	Sedalia	Missouri
Senath State Bank	Senath	Missouri
The Community Bank of Shell Knob	Shell Knob	Missouri
Old Missouri National Bank	Springfield	Missouri
First State Bank of St. Charles	St. Charles	Missouri
Midwest FS&LA of St. Joseph	St. Joseph	Missouri
Midwest BankCentre	St. Louis	Missouri
Edward D. Jones & Company	St. Louis	Missouri
The PrivateBank	St. Louis	Missouri
Bank of Thayer	Thayer	Missouri
Quarry City Savings and Loan Association	Warrensburg	Missouri
First State Bank of Cando	Cando	North Dakota
Citizens State Bank—Midwest	Cavalier	North Dakota
Union State Bank of Fargo	Fargo	North Dakota
U.S. Bank, N.A	Fargo	North Dakota
State Bank & Trust of Kenmare	Kenmare	North Dakota
Farmers & Merchants State Bank	Langdon	North Dakota
First Western Bank & Trust	Minot	North Dakota
Lakeside State Bank	New Town	North Dakota
McKenzie County Bank	Watford City	North Dakota
BankStar Financial	Elkton	South Dakota
Farmers State Bank	Flandreau	South Dakota
First State Bank of Claremont	Groton	South Dakota
Dakotaland Federal Credit Union	Huron	South Dakota
BankFirst	Sioux Falls	South Dakota
First Premier Bank	Sioux Falls	South Dakota
Home Federal Bank	Sioux Falls	South Dakota
Great Western Bank	Watertown	South Dakota
First State Bank	Wilmot	South Dakota
First National Bank South Dakota	Yankton	North Dakota

Federal Home Loan Bank of Dallas—District 9

First Community Bank	Batesville	Arkansas
Farmers Bank and Trust Company	Blytheville	Arkansas
First State Bank	Conway	Arkansas
River Town Bank	Dardanelle	Arkansas
First Financial Bank	El Dorado	Arkansas
Fordyce Bank & Trust Company	Fordyce	Arkansas
Forrest City Bank, NA	Forrest City	Arkansas
Benefit Bank	Ft. Smith	Arkansas
First State Bank of Northwest Arkansas	Huntsville	Arkansas
Simmons First Bank of South Arkansas	Lake Village	Arkansas
Southern State Bank	Malvern	Arkansas
Allied Bank	Mulberry	Arkansas

The First National Bank at Paris	Paris	Arkansas
Delta Trust & Bank	Parkdale	Arkansas
Pine Bluff National Bank	Pine Bluff	Arkansas
Simmons First Bank of Northwest Arkansas	Rogers	Arkansas
FNB of Stuttgart	Stuttgart	Arkansas
Red River Bank	Alexandria	Louisiana
E Federal Credit Union	Baton Rouge	Louisiana
Bank of Coushatta	Coushatta	Louisiana
St. Tammany Homestead Savings & Loan Association	Covington	Louisiana
City Savings Bank & Trust Company	DeRidder	Louisiana
Teche Federal Savings Bank	Franklin	Louisiana
Florida Parishes Bank	Hammond	Louisiana
Coastal Commerce Bank	Houma	Louisiana
Synergy Bank	Houma	Louisiana
Mutual Savings and Loan Association	Metairie	Louisiana
Eureka Homestead	Metairie	Louisiana
Guaranty Savings Bank	Metairie	Louisiana
Hibernia Homestead & Savings Association	New Orleans	Louisiana
Peoples Bank & Trust Company of Pointe Coupee Parish, Inc	New Roads	Louisiana
Homestead Bank	Ponchatoula	Louisiana
American Gateway Bank	Port Allen	Louisiana
Richland State Bank	Rayville	Louisiana
Bank of Ringgold	Ringgold	Louisiana
Bank of Ruston	Ruston	Louisiana
First Louisiana Bank	Shreveport	Louisiana
Bank of St. Francisville	St. Francisville	Louisiana
American Bank	Welsh	Louisiana
The Bank of Commerce	White Castle	Louisiana
Amory Federal Savings and Loan Association	Amory	Mississippi
Spirit Bank	Belmont	Mississippi
The Peoples Bank	Biloxi	Mississippi
Bank of Brookhaven	Brookhaven	Mississippi
The Cleveland State Bank	Cleveland	Mississippi
Commerce National Bank	Corinth	Mississippi
Bank of Holly Springs	Holly Springs	Mississippi
Community Bank of Meridian	Meridian	Mississippi
Britton & Koontz First National Bank	Natchez	Mississippi
Sycamore Bank	Senatobia	Mississippi
Mechanics Bank	Water Valley	Mississippi
First National Bank of Alamogordo	Alamogordo	New Mexico
International Bank	Raton	New Mexico
Tucumcari Federal Savings & Loan Association	Tucumcari	New Mexico
Reliance Standard Life Insurance Co. of Texas	Philadelphia	Pennsylvania
First State Bank	Athens	Texas
Community Resource Credit Union	Baytown	Texas
Fannin Bank	Bonham	Texas
First Financial Bank, N.A	Bridgeport	Texas
Texas Heritage Bank	Cross Plains	Texas
Zavala County Bank	Crystal City	Texas
Dallas National Bank	Dallas	Texas
NexBank, SSB	Dallas	Texas
Credit Union of Texas	Dallas	Texas
First United Bank	Dimmitt	Texas
First National Bank	Dublin	Texas
Fort Worth National Bank	Fort Worth	Texas
OmniAmerican Bank	Fort Worth	Texas
First State Bank	Frankston	Texas
Community Bank	Granbury	Texas
Bank of South Texas	Hebbronville	Texas
Community National Bank	Hondo	Texas
MetroBank, N.A	Houston	Texas
Central Bank	Houston	Texas
Southwestern National Bank	Houston	Texas
Texas State Bank	Joaquin	Texas
First State Bank Texas	Keene	Texas
Union State Bank	Killeen	Texas
First National Bank of Lake Jackson	Lake Jackson	Texas
First Federal Savings & Loan Association	Littlefield	Texas
Austin Bank	Longview	Texas
PlainsCapital Bank	Lubbock	Texas
Mason National Bank	Mason	Texas
Inter National Bank	McAllen	Texas
Mineola Community Bank S.S.B	Mineola	Texas
City National Bank	Mineral Wells	Texas
American National Bank	Mt. Pleasant	Texas
Commercial Bank of Texas, N.A.	Nacogdoches	Texas

Security State Bank	Odessa	Texas
Western National Bank	Odessa	Texas
Orange Savings Bank, SSB	Orange	Texas
Lone Star National Bank	Pharr	Texas
Beal Bank, SSB	Plano	Texas
Texas Republic Bank, N.A	Quanah	Texas
South Padre Bank, N.A	South Padre Island	Texas
Woodforest National Bank	Spring	Texas
First National Bank of Trinity	Trinity	Texas
Citizens State Bank	Tyler	Texas
First National Bank of Bosque County	Valley Mills	Texas
Community Bank and Trust	Waco	Texas
Extraco Banks, National Association	Waco	Texas
First National Bank of Central Texas	Waco	Texas

Federal Home Loan Bank of Topeka—District 10

Commerce Bank	Aurora	Colorado
Citywide Banks	Aurora	Colorado
Premier Members Federal Credit Union	Boulder	Colorado
First National Bank, Cortez	Cortez	Colorado
Del Norte Federal Bank	Del Norte	Colorado
Rocky Mountain Law Enforcement Federal Credit Union	Denver	Colorado
Premier Bank	Denver	Colorado
Colorado United Credit Union	Denver	Colorado
Bank of the San Juans	Durango	Colorado
FirstBank of Evergreen	Evergreen	Colorado
Fort Morgan State Bank	Fort Morgan	Colorado
FirstBank of Greeley	Greeley	Colorado
First National Bank	Julesberg	Colorado
Kit Carson State Bank	Kit Carson	Colorado
The State Bank	La Junta	Colorado
First National Bank of Lake City & Creede	Lake City	Colorado
Home State Bank	Loveland	Colorado
First National Bank of Paonia	Paonia	Colorado
FirstBank of Parker	Parker	Colorado
The First National Bank of Stratton	Stratton	Colorado
Prairie State Bank	Augusta	Kansas
First National Bank in Belleville	Belleville	Kansas
Bank of Commerce	Chanute	Kansas
Home Savings Bank	Chanute	Kansas
Farmers & Merchants Bank of Colby	Colby	Kansas
Legacy Bank	Colwich	Kansas
The State Bank of Conway Springs	Conway Springs	Kansas
Farmers & Drovers Bank	Council Grove	Kansas
Citizens State Bank & Trust Company	Ellsworth	Kansas
The State Bank of Kansas	Fredonia	Kansas
Gardner National Bank	Gardner	Kansas
Community Bank of the Midwest	Great Bend	Kansas
The Halstead Bank	Halstead	Kansas
Security Bank of Kansas City	Kansas City	Kansas
Douglas County Bank	Lawrence	Kansas
First National Bank and Trust Company of Leavenworth	Leavenworth	Kansas
National Bank of Kansas City	Leewood	Kansas
Western National Bank	Lenexa	Kansas
Lyons State Bank	Lyons	Kansas
Farmers State Bank	McPherson	Kansas
The Mission Bank	Mission	Kansas
Mulvane State Bank	Mulvane	Kansas
Farmers State Bank	Oakley	Kansas
First National Bank of Olathe	Olathe	Kansas
Valley View State Bank	Overland Park	Kansas
Citizens State Bank	Paola	Kansas
University National Bank	Pittsburg	Kansas
Alliant Bank	Sedgwick	Kansas
TriCentury Bank	Simpson	Kansas
First Bank	Sterling	Kansas
Valley State Bank	Syracuse	Kansas
The Tampa State Bank	Tampa	Kansas
The Kaw Valley State Bank and Trust Company	Topeka	Kansas
Community National Bank	Topeka	Kansas
INTRUST Bank, N.A	Wichita	Kansas
Chisholm Trail State Bank	Wichita	Kansas
Bank of The Valley	Bellwood	Nebraska
Bank of Bennington	Bennington	Nebraska
Washington County Bank	Blair	Nebraska

Custer Federal Savings and Loan Association	Broken Bow	Nebraska
First Central Bank	Cambridge	Nebraska
Citizens State Bank	Carleton	Nebraska
CerescoBank	Ceresco	Nebraska
First Bank and Trust Company	Cozad	Nebraska
Jefferson County Bank	Daykin	Nebraska
First National Bank in Exeter	Exeter	Nebraska
Farnam Bank	Farnam	Nebraska
First State Bank & Trust Company	Fremont	Nebraska
American National Bank of Fremont	Fremont	Nebraska
Gothenburg State Bank and Trust Company	Gothenburg	Nebraska
Five Points Bank of Hastings	Hastings	Nebraska
Henderson State Bank	Henderson	Nebraska
First State Bank	Imperial	Nebraska
Kearney State Bank & Trust Company	Kearney	Nebraska
Farmers State Bank	Maywood	Nebraska
First Central Bank McCook, NA	McCook	Nebraska
Farmers and Merchants Bank	Milligan	Nebraska
Centennial Bank	Omaha	Nebraska
Nebraska State Bank of Omaha	Omaha	Nebraska
First National Bank of Omaha	Omaha	Nebraska
The Potter State Bank of Potter	Potter	Nebraska
Peoples-Webster City Bank	Red Cloud	Nebraska
First State Bank	Shelton	Nebraska
Sutton State Bank	Sutton	Nebraska
First National Bank and Trust of Syracuse	Syracuse	Nebraska
Citizens Bank of Ada	Ada	Oklahoma
Stockmans Bank	Altus	Oklahoma
First National Bank in Altus	Altus	Oklahoma
The First National Bank and Trust Company of Broken Arrow	Broken Arrow	Oklahoma
Farmers Exchange Bank	Cherokee	Oklahoma
First National Bank and Trust Company of Chickasha	Chickasha	Oklahoma
1st Bank Oklahoma	Claremore	Oklahoma
Kirkpatrick Bank	Edmond	Oklahoma
Bank of Western Oklahoma	Elk City	Oklahoma
Inter Bank	Elk City	Oklahoma
Liberty Federal Savings Bank	Enid	Oklahoma
Fairview Savings and Loan Association	Fairview	Oklahoma
Oklahoma State Bank	Guthrie	Oklahoma
City National Bank & Trust Company	Guymon	Oklahoma
The Bank of Kremlin	Kremlin	Oklahoma
Liberty National Bank	Lawton	Oklahoma
Exchange National Bank	Moore	Oklahoma
The Morris State Bank	Morris	Oklahoma
Bank of Nichols Hills	Oklahoma City	Oklahoma
First Security Bank and Trust Company	Oklahoma City	Oklahoma
Oklahoma Educators Credit Union	Oklahoma City	Oklahoma
Citizens Bank of Oklahoma	Pawhuska	Oklahoma
Osage Federal Bank	Pawhuska	Oklahoma
Security Bank	Pawnee	Oklahoma
Exchange Bank and Trust Company	Perry	Oklahoma
Central National Bank of Poteau	Poteau	Oklahoma
First Pryority Bank	Pryor	Oklahoma
Peoples Bank & Trust Company	Ryan	Oklahoma
Southwest State Bank	Sentinel	Oklahoma
Advantage Bank	Spencer	Oklahoma
Bank of Commerce	Stilwell	Oklahoma
American Bank and Trust Company	Tulsa	Oklahoma
Bank South	Tulsa	Oklahoma
Sooner State Bank	Tuttle	Oklahoma
The Bank of Union	Union City	Oklahoma
First State Bank	Valliant	Oklahoma
Citizens' Bank	Velma	Oklahoma
First State Bank	Watonga	Oklahoma
Peoples Bank	Westville	Oklahoma
The Bank of Wyandotte	Wyandotte	Oklahoma
Yukon National Bank	Yukon	Oklahoma

Federal Home Loan Bank of San Francisco—District 11

Western Security Bank	Scottsdale	Arizona
Placer Sierra Bank	Auburn	California
Los Angeles National Bank	Buena Park	California
Burbank City Federal Credit Union	Burbank	California
Pacific Trust Bank	Chula Vista	California
Financial Partners Credit Union	Downey	California

Centennial Bank	Fountain Valley	California
Murphy Bank	Fresno	California
USC Credit Union	Los Angeles	California
Neighborhood National Bank	National City	California
Downey Savings and Loan Association	Newport Beach	California
Heritage Oaks Bank	Paso Robles	California
1st Centennial Bank	Redlands	California
Provident Credit Union	Redwood City	California
Provident Savings Bank	Riverside	California
Five Star Bank	Rocklin	California
First U.S. Community Credit Union	Sacramento	California
River City Bank	Sacramento	California
San Diego National Bank	San Diego	California
Pacific Coast Bankers' Bank	San Francisco	California
Bank of the Orient	San Francisco	California
Meriwest Credit Union	San Jose	California
Tamalpais Bank	San Rafael	California
Santa Cruz Community Credit Union	Santa Cruz	California
Los Padres Bank	Solvang	California
Sonoma Valley Bank	Sonoma	California
Bank of Stockton	Stockton	California
South Bay Bank, N.A	Torrance	California
Universal Bank, F.A	West Covina	California
Business Bank of Nevada	Las Vegas	Nevada

Federal Home Loan Bank of Seattle—District 12

Credit Union 1	Anchorage	Alaska
Bank of America Oregon, N.A	San Francisco	California
Citizens Security Bank (Guam), Inc	Agana	Guam
D.L. Evans Bank	Burley	Idaho
Idaho Central Credit Union	Chubbuck	Idaho
FirstBank Northwest	Clarkston	Idaho
Panhandle State Bank	Coeur D'Alene	Idaho
First Citizens Bank of Billings	Billings	Montana
First Citizens Bank of Butte	Butte	Montana
Dutton State Bank	Dutton	Montana
Valley Bank of Glasgow	Glasgow	Montana
1st Liberty Federal Credit Union	Great Falls	Montana
Independence Bank	Havre	Montana
Manhattan State Bank	Manhattan	Montana
First Security Bank of Missoula	Missoula	Montana
Community Bank-Missoula, Inc	Missoula	Montana
Community Bank	Ronan	Montana
Basin State Bank	Stanford	Montana
Evergreen Federal S&LA	Grants Pass	Oregon
Bank of Eastern Oregon	Heppner	Oregon
South Valley Bank and Trust	Klamath Falls	Oregon
USU Community Credit Union	Logan	Utah
Franklin Templeton Bank & Trust, FSB	Salt Lake City	Utah
American Marine Bank	Bainbridge Island	Washington
Charter Bank	Bellevue	Washington
Fife Commercial Bank	Fife	Washington
The Bank of Washington	Lynnwood	Washington
Whidbey Island Bank	Oak Harbor	Washington
Olympia Federal Savings & LA	Olympia	Washington
Twin County Credit Union	Olympia	Washington
First FS & LA of Port Angeles	Port Angeles	Washington
Seattle Savings Bank	Seattle	Washington
Northwest Business Bank	Seattle	Washington
Washington Mutual Bank fsb	Seattle	Washington
Asia Europe-Americas Bank	Seattle	Washington
Simpson Community Federal Credit Union	Shelton	Washington
Old Standard Life Insurance Company	Spokane	Washington
Farmers & Merchants Bank of Rockford	Spokane	Washington
Western United Life Assurance Company	Spokane Valley	Washington
Riverview Community Bank	Vancouver	Washington
Yakima Federal Savings & Loan Association	Yakima	Washington
Tri-County National Bank	Cheyenne	Wyoming
The Rock Springs National Bank	Rock Springs	Wyoming
American National Bank of Rock Springs	Rock Springs	Wyoming

II. Public Comments

To encourage the submission of public comments on the community support performance of Bank members, on or before the January 26, 2007, each Bank will notify its Advisory Council and nonprofit housing developers, community groups, and other interested parties in its district of the members selected for this community support review cycle. 12 CFR 944.2(b)(2)(ii). In reviewing a member for community support compliance, the Finance Board will consider any public comments it has received concerning the member. 12 CFR 944.2(d). To ensure consideration by the Finance Board, comments concerning the community support performance of members selected for this review cycle must be delivered to the Finance Board on or before the February 26, 2007 deadline for submission of Community Support Statements.

Dated: January 3, 2007.

John P. Kennedy,

General Counsel.

[FR Doc. 07–106 Filed 1–11–07; 8:45 am]

BILLING CODE 6725–01–U

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank 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 office 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 January 30, 2007.

A. Federal Reserve Bank of Kansas City (Donna J. Ward, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. Nancy A. Strohmeyer, Lakewood, Colorado; to retain voting shares of FirstBank Holding Company, and thereby indirectly retain voting shares of FirstBank of Colorado, both in Lakewood, Colorado.

2. Monty W. Rhine, Wamgeo, Kansas; to retain control of Republic Bancorp, Inc., and thereby indirectly retain voting shares of New Century Bank, National Association, both in Munden, Kansas.

Board of Governors of the Federal Reserve System, January 9, 2007.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E7–332 Filed 1–11–07; 8:45 am]

BILLING CODE 6210–01–S

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 *http://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 February 9, 2007.

A. Federal Reserve Bank of Atlanta (Andre Anderson, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309:

1. First Citizens Financial Corporation, Dawsonville, Georgia; to become a bank holding company by acquiring 100 percent of the outstanding shares of First Citizens Bank of Georgia, Dawsonville, Georgia (in organization).

Board of Governors of the Federal Reserve System, January 9, 2007.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E7–333 Filed 1–11–07; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension

AGENCY: Federal Trade Commission.

ACTION: Notice.

SUMMARY: The information collection requirements described below will be submitted to the Office of Management and Budget (''OMB'') for review, as required by the Paperwork Reduction Act (''PRA'') (44 U.S.C. 3501–3520). The Federal Trade Commission (''FTC'' or ''Commission'') is seeking public comments on its proposal to extend through May 31, 2010 the current PRA clearance for information collection requirements contained its Antitrust Improvements Act Rules (''HSR Rules'') and corresponding Notification and Report Form for Certain Mergers and Acquisitions (''Notification and Report Form''), 16 CFR. Parts 801–803. That clearance expires on May 31, 2007.

DATES: Comments must be filed by March 13, 2007.

ADDRESSES: Interested parties are invited to submit written comments. Comments should refer to ''HSR Rules: FTC File No. P989316'' to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope, and should be mailed or delivered, with two complete copies to the following address: Federal Trade Commission/Office of the Secretary, Room H 135 (Annex J), 600 Pennsylvania Avenue, NW., Washington, DC 20580. Because paper mail in the Washington area and at the Commission is subject to delay, please consider submitting your comments in electronic form, as prescribed below. However, if the comment contains any material for which confidential treatment is requested, it must be filed in paper form, and the first page of the document must be clearly labeled ''Confidential.''[1] The FTC is requesting

[1] Commission Rule 4.2(d), 16 CFR 4.2(d). The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must

Continued

that any comment filed in paper form be sent by courier or overnight service, if possible.

Comments filed in electronic form should be submitted by using the following weblink: *https://secure.commentworks.com/ftc-hsrpra* (and following the instructions on the Web-based form). To ensure that the Commission considers an electronic comment, you must file it on the Web-based form at the weblink: *https://secure.commentworks.com/ftc-hsrpra.* If this notice appears at www.regulations.gov, you may also file an electronic comment through that Web site. The Commission will consider all comments that regulations.gov forwards to it.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments, whether filed in paper or electronic form, will be considered by the Commission, and will be available to the public on the FTC Web site, to the extent practicable, at *www.ftc.gov.* As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the proposed information requirements should be addressed to B. Michael Verne, Compliance Specialist, 600 Pennsylvania Ave., NW., Room 301, Washington, DC 20580. Telephone: (202) 326–3100.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act (''PRA''), 44 U.S.C. 3501–3520, federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' means agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 CFR 1320.3(c). As required by section 3506(c)(2)(A) of the PRA, the FTC is providing this opportunity for public comment before requesting that OMB extend the existing paperwork clearance for the HSR Rules and the corresponding Notification and Report Form.

The FTC invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before March 13, 2007.

Background Information

Section 7A of the Clayton Act (''Act''), 15 U.S.C. 18a, as amended by the Hart-Scott-Rodino Antitrust Improvements Act of 1976, Pub. L. 94–435, 90 Stat. 1390, requires all persons contemplating certain mergers or acquisitions to file notification with the Commission and the Assistant Attorney General and to wait a designated period of time before consummating such transactions. Congress empowered the Commission, with the concurrence of the Assistant Attorney General, to require ''that the notification * * * be in such form and contain such documentary material and information * * * as is necessary and appropriate'' to enable the agencies ''to determine whether such acquisitions may, if consummated, violate the antitrust laws.'' 15 U.S.C. 18a(d). Congress similarly granted rulemaking authority to, *inter alia,* ''prescribe such other rules as may be necessary and appropriate to carry out the purposes of this section.'' *Id.*

Pursuant to that section, the Commission, with the concurrence of the Assistant Attorney General, developed the HSR Rules and the corresponding Notification and Report Form. As discussed below, several changes have been made to the HSR Rules and the Notification and Report Form since FTC staff last sought OMB approval for the clearance.

Burden Statement

Estimated total annual hours burden: 156,000 hours (rounded to the nearest thousand).

The following burden estimates are primarily based on FTC data concerning the number of HSR filings and staff's informal consultations with leading HSR counsel.

In its 2004 PRA submission to OMB regarding the HSR Rules and the Notification and Report Form, FTC staff estimated that there were 21 ''index filings'' under Clayton Act Sections 7A(c)(6) and 7A(c)(8) that required 2 hours per filing, and 2,192 non-index filings that required an average of 39 hours per filing.[2] Staff also estimated that a total of 50 transactions would require an additional 40 hours of burden associated with the more precise determination of transaction value as a result of the introduction of a tiered filing fee system. Thus, the total estimated hours burden was 87,530 hours [(21 index-filings × 2 hours) + (2,192 non-index filings × 39 hours) + (50 transactions × 40 hours)]. *See* 69 FR 18686 (April 8, 2004). In January 2005, staff obtained OMB approval for a nonsubstantive/nonmaterial change request to the FTC's previous burden estimate, resulting in a new burden estimate of 84,020 burden hours. The 3,510 burden hour reduction was based on an anticipated small decrease in the number of non-index filings due to annual adjustments to the statutory thresholds beginning in fiscal year 2005.[3]

There have been two amendments to the HSR Rules and one amendment to the Notification and Report Form since staff last obtained OMB approval in January 2005:

1. Revised treatment of unincorporated entities under the HSR Rules.[4] This amendment changed previously existing reporting requirements. However, based on filing

identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. *See* Commission Rule 4.9(c), 16 CFR 4.9(c).

[2] Clayton Act Sections 7A(c)(6) and (c)(8) exempt from the requirements of the premerger notification program certain transactions that are subject to the approval of other agencies, but only if copies of the information submitted to these other agencies are also submitted to the FTC and the Assistant Attorney General. Thus, parties must submit copies of these filings, which are included in the totals shown, but completing the task requires significantly less time than non-exempt transactions.

[3] Based on actual data concerning the number of non-index filings since then, staff does not anticipate that the annual adjustments will decrease the number of filings going forward. Furthermore, because the adjustments are based on annual change in gross domestic product, as the thresholds increase, the size-of-transactions should increase at the same rate, resulting in no net effect on the number of non-index filings received.

[4] 70 FR 11502 (March 8, 2005).

statistics from the effective date of the rulemaking, the amendment appears to have had a *de minimis* effect on the number of filings received and thereby has not impacted PRA burden.

2. Electronic submission of premerger notification filings.[5] Since the effective date of this rulemaking only one electronic submission has been made. FTC staff anticipates that as the business community becomes more familiar with the new submission process more persons will choose to e-file and that such persons will experience a one hour reduction in burden (the estimated time to print or make copies of the documents when filing the traditional way). However, due to the low volume of electronic filings, the availability of the e-filing system currently has a *de minimis* effect on burden and the FTC conservatively declines to reduce its burden estimate at this time.

3. Allowing Internet links to be used for responses to Items 4(a) and (b) of the Notification and Report Form.[6] Staff projects that 50 percent of non-index filings will utilize this alternative method of providing financial data, resulting in a reduction in burden of one hour per non-index filing.

Finally, since staff last obtained OMB approval, the switch of the base year from 1997 to 2002 became effective.[7] Arguably there is some burden involved in changing the revenue numbers from 1997 to 2002 for the base year. However, this data is reported by large companies to the U.S. Census Bureau every five years in the ordinary course of business and, thus, the FTC is not required to account for such burden under the PRA.[8] Furthermore, based on staff's informal consultations with industry, staff anticipates that any increase in burden would be offset by a reduction in burden because recent revenue data is generally more easily retrievable by and readily available to reporting persons than older data. Nonetheless, although it appears a reduction in burden may be warranted, staff conservatively declines to make an adjustment to its previous burden estimate on this basis.

There were 3,510 non-index filings and 48 index filings in fiscal year 2006. Based on an average increase of 13% in fiscal year 2004—fiscal year 2006 in the number of non-index filings, staff projects a total of 3,966 non-index filings for fiscal year 2007. Likewise based on an average decrease of 34% in index filings over the same time period, staff projects a total of 32 index filings for fiscal year 2007. Retaining the FTC's previous assumptions, staff estimates that non-index filings require approximately 39 burden hours per filing and index filings require an average of 2 hours per filing. Finally, staff continues to estimate that approximately 91 transactions will require an additional 40 hours of burden due to the need for a more precise valuation of transactions that are near a filing fee threshold.[9] Thus, the total estimated hours burden before adjustment is 158,378 hours [(3,966 non-index filings × 39 hours) + (32 index filings × 2 hours) + (91 acquiring person non-index filings requiring more precise valuation × 40 hours)]. Adjusting for the reduced burden due to incorporating Item 4(a) and Item 4(b) documents by reference to an Internet link reduces the total burden by 1,983 hours (3,966 non-index filings × .5 = 1,983 × 1 hour = 1,983 hours), resulting in total burden for fiscal year 2007 of 156,395 hours.

This is a conservative estimate. In estimating PRA burden, staff considered ''the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency.'' 5 CFR 1320.3(b)(1). This includes ''developing, acquiring, installing, and utilizing technology and systems for the purpose of disclosing and providing information.'' 5 CFR 1320.3(b)(1)(iv). Although not expressly stated in the OMB regulation implementing the PRA, the definition of burden arguably includes upgrading and maintaining computer and other systems used to comply with a rule's requirements. Conversely, to the extent that these systems are used in the ordinary course of business independent of the Rule, their associated upkeep would fall outside the realm of PRA ''burden.''

Industry has been subject to the basic provisions of the HSR Rules since 1978. Thus, businesses have had several years (and some have had decades) to integrate compliance systems into their business procedures. Accordingly, most companies now maintain records and provide updated order information of the kind required by the HSR Rules in their ordinary course of business. Nevertheless, staff conservatively assumes that the time devoted to compliance with the Rule by existing and new companies remains unchanged from its preceding estimate.

Estimated labor costs: $73,506,000 (rounded to the nearest thousand).

Using the burden hours estimated above and applying an estimated average of $470/hour for executive and attorney wages,[10] staff estimates that the total labor cost associated with the HSR Rules and the Notification and Report Form is approximately $73,505,650 (156,395 hours x $470/hour).

Estimated annual non-labor cost burden: $0 or minimal.

The applicable requirements impose minimal start-up costs, as businesses subject to the HSR Rules generally have or obtain necessary equipment for other business purposes. Staff believes that the above requirements necessitate ongoing, regular training so that covered entities stay current and have a clear understanding of federal mandates, but that this would be a small portion of and subsumed within the ordinary training that employees receive apart from that associated with the information collected under the HSR Rules and the corresponding Notification and Report Form.

William Blumenthal,

General Counsel.

[FR Doc. E7–293 Filed 1–11–07; 8:45 am]

BILLING CODE 6750–01–P

[5] 71 FR 35995 (June 23, 2006).

[6] 70 FR 73369 (December 12, 2005).

[7] The switch of the base year from 1997 to 2002 became effective December 30, 2005. 70 FR 77312 (December 30, 2005).

[8] See 5 CFR 1320.3(b)(2). Staff recognizes that the HSR Rules require companies to report total revenues for a specific NAICS code (whereas, the Census Bureau collects data for a specific NAICS code for each establishment). Nonetheless, staff anticipates that the burden tied to the aggregation of such data as required by the HSR Rules is *de minimis*.

[9] The FTC retains its previous estimate that 4.6% of non-index filings for acquiring persons will require a more precise valuation. Using staff's projections for fiscal year 2007, 91 transactions will undergo a more precise valuation process [(3,966 non-index filings / 2) = 1,983 (number of non-index filings for acquiring persons) × 4.6%].

[10] The FTC's previous estimate of $425 per hour has been increased by the Social Security COLA percentage for fiscal year 2004–fiscal year 2006 (fiscal year 2004 (2.7%), fiscal year 2005 (4.1%), fiscal year 2006 (3.3%)).

FEDERAL TRADE COMMISSION

Granting of Request for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration

and requires that notice of this action be published in the **Federal Register**.

The following transactions were granted early termination of the waiting period provided by law and the premerger notification rules. The grants were made by the Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period.

Trans #	Acquiring	Acquired	Entities
TRANSACTIONS GRANTED EARLY TERMINATION—12/18/2006			
20070345	GTCR Fund IX/A, L.P	3M Company	3M Innovative Properties Company.
			Riker Laboratories, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—12/19/2006			
20070341	Cadent Energy Partners I, L.P	George W. Mullane, Jr	Logan Oil Tools, Inc.
20070371	Green Equity Investors IV, L.P	Brickman Group Holdings, Inc	Brickman Group Holdings, Inc.
20070378	Cooper Industries, Ltd	Wire-Pro, Inc	Viking Electronics, Inc., Wire-Pro, Inc., WPI-Boston Division, Inc., WPI-Sarasota Division, Inc., WPI-Viking Division, S.A. de C.V.
20070391	United Technologies Corporation	Longville Group Ltd	Longville Group Ltd.
20070411	Blum Strategic Partners III, L.P	Kinetic Concepts, Inc	Kinetic Concepts, Inc.
20070438	Sterling Investment Partner II, L.P	Fairway Operating Corp	Fairway Operating Corp.
20070441	Deutsche Post AG	Atlas Air Worldwide Holdings, Inc	Polar Air Cargo Worldwide, Inc.
20070465	Hewlett-Packard Company	Knightsbridge Solutions Holdings Corp.	Knightsbridge Solutions Holding Corp.
TRANSACTIONS GRANTED EARLY TERMINATION—12/20/2006			
20070168	H.I.G. TestAmerica, Inc	Severn Trent Plc	Aerotech Holdings, Inc., En Novative Technologies, Inc., Severn Trent Laboratories, Inc.
20070383	Carylyle Partners IV, L.P	Sharon Tube Corporation	Sharon Tube Corporation.
20070392	Smith & Wesson Holding Corporation.	Bear Lake Acquisition Corp	Bear Lake Acquisition Corp.
20070440	Tullett Prebon plc	C&W Corporate Securities LLC	Chapdelaine Corporate Securities & Co.
20070442	Oak Hill Capital Partners II, L.P	Frank A. Critz, M.D	Radiotherapy Clinics of Georgia.
20070443	Lonza Group Limited	Cambrex Corporation	Cambrex Corporation.
20070448	Lawrence Flinn, Jr	Barry O'Callaghan	HM Rivergroup, PLC.
20070455	Edward W. Stack	Golf Galaxy, Inc	Golf Galaxy, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—12/21/2006			
20070397	Group 1 Automotive, Inc	A. Baron Cass III	Baron Development Company, LLC, Baron Motorwerks, LLC, Baron Volkswagen, Inc.
20070398	Group 1 Automotive, Inc	Barton J. Cohen	Baron Development Company, LLC, Baron Motowerks, LLC, Baron Volkswagen, Inc.
20070407	Partners HealthCare System, Inc	Martha's Vineyard Hospital, Inc	Martha's Vineyard Hospital, Inc.
20070410	Partners HealthCare System, Inc	Nantucket Cottage Hospital	Nantucket Cottage Hospital.
20070431	Third Point Offshore Fund, Ltd	Pogo Producing Company	Pogo Producing Company.
TRANSACTIONS GRANTED EARLY TERMINATION—12/22/2006			
20070367	Medstead Luxco S.a.r.l	Permira Europe II L.P.2	Ferretti S.p.A.
20070369	Bain Capital (OSI) IX, L.P	OSI Restaurant Partners, Inc	OSI Restaurant Partners, Inc.
20070400	Sonoco Products Company	Snyder Investment Holdings LLC	Clear Pack Company.
20070403	Goldstein Group, Inc	Velia Samuels Common Stock Trust	Samuels Recycling Company.
20070415	Starwood Capital Hospitality Fund I–2, L.P.	elevenseven Holdings, L.L.C	elevenseven Holdings, L.L.C.
20070425	Freeport-McMoRan Cooper & Gold Inc.	Phelps Dodge Corporation	Phelps Dodge Corporation.
20070427	Glide Buy-Out Fund III CV	Rockwood Holdings, Inc	Gruop Novasep SAS.
20070429	ArcLight Energy Partners Fund III, L.P.	AltairStrickland Group, Inc	AltairStrickland Group, Inc.
20070457	Harbinger Capital Partners Offshore Fund I, Ltd.	Calpine Corporation	MEP Pleasant Hill, LLC.
20070460	Mr. Jostein Eikeland	Fiat S.p.A	Meridian Technologies, Inc.
20070467	Behrman Capital III L.P	The Jerry L. Hayden Trust dated April 22, 1994.	Peacock Engineering Company.
20070468	Geodis S.A	TNT N.V	TNT Freight Management Holdings.
20070474	Marubeni Corporation	Mark J. Vallely	Intragrated Resources Holdings, Inc.

Trans #	Acquiring	Acquired	Entities
20070475	Colam Entreprendre S.A	Crawford Electric Supply Company, Ltd.	Crawford Electric Supply Company, Ltd.
20070477	Standex International Corporation	Associated American Industries, Inc	Associated American Industries, Inc.
20070480	General Motors Corporation	Con-way Inc	Vector SCM, LLC.
20070482	GS Capital Partners V, L.P	McJunkin Corporation	McJunkin Corporation.
20070483	General Electric Company	Moseley Associates, Inc	Microwave Data Systems, Inc.
20070484	Graeme Hart	International Paper Company	International Paper Company.
20070485	Veritas Capital Fund III, L.P	Pearson plc	NCS Pearson Venezuela, NCS Services de Mexico, S.A. de C.V., Pearson Analytic Solutions, Inc., Pearson Canada Solutions Limited, Pearson Government Solution, Inc., Pearson Soluciones S.A., Soluciones Pearson Mexico, S.A. de C.V.
20070489	Cardiovascular Hospitals of America, LLC.	St. Francis Health Care System of Hawaii.	Hawaii Health Ventures, LLC, SFMC Joint Ventures, LLC, St. Francis Imaging, LLC, St. Francis Medical Center, St. Francis Medical Center—West.
TRANSACTIONS GRANTED EARLY TERMINATION—12/26/2006			
20070478	Scott Sheridan	INVESTools, Inc	INVESTools Inc.
20070479	Tom Sosnoff	INVESTools Inc	INVESTools Inc.
20070488	Motorola, Inc	Netopia, Inc	Netopia, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—12/28/2006			
20060776	General Dynamics Corporation	SNC-Lavalin Group Inc	SNC Technologies Corp., SNC Technologies Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—12/29/2006			
20061812	The TriZetto Group, Inc	Quality Care Solutions, Inc	Quality Care Solutions, Inc.

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay, Contact Representative, or Renee Hallman, Contact Representative, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room H–303, Washington, DC 20580, (202) 326–3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 07–81 Filed 1–11–07: 8:45 am]

BILLING CODE 6750–01–M

GENERAL SERVICES ADMINISTRATION

FAI–2007–N01

Federal Acquisition Institute/Defense Acquisition University Vendor Meeting

AGENCY: Office of the Chief Acquisition Officer, GSA

ACTION: Notice of meeting.

SUMMARY: The Federal Acquisition Institute (FAI) and the Defense Acquisition University (DAU) will hold a vendor meeting to provide information on shared initiatives and activities. FAI will describe plans and requirements for training related services under the Acquisition Workforce Training Fund (AWTF).

FAI and DAU work together to address many of the acquisition workforce training needs of the Federal government. Partnering with DAU enables FAI to build upon existing DAU training, develop governmentwide curriculum, and promote a cohesive and agile workforce. At the vendor meeting, DAU will present information on recent contracting curriculum changes. FAI will discuss how the curriculum changes impact the federal acquisition workforce.

WHO SHOULD ATTEND? Training developers, vendors with Commercial-Off-The-Shelf (COTS) training products, vendors with capabilities related to the full Instructional System Design (ISD) methodologies, and acquisition training experts.

The meeting will be held January 24, 2007 from 10:00 a.m. to 12:00 p.m., GSA Auditorium located at 1800 F Street, NW, Washington, D.C. Register by e-mail: *maria__hernandez@sra.com*, or telphone (703) 284–6988.

FOR FURTHER INFORMATION CONTACT: Ms. Maria Hernandez, by telephone at 703–284–6988 or by e-mail at *maria__hernandez@sra.com*.

Dated: January 8, 2007.

Rachael M. Lerum,

Procurement Analyst, Office of National & Regional Acquisition Development.

[FR Doc. E7–297 Filed 1–11–07; 8:45 am]

BILLING CODE 6820–61–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Privacy and Confidentiality.

Time and Date: January 23, 2007 9 a.m.–4 p.m.

Place: National Center for Health Statistics, 3311 Toledo Road, Hyattsville, MD 20787.

Status: Open.

Purpose: The purpose of this working session will be to discuss privacy issue around personal health records (PHR) and non-covered health care providers (such as cash-only operations).

Contact Person for More Information: Substantive program information as well as

summaries of meetings and a roster of committee members may be obtained from Maya A. Bernstein, Lead Staff for Subcommittee on Privacy and Confidentiality, Office of the Assistant Secretary for Planning and Evaluation, 434E Hubert H. Humphrey Building, 200 Independence Avenue, SW., 20201; telephone (202) 690–7100; or Majorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Center for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458–4245. Information also is available on the NCVHS home page of the HHS website: *http://www.ncvhs.hhs.gov/*, where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458–4EEO (4336) as soon as possible.

Dated: January 8, 2007.

James Scanlon,

Deputy Assistant Secretary for Planning and Evaluation (OSDP), Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 07–95 Filed 1–11–07; 8:45 am]

BILLING CODE 4151–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10095, CMS–10028 A, B and C and CMS–10108]

Agency Information Collection Activities: Proposed Collection; Comment Request

Agency: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Detailed Explanation of Non-Coverage and Notice of Medicare Non-Coverage and Supporting Regulations in 42 CFR 422.624 and 42 CFR 422.626; *Use:* Providers will deliver a Notice of Medicare Non-Coverage to enrollees at least two days prior to the end of covered services in skilled nursing facilities, home health agencies, and comprehensive outpatient rehabilitation facilities. Enrollees will use this information to determine whether they wish to appeal the service termination to the Quality Improvement Organization (QIO) in their State. If the enrollee decides to appeal, the Medicare Health organization will send the QIO and the enrollee a Detailed Explanation of Non-Coverage detailing the rationale for the termination decision. *Form Number:* CMS–10095 (OMB#: 0938–0910); *Frequency:* Reporting: Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 454; *Total Annual Responses:* 47,558; *Total Annual Hours:* 23,780.52.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* State Health Insurance Assistance Program (SHIP) Client Contact Form, Public and Media Activity Form, and Resource Report Form; *Use:* The information collected is used to fulfill the reporting requirements described in Section 4360(f) of OBRA 1990. Also, the data will be accumulated and analyzed to measure State Health Insurance Assistance Program (SHIP) performance in order to determine whether and to what extent the SHIPs have met the goals of improved CMS customer service to beneficiaries and better understanding by beneficiaries of their health insurance options. Further, the information will be used in the administration of the grants, to measure performance and appropriate use of the funds by the state grantees, to identify gaps in services and technical support needed by SHIPs, and to identify and share best practices. *Form Number:* CMS–10028–A, B and C (OMB#: 0938–0850); *Frequency:* Reporting: Quarterly and Semi-annually; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 12,000; *Total Annual Responses:* 1,056,000; *Total Annual Hours:* 87,965.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Managed Care Regulations for 42 CFR 438.6, 438.8, 438.10, 438.12, 438.50, 438.56, 438.102, 438.114, 438.202, 438.204, 438.206, 438.207, 438.240, 438.242, 438.402, 438.404, 438.406, 438.408, 438.410, 438.414, 438.416, 438.604, 437.710, 438.722, 438.724, and 438.810; *Use:* These information collection requirements implement regulations that allow States greater flexibility to implement mandatory managed care programs, implement new beneficiary protections, and eliminate certain requirements viewed by State agencies as impediments to the growth of managed care programs. Information collected includes information about managed care programs, grievances and appeals, enrollment broker contracts, and managed care organizational capacity to provide health care services. *Form Number:* CMS–10108 (OMB#: 0938–0920); *Frequency:* Reporting: Occasionally; *Affected Public:* State, Local, or Tribal Government; *Number of Respondents:* 39,114,558; *Total Annual Responses:* 4,640,344; *Total Annual Hours:* 3,930,093.5.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on *March 13, 2007.* CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—C, Attention: Bonnie L. Harkless, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 5, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E7–216 Filed 1–11–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–204, CMS–10208 and CMS–R–234]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Agency: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Data Collection for the Second Generation Social Health Maintenance Organization Demonstration; *Use:* The purpose of the Second Generation Social Health Maintenance Organization Demonstration (S/HMO–II) is to refine the targeting and financing methodologies, and benefit design of the Social Health Maintenance Organization Demonstration model. Four primary components of the S/HMO–II demonstration are: (1) A geriatric care approach that will be applied across the entire spectrum of S/HMO–II enrollees; (2) expanded community care coordination through links between chronic care case-management and acute care providers; (3) provision of long-term-benefits; and (4) an adjusted average per capita costs based risk-adjusted payment methodology. *Form Number:* CMS–R–204 (OMB#: 0938–0709); *Frequency:* Reporting—Yearly; *Affected Public:* Individuals or households; *Number of Respondents:* 17,624; *Total Annual Responses:* 17,624; *Total Annual Hours:* 3,425.

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Assessing Degrees of Health Care Involvement Survey Use: It is not sufficient to merely mail information about the Medicare program to each beneficiary. CMS needs to know that the beneficiaries received the information, understood the information and found the information useful in making choices about their Medicare participation. To this end, CMS must have measure(s) over time of what beneficiaries know and understand about the Medicare program now to be able to quantify and attribute any changes to their understanding or behavior to information/education initiatives. Measuring beneficiary information needs and knowledge over time will help CMS to evaluate the impact of information/education and other initiatives, as well as to understand how the population is changing separate from such initiatives. *Form Number:* CMS–10208 (OMB#: 0938–NEW); *Frequency:* Reporting—Weekly; *Affected Public:* Individuals or households; *Number of Respondents:* 4,000; *Total Annual Responses:* 3,500; *Total Annual Hours:* 1,200.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Subpart D—Private Contracts and Supporting Regulations in 42 CFR 405.410, 405.430, 405.435, 405.440, 405.445, and 405.455; *Use:* Under the section 4507 of the Balanced Budget Act of 1997, CMS is required to permit certain physicians and practitioners to opt out of Medicare and furnish covered services to Medicare beneficiaries through private contracts. *Form Number:* CMS–R–234 (OMB#: 0938–0730); *Frequency:* Reporting—Biennially; *Affected Public:* Business or other for-profits; *Number of Respondents:* 26,820; *Total Annual Responses:* 26,820; *Total Annual Hours:* 7,197.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503. Fax Number: (202) 395–6974.

Dated: January 5, 2007.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E7–225 Filed 1–11–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Protection and Advocacy (P&A) Voting Access Annual Report.

OMB No.: New Collection.

Description: An annual report is required by Federal statute (the Help America Vote Act (HAVA) of 2002, Public Law 107–252, Section 291, Payments for Protection and Advocacy Systems, 42 U.S.C. 15461). Each State Protection & Advocacy (P&A) System must prepare and submit an annual report at the end of every fiscal year. The report addresses the activities conducted with the funds provided during the year. The information from the annual report will be aggregated into an annual profile of how HAVA funds have been spent. The report will also provide an overview of the P&A goals and accomplishments and permit the Administration on Developmental Disabilities to track progress to monitor grant activities.

Respondents: Protection & Advocacy Systems—All States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, American Samoa, and Guam.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Protection and Advocacy (P&A) Voting Access Annual Report	55	1	16	880
Estimated Total Annual Burden Hours:				880

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. *E-mail address: infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: January 8, 2007.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 07–86 Filed 1–11–07; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Help America Vote Act (HAVA) Voting Access Annual Report.

OMB No.: New Collection.

Description: An annual report is required by Federal statute (the Help America Vote Act (HAVA) of 2002, Public Law 107–252, Section 291, Payments for Protection and Advocacy Systems, 42 U.S.C. 15461). Each State or Unit of Local Government must prepare and submit an annual report at the end of every fiscal year. The report addresses the activities conducted with the funds provided during the year. The information collected from the annual report will be aggregated into an annual profile of how States have utilized the funds and establish best practices for election officials. It will also provide an overview of the State election goals and accomplishments and permit the Administration on developmental Disabilities to track voting progress to monitor grant activities.

Respondents: Secretaries of State, Directors, State Election Boards, State Chief Election Officials.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Help America Vote Act (HAVA) Voting Access Annual Report	55	1	24	1,320
Estimated Total Annual Burden Hours:				1,320

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for children and Families is soliciting public comment on the specific aspects of the information collection described above.

Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. *E-mail address: information@acf.hshs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: January 8, 2007.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 07–87 Filed 1–11–07; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0528]

Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Requirements

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 information collection regarding the manufacture of infant formula, including infant formula labeling, quality control procedures, notification requirements, and recordkeeping.

DATES: Submit written or electronic comments on the collection of information by March 13, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (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: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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 these topics: (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.

Infant Formula Requirements—21 CFR Parts 106 and 107 (OMB Control Number 0910–0256)—Extension

Statutory requirements for infant formula under the Federal Food, Drug, and Cosmetic Act (the act) are intended to protect the health of infants and include a number of reporting and recordkeeping requirements. Among other things, section 412 of the act (21 U.S.C. 350a) requires manufacturers of infant formula to establish and adhere to quality control procedures, notify FDA when a batch of infant formula that has left the manufacturers' control may be adulterated or misbranded, and keep records of distribution. FDA has issued regulations to implement the act's requirements for infant formula in 21 CFR part 106 and part 107 (21 CFR parts 106 and 107). FDA also regulates the labeling of infant formula under the authority of section 403 of the act (21 U.S.C. 343). Under the labeling regulations for infant formula in part 107, the label of an infant formula must include nutrient information and directions for use. The purpose of these labeling requirements is to ensure that consumers have the information they need to prepare and use infant formula appropriately. In a notice of proposed rulemaking published in the **Federal Register** of July 9, 1996 (61 FR 36154) (the 1996 proposed rule), FDA proposed changes in the infant formula regulations, including some of those listed in tables 1 and 2 of this document. The 1996 proposed rule included revised burden estimates for the proposed changes and solicited public comment. In the interim, however, FDA is seeking an extension of OMB approval for the current regulations so that it can continue to collect information while the proposal is pending.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Federal Food, Drug, and Cosmetic Act or 21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses[2]	Hours per Response	Total Hours
Section 412(d) of the act	5	13	65	10	650
21 CFR 106.120(b)	5	0.25	1.25	4	5
21 CFR 107.10(a) and 107.20	5	13	65	8	520
21 CFR 107.50(b)(3) and (b)(4)	3	2	6	4	24
21 CFR 107.50(e)(2)	3	0.33	1	4	4
Total					1,203

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Manufacturers may submit infant formula notifications in electronic format.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
106.100	5	10	50	4,000	200,000
107.50(c)(3)	3	10	30	3,000	90,000
Total					290,000

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

In compiling these estimates, FDA consulted its records of the number of infant formula submissions received in the past. The figures for hours per response are based on estimates from experienced persons in the agency and in industry.

Dated: January 8, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–331 Filed 1–11–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Section 340B of the Public Health Service Act implements a drug pricing program in which manufacturers who sell covered outpatient drugs to covered entities must agree to charge a price that will not exceed an amount determined under a statutory formula. The purpose of this notice is to inform interested parties of proposed guidelines regarding contract pharmacy services that will allow covered entities to utilize contract pharmacy services arrangements previously limited to the Alternative Methods Demonstration Project program.

DATES: The public is invited to comment on the proposed guidelines by March 13, 2007. After consideration of the submitted comments, the Health Resources and Services Administration (HRSA) will issue the final guidelines.

ADDRESSES: Address all comments to Mr. Bradford R. Lang, Public Health Analyst, Office of Pharmacy Affairs (OPA), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mr. Jimmy Mitchell, Director, OPA, HRSA, 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857, or by telephone through the Pharmacy Services Support Center at 1–800–628–6297.

SUPPLEMENTARY INFORMATION:

A. Background

Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act, Limitation on Prices of Drugs Purchased by Covered Entities. Previous guidelines pertaining to contract pharmacy services for the 340B drug pricing program (61 FR 43549, Aug. 23, 1996) stated that a covered entity could contract with only one pharmacy to provide all pharmacy services for any particular site of the covered entity. Furthermore, if the contract pharmacy had multiple locations, the covered entity site had to choose one, and only one, contract pharmacy location for provision of these services.

In 2001, HRSA established Alternative Methods Demonstration Projects (AMDPs) which allowed covered entities that applied and were approved by HRSA to pursue alternatives to contracting with a single pharmacy. These alternative models included the following: (1) The use of multiple contract pharmacy service sites, (2) the utilization of a contract pharmacy to supplement in-house pharmacy services, and/or (3) the development of a network of 340B covered entities. The intent was to allow community health centers and other 340B safety-net providers to develop new ways to improve access to 340B prescription drugs for their patients. From the time of the program's inception until the end of April 2006, a total of 18 AMDPs were approved. Of those, 11 utilize a multiple contract pharmacies model, four establish a network of 340B covered entities, one is a combination of the network model and the multiple contract pharmacies model, one utilizes a contract pharmacy to supplement an in-house pharmacy, and one utilizes multiple contract pharmacies to supplement an in-house pharmacy. All but one of the projects is currently ongoing. A condition of AMDP approval is the requirement that the approved demonstration project be audited annually by an independent, outside auditor for drug diversion and duplicative discounts under Medicaid. The results of the audits are required to be reported to the Office of Pharmacy Affairs (OPA). To date, there has been no evidence of drug diversion or duplicate manufacturer's discounts on 340B drugs in the AMDP program.

HRSA, acting through OPA, is proposing new guidelines that would allow covered entities to utilize multiple contract pharmacy service sites and the utilization of a contract pharmacy to supplement in-house pharmacy services that were previously limited to approved AMDPs. This proposed change is due to the success of the AMDPs, and the urging of safety net providers who wish to utilize alternatives to the single entity site/single pharmacy location contractor model to provide broader access to 340B discounted drugs to eligible patient populations. Other than permitting these specified models, HRSA is not proposing other substantive changes to the contract pharmacy guidelines. The AMDP process will continue for those covered entities wishing to develop 340B networks of covered entities. OPA will continue to review the utilization of network demonstration projects and consider adapting the rules to include them in the future. Of particular importance is the continued requirement that appropriate procedures be in place to prevent diversion of 340B drugs or a duplicative 340B drug discount and a Medicaid rebate on the same drug, which are prohibited under the statute.

These proposed guidelines replace all sections of previous 340B Program guidance documents addressing non-network contract pharmacy services, including, but not limited to, the ''Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services,'' 61 FR

43549 and any individual correspondence issued by HRSA on the subject. Demonstration projects previously approved under the multiple contract pharmacy model, the supplement to in-house pharmacy model, or a combination of the two models when this Federal guidance goes into effect, would be governed by this guidance and would no longer be subject to expiration of AMDPs, interim reporting or annual audits currently mandatory for all demonstration projects (this guidance only applies to audits required under the AMDP and leaves unchanged audit requirements under any other authority or program). While annual audits will no longer be required to be provided to OPA annually, covered entities are required to maintain fully auditable records and OPA expects covered entities to include appropriate sampling of multiple contract pharmacy arrangements in the course of routine annual audits. Demonstration projects previously approved to utilize the network model would continue to be subject to all program requirements and conditions set up under the AMDP. Any covered entity wishing to utilize a network model would still be required to seek approval under the AMDP and may not do so without formal approval.

B. Contract Pharmacy Services Mechanism

(1) Basic Requirements for Utilization of Contract Pharmacy Arrangements

Covered entities that wish to utilize contract pharmacy services to dispense section 340B outpatient drugs must have a written contract in place between themselves and a pharmacy. This mechanism is designed to facilitate program participation for those covered entities that do not have access to available or appropriate ''in-house'' pharmacy services, those covered entities who have access to ''in-house'' pharmacy services but who wish to supplement these ''in-house'' services, and covered entities that wish to utilize multiple contract pharmacies to increase patient access to 340B drugs. The covered entity has the responsibility to: ensure against illegal diversion and duplicate discounts, maintain readily auditable records, and meet all other 340B Drug Pricing Program requirements. OPA has provided a model agreement format below as guidance for the type of contractual provisions expected in such agreements as well as suggested contract provisions in the Appendix. All covered entities utilizing a contract pharmacy must comply with the certification requirements described in (4) below.

(2) Potential Alternatives to Single Location, Single Pharmacy Model

In addition to contracting with a single pharmacy for each clinical site, covered entities may pursue more complex arrangements that include multiple pharmacies only if: (a) There is a written agreement and procedures meeting the basic requirements outlined in (1) above between the covered entity and each pharmacy; (b) the operation continues to meet all 340B Drug Pricing Program requirements and does not create unlawful diversion or duplicate discounts; and (c) the arrangements are one of the two following models individually or in combination: (i) The use of multiple contract pharmacy service sites, and/or (ii) the utilization of a contract pharmacy (ies) to supplement in-house pharmacy services. The use of multiple contract pharmacy service sites refers to any arrangement wherein a covered entity site seeks to provide drugs at 340B discounted prices for its patients at more than one pharmacy location. Supplementing in-house pharmacy services with a contract pharmacy refers to any arrangement wherein a covered entity site seeks to purchase drugs at 340B discounted prices for its patients at both an in-house pharmacy and at least one additional contract pharmacy location.

(3) Model Agreement Provisions

The following are suggested provisions for a model agreement:

(a) The covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price, pursuant to the terms of a HHS grant (if applicable) and any applicable state and local laws and consumer protection laws.

A ''ship to, bill to'' procedure is used in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity for the drug that it purchased, but ships the drug directly to the contract pharmacy (Section 1 of Appendix.) In cases where a covered entity has more than one site, it may choose between having each site billed individually or designating a single covered entity billing address for all 340B drug purchases.

(b) The contract pharmacy will provide comprehensive pharmacy services (e.g., dispensing, recordkeeping, drug utilization review, formulary maintenance, patient profile, patient counseling, and medication therapy management services). Each covered entity which purchases its covered outpatient drugs has the option of individually contracting for pharmacy services with a pharmacy(ies) of its choice.

(c) The covered entity health care provider will inform the patient of his or her freedom to choose a pharmacy provider. If the patient does not elect to use the contracted service, the patient may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice.

When a patient obtains a drug from a retail pharmacy other than a covered entity's contract pharmacy, the manufacturer is not required to offer this drug at the 340B price.

(d) The contract pharmacy may provide other services to the covered entity at the option of the covered entity (e.g., home care, delivery, reimbursement services). Regardless of the services provided by the contract pharmacy, access to 340B pricing will always be restricted to only patients of the covered entity.

(e) The contract pharmacy and the covered entity will adhere to all Federal, State, and local laws and requirements. Additionally, all HHS grantees, disproportionate share hospitals and FQHC Look-Alikes will adhere to all rules and regulations that apply to them as grantees or otherwise eligible entities.

Both the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties if the covered entity and/or the contract pharmacy violate Federal or State law. [The Department reserves the right to take such action as may be appropriate if it determines that such a violation has occurred.]

(f) The contract pharmacy will provide the covered entity with reports consistent with customary business practices (e.g., quarterly billing statements, status reports of collections and receiving and dispensing records). *See* Section 2 of Appendix.

(g) The contract pharmacy, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B drugs to individuals who are not patients of the covered entity. Customary business records may be used for this purpose. The covered entity will establish a process for a periodic comparison of its prescribing records with the contract pharmacy's dispensing records to detect potential irregularities. *See* Section 3 of Appendix.

(h) The covered entity and the contract pharmacy will develop a system to verify patient eligibility, as defined by HRSA guidelines.

Both parties agree that they will not resell or transfer a drug purchased at section 340B prices to an individual who is not a patient of the covered entity. *See* 42 U.S.C. 256a(a)(5)(B). The covered entity understands that it can be removed from the list of covered entities because of its participation in drug diversion and no longer be eligible for 340B pricing. *See* Section 4 of Appendix.

(i) Neither party will use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported to the Office of Pharmacy Affairs by the covered entity.

(j) Both parties understand that they are subject to audits (by the Department and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate discounts. *See* 42 U.S.C § 256a(a)(5).

The contract pharmacy will assure that all pertinent reimbursement accounts and dispensing records, maintained by the pharmacy, will be accessible separately from the pharmacy's own operations and will be made available to the covered entity, the Department, and the manufacturer in the case of an audit.

(k) Upon written request to the covered entity, a copy of this contract pharmacy service agreement will be provided to a participating manufacturer which sells covered outpatient drugs to the covered entity. All confidential or proprietary information may be deleted from the document.

(4) Certification

Under section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price. If the entity directs the drug shipment to its contract pharmacy(ies), we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance. However, the entity must comply, under any distribution mechanism, with the statutory prohibition on drug diversion and duplicate discounting.

To provide OPA and manufacturers with assurance that the covered entity has acted in a manner which limits the potential for drug diversion, the covered entity is required to submit to OPA a certification that it has signed and has in effect an agreement with the contract pharmacy(ies) containing the aforementioned provisions (see 3 above). However, if a covered entity wishes to utilize an agreement with provisions different from those listed above that it believes meets 340B requirements; OPA will review the proposed agreement provisions for sufficiency. The names of those covered entities which submit a certification, or an alternate mechanism approved by OPA, will be listed on the OPA Web site for the convenience of participating drug manufacturers and wholesaler distributors.

In addition, any covered entity that has opted to utilize any pharmacy arrangement described in (2) must specify which arrangement or combination of arrangements it is utilizing, the names and 340B identification numbers of all covered entities participating, and the names of any pharmacies participating.

(5) Anti-Kickback Statute

Contract pharmacies and covered entities should be aware of the potential for civil or criminal penalties if the contract pharmacy violates Federal or State law. In negotiating and executing a contract pharmacy service agreement pursuant to these guidelines, contract pharmacies and covered entities should be aware of and take into consideration the provisions of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. 1320a–7b(b). This statute makes it a felony for a person or entity to knowingly and willfully offer, pay, solicit, or receive remuneration with the intent to induce, or in return for the referral of, Medicare or a State health care program business. State health care programs are Medicaid, the Maternal and Child Health Block Grant program, and the Social Services Block Grant program. Apart from the criminal penalties, a person or entity is also subject to exclusion from participation in the Medicare and State health care programs for a knowing and willful violation of the statute pursuant to 42 U.S.C. 1320a–7(b)(7).

The anti-kickback statute is very broad. Prohibited conduct covers not only remuneration intended to induce referrals of patients, but also includes remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or a State health care program. The statute specifically identifies kickbacks, bribes, and rebates as illegal remuneration, but also covers the transferring of anything of value in any form or manner whatsoever. This illegal remuneration may be furnished directly or indirectly, overtly or covertly, in cash or in kind and covers situations where there is no direct payment at all, but merely a discount or other reduction in price or the offering of a free good(s).

Arrangements between contract pharmacies and covered entities that could violate the anti-kickback statute would include any situation where the covered entity agrees to refer patients to the contract pharmacy in return for the contract pharmacy or an entity owned or controlled by the contract pharmacy agreeing to undertake or furnish certain activities or services to the covered entity at no charge or at a reduced or below cost charge. These activities or services would include the provision of contract pharmacy services, home care services, money or grants for staff or service support, or medical equipment or supplies, or the remodeling of the covered entity's premises. For example, if a contract pharmacy agreed to furnish covered outpatient drugs in return for the covered entity referring its Medicaid patients to the contract pharmacy to have their prescriptions filled, the arrangement would violate the anti-kickback statute. Similarly, if the contract pharmacy agreed to provide billing services for the covered entity at no charge in return for the covered entity referring its patients to the contract pharmacy for home or durable medical equipment, the statute would be violated.

Pursuant to the authority in 42 U.S.C. 1320a–7b(b)(3), the Secretary of HHS has published regulations setting forth certain exceptions to the anti-kickback statute, commonly referred to as ''safe harbors.'' These regulations are codified at 42 CFR 1001.952. Each of the safe harbors sets forth various requirements which must be met in order for a person or entity to be immune from prosecution or exclusion under the safe harbors.

C. Appendix—Suggested Contract Provisions

(1) ''The covered entity owns covered drugs and arranges to be billed directly for such drugs. The pharmacy will compare all shipments received to the orders and inform the covered entity of any discrepancy within five (5) business days of receipt. The covered entity will make timely payments for such drugs delivered to the (pharmacy).''

(2) ''The covered entity will verify, using the contract pharmacy's (readily retrievable) customary business records, that a tracking system exists which will

ensure that drugs purchased under the 340B Drug Pricing Program are not diverted to individuals who are not patients of the covered entity. Such records can include: prescription files, velocity reports, and records of ordering and receipt. These records will be maintained for the period of time required by State law and regulations.''

(3) ''Prior to the contract pharmacy providing pharmacy services pursuant to this agreement, the covered entity will have the opportunity, upon reasonable notice and during business hours, to examine the tracking system. For example, such a tracking system may include quarterly sample comparisons of eligible patient prescriptions to the dispensing records and a six (6) month comparison of 340B drug purchasing and dispensing records as is routinely done in other reconciliation procedures. The contract pharmacy will permit the covered entity or its duly authorized representatives to have reasonable access to contract pharmacy's facilities and records during the term of this agreement in order to make periodic checks regarding the efficacy of such tracking systems. The contract pharmacy agrees to make any and all adjustments to the tracking system which the covered entity advises are reasonably necessary to prevent diversion of covered drugs to individuals who are not patients of the covered entity.''

(4) ''The pharmacy will dispense covered drugs only in the following circumstances: (a) Upon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient of the covered entity, and the signature of a legally qualified health care provider affiliated with the covered entity; or (b) receipt of a prescription ordered by telephone or other means of electronic transmission that is permitted by State or local law on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient. The covered entity will furnish a list to the pharmacy of all such qualified health care providers and will update the list of providers to reflect any changes. If a contract pharmacy is found to have violated the drug diversion prohibition, the contract pharmacy will pay the covered entity the amount of the discount in question so that the covered entity can reimburse the manufacturer.''

Dated: December 22, 2006.

Elizabeth M. Duke,

Administrator.

[FR Doc. E7–334 Filed 1–11–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of ''Patient''

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Section 602 of Public Law 102–585, the ''Veterans Health Care Act of 1992,'' enacted Section 340B of the Public Health Service (PHS) Act ''Limitation on Prices of Drugs Purchased by Covered Entities.'' Section 340B provides that in order to obtain Medicaid reimbursement for its covered outpatient drugs, a manufacturer must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price to covered entities for outpatient drugs that will not exceed an amount determined under a statutory formula. Section 340B is administered as the ''340B Drug Pricing Program'' and is commonly referred to as ''the 340B Program.''

Section 340B states that it is illegal for covered entities to sell medications purchased under the 340B Program to persons who are not considered ''patients'' of the covered entity. The purpose of this notice is to inform interested parties of proposed clarifications to the definition of ''patient'' for whom the covered entity can purchase discounted pharmaceuticals under the 340B Program. This clarification is necessary to protect the integrity of the 340B Program and to assist covered entities and other participants in their compliance efforts.

DATES: The public is invited to submit comments on the proposed guidelines by March 13, 2007. After consideration of the comments submitted, the Secretary will issue final guidelines.

ADDRESSES: Address all comments to Mr. Bradford R. Lang, Public Health Analyst, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mr. Jimmy Mitchell, Director, OPA, HSB, HRSA, 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857, or by telephone through the Pharmacy Services Support Center at 1–800–628–6297.

SUPPLEMENTARY INFORMATION:

Introduction

Section 340B(a)(4) of the PHS Act and section 1927(a) of the Social Security Act list the various types of organizations eligible to participate in and purchase discounted drugs under the 340B Program. Eligibility for participation in the 340B Program is strictly limited to the specific categories of entities specified in these statutes.

Section 340B(a)(5)(B) of the PHS Act prohibits entities from selling (or otherwise transferring) drugs purchased under the 340B Program to anyone who is not a patient of the covered entity. Responsibility for ensuring compliance with this provision rests with the covered entity. Congress did not define the term ''patient'' in Section 340B, and initial HRSA guidelines implementing the 340B Program directed covered entities to ''develop and institute adequate safeguards to prevent the transfer of discounted outpatient drugs to individuals who are not eligible for the discount'' in order to prevent diversion. To accomplish this, entities were encouraged to utilize a separate purchasing account and separate dispensing records (See 59 FR 25110).

As covered entities, manufacturers, and others began to implement the 340B Program, it became apparent that additional clarification of the patient definition was needed and on October 24, 1996, HRSA issued additional guidelines regarding the definition of a covered entity ''patient'' (61 FR 55156). These guidelines stated that the following definition of patient would apply for the purposes of the 340B Program:

An individual is a ''patient'' of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:

1. *The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and*

2. *The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity; and*

3. *The individual receives a health care service or range of services from the covered entity which is consistent with the service or*

range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

An individual will not be considered a ''patient'' of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self administration or administration in the home setting.

An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under Title XXVI of the PHS Act will be considered a ''patient'' of the covered entity for purposes of this definition if so registered as eligible by the State program. (61 FR 55157–8).

The definition of a ''patient'' was developed in order to identify those individuals eligible to receive 340B drugs from covered entities. Because of the large number of covered entities and the wide diversity of eligible groups (e.g., comprehensive hemophilia treatment centers, HIV/AIDS programs funded through the Ryan White CARE Act, black lung clinics, consolidated health centers, Disproportionate Share Hospitals (DSH), and Title X clinics), it was essential that HRSA work closely with each Federal program office to develop a definition flexible enough to describe accurately each covered entity's patients.

As of October 1, 2005, participation in the 340B Program has grown to more than 12,000 entities. Through covered entity networking, contracting, and other arrangements, additional questions about the definition of a 340B patient have arisen. HRSA believes that the existing patient definition provides sufficient guidance to answer many of these questions. However, it is possible that some 340B covered entities may have interpreted the definition too broadly, resulting in the potential for diversion of medications purchased under the 340B Program. Therefore, HRSA finds it necessary to issue this Notice, and to include several examples that further illustrate the guidance. While similar to the existing patient definition, this clarification provides covered entities with more explicit guidance regarding the relationship between a covered entity and an individual that makes that individual a ''patient'' of the covered entity.

Related to the definition of a ''patient'' is the question of which entities are eligible to provide 340B drugs. HRSA has been receiving an increasing number of questions specifically related to which entities qualify for inclusion in the 340B Program under Section 340B(a)(4)(L) of the PHS Act. HRSA invites comments with respect to which elements should be required in private non-profit hospitals' contracts with State or local governments ''to provide health care services to low income individuals who are not entitled to benefits under Title XVIII of the Social Security Act or eligible for assistance under the State plan * * * '' under Section 340B(a)(4)(L)(i) of the PHS Act. HRSA is also seeking comments regarding the different situations where private, non-profit hospitals are formally granted government powers under Section 340B(a)(4)(L)(i) of the PHS Act.

Final guidelines will replace all previous 340B Program guidance addressing the definition of a patient, including, but not limited to, the ''Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility,'' 61 FR 55156 and any individual correspondence issued by HRSA on the subject.

Definition of a Patient

Under these proposed guidelines, the criteria determining whether an individual is a ''patient'' of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) are:

1. The covered entity has established responsibility for the outpatient health care services it provides to the individual, such that the covered entity maintains ownership, control, maintenance, and possession of records of the individual's health care, including records that appropriately document health care services that result in the use of, or prescription for, 340B drugs;

2. The individual receives outpatient health care services that result in the use of, or a prescription for, 340B drugs as part of the diagnosis and treatment from a health care provider who is employed by the covered entity, or provides health care to patients of the covered entity under a valid, binding, and enforceable contract. If the individual received health care services from a health care provider employed by or under contract with the covered entity, then the individual may be referred for followup care for the same condition by that health care provider, to an outside health care provider and still remain a patient of the covered entity for purposes of this guidance, so long as ongoing responsibility for the outpatient health care service that results in the use of (or prescription for) 340B drugs, remains with the covered entity; and

3. The outpatient health care services the individual receives from the covered entity that result in the use of, or prescription for, 340B drugs are:

a. Part of a health care service or range of services for which grant funding or Federally-Qualified Health Center look-alike status has been provided to the covered entity; or

b. Provided by a Disproportionate Share Hospital (DSH) or by a location that qualified as a provider-based facility within a DSH under 42 CFR 413.65. If the individual received care from such DSH or qualifying provider-based facility, then the individual may be referred for followup care for the same condition by such a health care provider to an outside health care provider and still remain a patient of the covered entity for purposes of this rule, so long as the covered entity (either the DSH or a qualified provider-based facility) retains ongoing responsibility for the outpatient health care service that results in the use of (or prescription for) 340B drugs. To demonstrate the necessary retention of ongoing responsibility for the health care it is expected that, at a minimum, the covered entity will provide health care to the individual in the DSH or the qualified provider-based facility of the DSH within 12 months after the time of referral.

The individual's health care relationship with the covered entity is the most important factor in determining whether an individual satisfies the criteria above. For a prescription to qualify under 340B, the covered entity must be primarily responsible for the health care which results in the use of, or prescription for 340B drugs. An individual will not be considered a ''patient'' of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self administration or administration in the home setting. An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under Title XXVI of the PHS Act will be considered a ''patient'' of the covered entity for purposes of this definition if so registered as eligible by the State program.

The first criterion of the patient definition above requires covered entities to establish a relationship with each individual such that the covered entity maintains records of the individual's health care. The covered entity will document in the individual's health care records the health care service provided and the drugs

prescribed or used in the covered entity for this individual. A shared electronic record where several parties have access and ability to add/edit the records from their physical location would satisfy the requirements of the 340B Program guidelines, as long as the covered entity maintains control, ownership, maintenance, and possession of the individual's health care record. Mere contractual right to obtain records from a health care provider, without actual control and maintenance of the record, would not satisfy the requirements of the 340B Program.

The second criterion of the patient definition requires that the responsibility for the health care services that result in the use of, or prescription for, 340B drugs remains with the covered entity. Where a referral is utilized for specialty health care, in order to result in a valid 340B prescription, the referral must be for followup care for the same condition and must originate from a health care provider who is employed by or under a valid, binding, and enforceable contract with the covered entity which retains ongoing responsibility for the health care and treatment of the individual.

For the purpose of this guidance, the provision of administrative services alone, such as case management services from someone other than a health care provider, is not sufficient to demonstrate the necessary health care services set forth in the definition above. The statute requires that 340B drugs be provided for the patients of the covered entity, as opposed to offering other services to individuals who are patients of health care providers who are not part of a covered entity as defined in the statute. In cases where an individual has received health care services from a non-covered entity resulting in a prescription, the administrative act of recording such information, incorporating it into the health record, and filling the prescription does not constitute health care services for the patient's health care for purposes of the 340B Program.

To demonstrate responsibility for the health care that results in the use of, or prescription for 340B drugs, health care must be provided by the covered entity through health care providers who meet the second criterion and who have the capacity and authority to issue the 340B prescription. Mere acceptance *pro forma* or rubberstamping of an outside health care provider's diagnosis or medical opinion does not demonstrate such responsibility. While the health care providers of the covered entity can take into account the diagnosis and prescription of other health care providers, they must exercise their own judgment in taking responsibility for their own patients.

The third criterion of the patient definition above requires that 340B drugs be prescribed only in conjunction with outpatient services. Furthermore, subsection (a) clarifies that the provision of 340B drugs must fall within the scope of the grant funding or Federally Qualified Health Center look-alike status which forms the basis for the eligibility of the covered entity to participate in the 340B Program.

Subsection (b) of the third criterion likewise provides clarification for DSHs that the use of, or prescription for, 340B drugs must be within the scope of the basis for including such institutions in the 340B Program. In order for an outpatient facility of a DSH to be eligible for the 340B Program, it must be demonstrated that the outpatient facility is an integral part of the DSH. HRSA has chosen to rely on the category of provider-based facilities as set forth by the Centers for Medicare and Medicaid Services (CMS) under Title XVIII of the Social Security Act (Medicare). This decision has been made because HRSA believes that the requisite integration of facilities necessary to demonstrate that the secondary facility is functioning as part of the DSH under 42 CFR 413.65 is appropriate for facilities eligible under the 340B Program. Compliance with the rule for provider-based facilities would provide clear guidance to DSHs that wish to prescribe 340B drugs to patients at these outpatient facilities and ensure that the individuals are truly patients of the DSH. Ultimately the facility's provider-based status must be reflected in the covered entity's Medicare Cost Report. The covered entity may provide a copy of the attestation provided to its fiscal intermediary pursuant to 42 CFR 413.65 to demonstrate compliance with this guideline until such time as the facility is listed on the DSH's Medicare Cost Report. The DSH shall retain the responsibility to promptly notify the OPA in the event that the outpatient facility's provider-based status is rejected or otherwise called into question.

Examples

The following examples describe the issues that HRSA has identified as problematic and the relationships that do not meet the definition of ''patient'' for purposes of compliance with the 340B Program guidelines.

Example 1: Certain Case Management Constructs

HRSA has become aware that some covered entities may be using case management arrangements that inappropriately expand their ''patient'' populations, diverting 340B drugs to individuals who are not eligible patients of the 340B covered entity. In some cases, the covered entities claim to provide the requisite ''health care services'' through a third party that operates through a case management construct or call center. Although the covered entity may retain records of the encounters, supervise personnel, oversee billing, payment, and other administrative tasks in the program, the covered entity is not providing the actual outpatient health care services that can be linked to the prescriptions written for the individuals in question.

An individual whose sole relationship with a covered entity is through case management services or other administrative measures, not accompanied by actual medical services from a health care provider that meets criterion 2, would not be considered a patient of the covered entity eligible to receive 340B drugs.

Example 2: Loose Affiliation Networks

Some DSHs have been contracting with health care providers to create a loose affiliation model for outpatient health care services. The individuals, receiving services from affiliated health care providers, have been filling prescriptions written by these health care providers with 340B drugs. The ''contracts'' are often simple, one-page documents that do not create contractually enforceable duties or obligations for either the health care provider or covered entity. These affiliation models claim to meet the patient definition by specifying that the individual's health care records would be available at the covered entity, that ''responsibility for the patient'' would also reside with the covered entity, and that in some instances, individuals would be seen by a case manager at the covered entity at specified intervals.

Under this model, the services being provided directly by the covered entity are often more appropriately characterized as administrative services rather than health care services. Ultimately, the treatment plan followed is determined by the affiliated health care provider and not the covered entity. The ongoing responsibility for the individual's health care resides with the affiliated health care provider and not the covered entity. The individuals enrolled in these programs are treated

by health care providers too loosely affiliated with the covered entity for the ongoing responsibility to rest with the covered entity for the patient's health care resulting in the use of, or prescription for, 340B drugs.

This model improperly seeks to expand the definition of a patient beyond that envisioned by Congress in prohibiting the resale of 340B drugs outside the eligible covered entity limits. In particular, HRSA is concerned that the affiliation model extends the ability of covered entities to purchase 340B drugs for individuals who are not receiving healthcare from a health care provider employed by or having a valid, binding, and enforceable contract with the covered entity. In the DSH context, since such affiliated healthcare providers may have privileges without actually being required to provide health care services at the DSH, HRSA believes that it is reasonable to require that either the prescribing, or the referring, health care provider be employed by or have a valid, binding, and enforceable contract with the covered entity to provide outpatient medical care to patients of the DSH.

Example 3: Provider-Based Designations

HRSA is concerned that a number of DSHs may be attempting to expand their eligible facilities to include locations that are not integrated parts of the qualifying DSH. As noted above, HRSA has chosen to rely on a location's status as a provider-based facility as provided under 42 CFR 413.65 to demonstrate that the secondary facility is functioning as part of the DSH. While HRSA is aware of the 35 mile distance exemption that exists for certain 340B-DSHs under 42 CFR 413.65(e)(3)(i), these DSH provider-based facilities remain subject to the other requirements as set forth in 42 CFR 413.65. This requirement also applies to nursing home facilities, rehabilitation hospitals, hospice, and home health agencies. Please note that even if these facilities qualify as part of the DSH, only patients receiving outpatient health care services in these facilities would be eligible to receive 340B drugs. In addition, if HRSA suspects that these entities are being improperly designated as provider-based facilities, HRSA will decline to add the facilities to the HRSA 340B database of covered entities until it has received portions of the Medicare Cost Report demonstrating provider-based status and/or the attestation of provider-based status the covered entity provides to its fiscal intermediary pursuant to 42 CFR 413.65. Likewise, if HRSA discovers that certain covered entities may have improperly listed facilities on the 340B database with the implication that they are provider-based, HRSA will request the covered entity to provide the relevant portions of the Medicare Cost Report and/or attestation within 45 days to verify the facility's provider-based status and to verify that such health care services are being provided on an outpatient basis. If HRSA does not receive appropriate documentation to verify provider-based status within this time period, it will remove the facility from the 340B covered entity database. The covered entity shall be required to notify HRSA immediately if its provider-based status has been rejected or questioned by CMS or its fiscal intermediary. In cases where provider-based status has been rejected, the facility will be removed from the 340B covered entity database immediately.

Example 4: Employees

HRSA receives many questions about whether employees of a covered entity are ''patients'' for purposes of the 340B Program. These questions come from covered entities that provide health care coverage to employees under their own self-insured health plan, and those whose employees have third party health coverage as an employment benefit. Employees of a covered entity, regardless of their health care coverage, are not considered patients of the covered entity for the purpose of the 340B Program unless they receive health care from a provider employed by or under contract with the covered entity. The fact that the person is an employee of the covered entity, or that they receive health care benefits from their covered entity-employer is not relevant. The relevant circumstance is that the employee is a patient of the covered entity. If an employee is a patient of another provider in the community, and is referred to and receives health care from the covered entity, they can receive 340B drugs only if the other provisions of the patient definition are met. Where a covered entity operates a self-insured health plan, the covered entity retains the requisite responsibility for the individual as a patient only if the individual receives outpatient health care services under the terms of this notice. Responsibility for the patient does not extend to cover the individual if the covered entity's sole responsibility for the individual is as the administrator of its self-insured plan. Meeting administrative requirements for maintaining employee health records so as to ensure that the employees are compliant with both State and Federal health care provider regulations alone, is not sufficient for the purpose of establishing patient eligibility for the 340B Program. Rather, the covered entity must provide health care to these individuals that results in the use of, or prescription for, 340B drugs. Furthermore, employees who merely receive required health physicals as a condition of their employment by a covered entity with no other health care provided are not patients of the covered entity.

Example 5: Indian Tribes and Tribal Organizations

In the case of Indian tribes or tribal organizations, any attempt to serve non-Indian Health Service beneficiaries must receive prior formal approval by the Indian Health Service.

Example 6: Grantee Subgrantees and Subcontractors

In certain circumstances, organizations may be functioning as subgrantees to grantees who are eligible to purchase 340B drugs (section 340B(a)(4) of the PHS Act). In these situations, subgrantees are reminded that they must meet the standards set forth in 45 CFR Part 74 and 45 CFR Part 92, as applicable. As subgrantees of a covered entity's grant, these organizations are eligible to access 340B drugs for only those patients to whom they are providing health care services under the scope of their subgrant. In these instances, individuals may only receive 340B drugs for the pharmaceuticals utilized under the scope of the project for which grant funds were received by the subgrantee. Subgrantees must register with HRSA in order to participate in the 340B Program and must be listed in the HRSA 340B database of covered entities to purchase 340B drugs.

Subgrantees must maintain information systems that permit them to segregate the 340B eligible patient population from the rest of their patients, and to order 340B drugs only for 340B eligible patients.

If an entity is a subcontractor of a covered entity, rather than a subgrantee, all 340B drugs must be purchased by the covered entity. The covered entity, in turn, must maintain records documenting its purchase of 340B drugs for its subcontractors. Both the covered entity and the subcontractor would be responsible for ensuring the 340B drugs were ordered only for the portion of the subcontract which is within the scope of a covered entity's grant.

Dated: December 22, 2006.

Elizabeth M. Duke,

Administrator.

[FR Doc. E7–335 Filed 1–11–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Macrocyclic Grb2 SH2 Domain-Binding Inhibitors: New Anti-Cancer and Anti-Angiogenic Therapeutic Agents

Description of Technology: Growth factor receptor bound 2 (Grb2) SH2 domain is involved in signaling events leading to a variety of proliferative diseases including erb-2 dependent breast cancers and c-met dependent renal cancers. Inhibiting the Grb2 SH2 domain binding has great potential therapeutic utility in the treatment of certain cancers.

This technology discloses the design and synthesis of new macrocyclic inhibitors of Grb2 SH2 domain binding. More specifically, a simple synthetic approach using upper achiral junctions has been utilized that does not require complex stereoselective synthesis. These new series of compounds have synthetic advantage over similar macrocyclic compounds and retain good binding affinity towards Grb2 SH2 domain.

Applications and Modality: (1) New macrocyclic inhibitors of Grb2 SH2 domain binding; (2) New compounds have good binding affinity for Grb2 SH2 domain and can be potential anti-cancer and anti-angiogenic agents; (3) Utilization of simple achiral upper ring junctions that do not require complex stereoselective synthesis; (4) New compounds have synthetic advantage over more structurally complex inhibitors.

Market: (1) In 2006, receptor tyrosine kinase inhibitor drug sales were estimated at more than $1B dollars; (2) In 2006, cancer drug sales were estimated to be $25 billion.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Terrence R. Burke Jr. and Fa Liu (NCI)

Relevant Publications:

1. F Liu *et al.* Utilization of achiral alkenyl amines for the preparation of high affinity Grb2 SH2 domain-binding macrocycles by ring-closing metathesis. Org. Biomol. Chem. 2007;5:367–372.
2. N Atabey *et al.* Potent blockade of hepatocyte growth factor-stimulated cell motility, matrix invasion and branching morphogenesis by antagonists of Grb2 Src homology 2 domain interactions. J. Biol. Chem. 2001 Apr 27;276(17):14308–14314.
3. C–Q Wei *et al.* Macrocyclization in the design of Grb2 SH2 domain-binding ligands exhibiting high potency in whole cell systems. J. Med. Chem. 2003 Jan 16;46(2):244–254.

Patent Status: U.S. Provisional Application No. 60/867,307 filed 27 Nov 2006 (HHS Reference No. E–305–2006/0–US–01)

Licensing Status: Available for exclusive and non-exclusive licensing.

Licensing Contact: Adaku Madu, J.D.; 301/435–5560; *madua@mail.nih.gov*

Collaborative Research Opportunity: The National Cancer Institute Laboratory of Medicinal Chemistry is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize macrocyclic Grb2 SH2 domain-binding antagonists. Please contact John D. Hewes, Ph.D. at 301/435–3121 or *hewesj@mail.nih.gov* for more information.

Cyclic Phosphopeptide Inhibitors of Protein Phosphatase 2C Delta, Wip1

Description of Technology: Wip1 (PP2Cdelta or PPM1D) is a protein phosphatase 2C (PP2C) family member that negatively regulates the p38 MAP kinase pathway. By dephosphorylating p38 kinase, p38 is unable to activate the p53 pathway; this prevents p53-mediated cell-cycle arrest and apoptosis, suggesting that Wip1 overexpression and over-activity may have implications during oncogenesis. Significantly, Wip1 is overexpressed in several human cancers, including breast cancer, ovarian clear cell adenocarcinoma and neuroblastomas. Thus, inhibitors of Wip1 may have promise as anti-cancer therapeutics. Unfortunately, no specific inhibitors have been designed to show proof of this concept.

The instant technology involves the development of specific peptides for the inhibition of the Wip1 catalytic site. The inventors have modified the optimal Wip1 substrate sequence in such a manner that it successfully inhibits Wip1 activity. Importantly, the peptide effectively inhibited Wip1 without significantly affecting the activity of other PP2C family members. Thus, this compound has potential for examination as an anti-cancer agent.

Claims in this technology are directed to compositions comprising the Wip1 inhibitors, as well as methods of using the inhibitors to inhibit Wip1 activity in a cell.

Application: The inhibitors can be developed as anti-cancer therapeutics.

Market: The cancer therapeutic market is expected to reach $27 billion by 2009.

Development Status: The technology is at the pre-clinical stage. Optimization of the peptide sequence for delivery and efficacy, as well as the design of mimetics, are contemplated for further development.

Inventors: Ettore Appella, Stewart R. Durell, Hiroshi Yamaguchi, Yawen Bai (NCI), *et al.*

Publications:

1. H Yamaguchi *et al.* Substrate specificity of the human protein phosphatase 2Cdelta, Wip1. Biochemistry 2005 Apr 12;44(14):5285–5294.
2. DV Bulavin *et al.* Inactivation of the Wip1 phosphatase inhibits mammary tumorigenesis through p38 MAPK-mediated activation of the p16(Ink4a)-p19(Arf) pathway. Nat Genet. 2004 Apr;36(4):343–350.
3. H Yamaguchi *et al.* Development of substrate-based cyclic phosphopeptide inhibitor of protein phosphatase 2Cdelta, Wip1. Biochemistry 2006 Nov 7;45(44):13193–13202.
4. S Shreeram *et al.* Regulation of ATM/p53-dependent suppression of myc-induced lymphomas by Wip1 phosphatase. J. Exp. Med. 2006 Dec 25;203(13): 2793–2799.

Patent Status: U.S. Provisional Application No. 60/850,218 filed 06 Oct 2006 (HHS Reference No. E–288–2006/0-US–01) Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: David Lambertson, PhD; 301/435–4632; *lambertsond@od.nih.gov*

Collaborative Research Opportunity: The NCI CCR, LCB is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Cyclic Phosphopeptide Inhibitors of Protein Phosphatase 2C Delta, Wip1. Please contact John D. Hewes, Ph.D. at 301/435–3121 or *hewesj@mail.nih.gov* for more information.

New Tumor Endothelial Markers: Genes That Distinguish Physiological and Pathological Angiogenesis

Description of Technology: Angiogenesis, the formation of new blood vessels, is associated with normal physiological processes such as wound healing, ovulation or menstruation as well as with many diseases. Presently, it is thought to be required for the progressive growth of solid tumors and age-related macular degeneration. Lack of disease-specific endothelial markers has hindered the development of cancer therapies targeted against angiogenesis.

This invention describes specific markers that can be used to identify tumor angiogenesis, separate from normal physiological angiogenesis. Several markers have been identified which may serve as potential targets for tumor vessels by using comparative gene expression analysis on various normal and tumor endothelial cells. Furthermore, the invention describes several organ-specific endothelial markers that can aid in the selective delivery of molecular medicine to specific sites. For example, brain endothelial markers (BEMs) and liver endothelial markers (LEMs) described herein could potentially be used to direct molecular medicine specifically to these tissues.

The novel tumor endothelial markers (TEMs) described in this invention also have potential diagnostic ability. These markers can be used to distinguish between normal and tumor tissues. Some of the secreted TEMs can serve as surrogate markers in the determination of the optimum biological dose (OBD) for the current anti-angiogenic drugs in clinical trials.

Applications and Modality: (1) Novel therapeutic targets associated with tumor vessels; (2) New agents can be developed against these novel targets; (3) Novel endothelial markers that distinguish pathological angiogenesis from normal physiological angiogenesis; (4) Surrogate tumor endothelial markers that can be used to determine optimal biological dose (OBD) of anti-angiogenic drugs.

Market: (1) Sales of the first FDA approved anti-angiogenic drug Avastin™ has reached $600 million; (2) Another promising anti-angiogenic molecule, Thalidomide™, has been approved as an anti-cancer agent and for other use in Europe and Australia.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Brad St.Croix and Steven Seaman (NCI)

Relevant Publication: A Nanda and B St. Croix. Tumor endothelial markers: new targets for cancer therapy. Curr Opin Oncol. 2004 Jan;16(1):44–49.

Patent Status: U.S. Provisional Application No. 60/858,068 filed 09 Nov 2006 (HHS Reference No. E–285–2006/0-US–01) Licensing Status: Available for exclusive and non-exclusive licensing.

Licensing Contact: Adaku Madu, J.D.; 301/435–5560; *madua@mail.nih.gov*

Collaborative Research Opportunity: The NIH National Cancer Institute, Tumor Angiogenesis Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize specific biomarkers that can be used to identify tumor angiogenesis. Please contact John D. Hewes, PhD at 301/435–3121 or *hewesj@mail.nih.gov* for more information.

A New Method for Improving the Therapeutic Efficacy of L-Asparaginase in Multiple Types of Cancer

Description of Technology: For the last several decades, L-asparaginase (L-ASP) has been widely used as a clinical treatment for leukemias. Studies show that cancer cells that contain less asparagine synthetase (ASNS) are more susceptible to L-ASP. The response to L-ASP therapy is often better when the expression of ASNS is limited.

The present invention describes a new method for enhancing L-ASP activity by combining it with antagonists of ASNS—such as siRNAs, antisense nucleotides, antibodies or small-molecule inhibitors—for treatment of cancers. Reducing or suppressing the expression of ASNS potentiates the growth inhibitory activity of L-ASP.

Additionally, the invention discloses a novel biomarker screening tool to identify leukemia, ovarian, and other cancer patients that would be most likely to respond to L-ASP treatment.

Applications and Modality: A new method for improving the therapeutic efficacy of L-asparaginase.

ASNS antagonists such as siRNA, antibodies, antisense nucleotides, or small-molecule inhibitors can potentially be used in combination with L-ASP in the treatment of cancers.

ASNS gene or protein expression can serve as a therapeutic response biomarker for personalization of cancer therapy with the aforementioned combinations.

Market: There were more than 500,000 deaths from cancer in 2006. The current technology has the potential of being used in conjunction with L–ASP in treating cancer patients.

Oncaspar™, the PEG-derivitized L-ASP developed by Enzon Pharmaceuticals, registered annual sales of about $25 million in 2006, largely on the basis of treatment of acute lymphoblastic leukemia. The present invention may make L–ASP applicable to treatment of types of cancers that are much more common.

Development Status: The technology is currently in the pre-clinical stage of development. With respect to L–ASP treatment of patients with solid tumors, Phase I clinical trials have been initiated (Principal Investigator Daniel D. Von Hoff, TGen, Inc.) at three institutions using L–ASP in combination with gemcitabine.

Inventors: Philip L. Lorenzi, *John N. Weinstein* and *Natasha J. Caplen* (NCI)

Publication: PL Lorenzi *et al.* Asparagine synthetase as a causal, predictive biomarker for L-asparaginase activity in ovarian cancer cells. Mol Cancer Ther. Nov; 5(11):2613–2623. Epub 2006 Nov 6, doi 10.1158/1535–7163.MCT–06–0447.

Patent Status: U.S. Provisional Application No. 60/779,143 filed 03 Mar 2006 (HHS Reference No. E–132–2006/0–US–01); U.S. Provisional Application No. 60/833,027 filed 25 Jul 2006 (HHS Reference No. E–132–2006/0–US–02).

Licensing Status: Available for exclusive and non-exclusive licensing.

Licensing Contact: Mojdeh Bahar, J.D.; 301/435–2950, *baharm@mail.nih.gov*

Collaborative Research Opportunity: The National Cancer Institute's Genomics & Bioinformatics Group in the Laboratory of Molecular Pharmacology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the combination therapies described in this abstract. Please contact John D. Hewes, Ph.D. at 301/435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: November 8, 2007.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E7–349 Filed 1–11–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

In Vivo Assessment of Tissue Microstructure and Microdynamics: Estimation of the Average Propagator From Magnetic Resonance Data

Description of Technology: This invention relates to diffusion-weighted magnetic resonance imaging (DW–MRI) and describes a novel method for estimating the 3–D average propagator from DW–MRI data. The average propagator measures the probability that water molecules move from one place to another during a given diffusion time. This quantity provides local information about the tissue microstructure and the microenvironment in which water diffuses without making any *a priori* assumptions about the underlying diffusion process itself. Several methods, such as 3D q-space magnetic resonance imaging (MRI) and diffusion spectrum imaging have been developed to measure the average propagator, but these techniques currently require acquisition of large numbers of DW images, making them infeasible for routine animal and clinical imaging. The proposed methodology introduces a new data reconstruction concept, which involved using computer tomography (CT) algorithms to estimate the average propagator from the MR data. The proposed CT reconstruction requires many fewer DW–MRI data than conventional methods consistent with a clinically feasible period of MR image acquisition. The novel technique can be used to diagnose medical disorders that are associated with alterations in water diffusion, such as stroke and several neurodegenerative diseases and other disorders for which diffusion tensor MRI is currently used. Additional applications include drug development (screening drug candidates), material science (testing the quality of materials that have restricted and hindered compartments, e.g. porous media, gels and films) and food processing (testing structural changes in food).

Applications: In vivo Functional MRI of humans and animals; Drug development; Material science; Food processing.

Development Status: Early stage; only testing using fixed tissues and numerical phantoms have been performed at this time.

Inventors: Peter J. Basser and Valery Pickalov (*NICHD*).

Patent Status: U.S. Patent Application No. 11/407,096 filed 20 Apr 2006 (HHS Reference No. E–164–2006/0–US–01).

Licensing Status: Available for non-exclusive or exclusive licensing, as well as for collaborative research, provided that non-disclosure agreements and MTAs have been executed.

Licensing Contact: Chekesha S. Clingman, Ph.D.; 301/435–5018; *clingmac@mail.nih.gov.*

Collaborative Research Opportunity: The NICHD Laboratory of Integrative and Medical Biophysics, Section on Tissue Biophysics and Biomimetics, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Peter J. Basser, Ph.D. at *pjbasser@helix.nih.gov* for more information.

Fast Electron Paramagnetic Resonance Imaging (EPRI) Using CW–EPR Spectrometer With Sinusoidal Rapid-Scan and Digital Signal Processing

Description of Technology: Electron Paramagnetic Resonance (EPR) Imaging is an indispensable tool that may be applied to a variety of disciplines for evaluation of chemical species having unpaired electrons such as free radicals and transition metal ions. In Continuous Wave (CW)–EPR the sample is continuously irradiated with weak RF radiation while sweeping the magnetic field relatively slowly. Existing CW–EPR techniques utilize a signal detection method known as phase-sensitive detection which results in data acquisition times that are too long for *in vivo* applications. The present technology represents significant improvements on conventional CW–EPR.

The subject technology includes three approaches to collecting image data with increased spatial, temporal and spectral resolution and improved sensitivity. Spectral data acquisition is performed by a direct detection strategy involving mixing a signal to base-band and acquiring data with a fast-digitizer. Projection data is acquired using a sinusoidal magnetic field sweep under gradient magnetic fields. Data collection times are decreased with the utility of rotating gradients. Further, the current technology improves sensitivity by employing Digital Signal Processing, which decreases background analog noise.

Increased speed and sensitivity makes CW–EPR a potentially useful and complementary tool to Magnetic Resonance Imaging for *in vivo* imaging. The presently described improvements to CW–EPR will allow changes of blood perfusion and oxygenation in tumors to be observed in nearly real-time, while improved resolution will permit angiogenesis in and around tumors to be carried out in a non-invasive manner. Additionally, rapid scan imaging provides excellent temporal resolution and will help quantify pharmaco-kinetics and metabolic degradation kinetics of bioactive free radicals.

Applications: (1) Enhanced spatial, temporal, and spectral resolution of Continuous Wave-Electron Paramagnetic Resonance Imaging; (2) Real-time assessment of changes in blood perfusion and oxygenation.

Development Status: Preliminary experiments have been conducted and the technology has been tested for feasibility.

Inventors: Sankaran Subramanian, Nallathamby Devasahayam, Janusz Koscielniak, *James Mitchell,* and *Murali Krishna* (NCI).

Publication: S Subramanian, JW Koscielniak, N Devasahayam, RH Pursley, TJ Pohida, TJ Pohida, MC Krishna. A new strategy for fast radiofrequency CW–EPR imaging: Direct detection with rapid scan and rotating gradients. Submitted to Journal of Magnetic Resonance for publication.

Patent Status: U.S. Provisional Application No. 60/818,052, filed 30 Jun 2006 (HHS Reference No. E–221–2005/0–US–01).

Licensing Status: Available for non-exclusive or exclusive licensing and commercial development.

Licensing Contact: Chekesha S. Clingman, PhD; 301/435–5018; *clingmac@mail.nih.gov.*

Collaborative Research Opportunity: The Radiation Biology Branch, National Cancer Institute, NIH, Bethesda, MD is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the above Rapid scan-Rotating gradients strategy for performing routine *in vivo* Radiofrequency CW–EPR imaging in small animals. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: January 5, 2007.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E7–350 Filed 1–11–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Conference Grants (R13).

Date: January 24, 2007.

Time: 8 a.m. to 9 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference).

Contact Person: Valerie L. Prenger, PhD, Scientific Review Administrator, Review Branch, Room 7214, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, MSC 7294, Bethesda, MD 20892–7294, (301) 435–0270, *prengerv@nhibi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Shared Resource Grant (R24).

Date: January 25, 2007.

Time: 3 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Shelley S. Sehnert, PhD, Scientific Review Administrator, Review Branchy, NIH/NHLBI, 6701 Rockledge Drive, Room 7206, Bethesda, MD 20892–7294, (301) 435–0303, *ssehnert@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 8, 2007.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–101 Filed 1–11–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Nursing Research Initial Review Group.

Date: March 5–6, 2007.

Time: 8:15 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza Hotel, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Jeffrey M. Chernak, PhD, Scientific Review Administrator, Office of Review, National Institute of Nursing Research, 6701 Democracy Plaza, Suite 710, MSC 4870, Bethesda, MD 20892, (301) 402–6959, *chernak@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: January 8, 2007.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–98 Filed 1–11–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2) notice is hereby given of a meeting of the National Advisory Environmental Health Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Environmental Health Sciences Council.

Date: February 15, 2007.

Open: 8:30 a.m. to 1 p.m.

Agenda: Discussion of program policies and issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: 1 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Open: 2:30 p.m. to 5 p.m.

Agenda: Discussion of program policies and issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Contact Person: Dennis R. Lang, PhD, Acting Director, Division of Extramural Research and Training, Nat. Inst. of Environmental Health Sciences, National Institutes of Health, P.O. Box 12233/EC–3431, 79 Alexander Drive, Research Triangle Park, NC 27709, (919) 541–7729, *lang4@niehs.nih.gov*.

Information is also available on the Institute's/Center's home page: *http://www.niehs.nih.gov/dert/c-agenda.htm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: January 8, 2007.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–99 Filed 1–11–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group, Clinical Trials Review Committee.

Date: February 26–27, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Intercontinental Harbor Courtyard Baltimore, 550 Light Street, Baltimore, MD 20202.

Contact Person: Patricia A. Haggerty, PhD, Section Chief, Clinical Studies and Training Scientific Review Group, Review Branch, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, NIH, 6701 Rockledge Drive, Room 7194, MSC 7924, Bethesda, MD 20892, 301/435–0288, *haggertp@nhlbi.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 4, 2007.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–97 Filed 1–11–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Biodegradable Stents.

Date: February 13, 2007.

Time: 2 p.m. tp 3 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Youngsuk Oh, Scientific Review Administrator, National Heart, Lung, and Blood Institute, Two Rockledge Centre, Room 7182, 6701 Rockledge Drive, Bethesda, MD 20817, 301–435–0273, *yoh@mail.nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, VAD Technologies.

Date: February 20, 2007.

Time: 2 p.m. to 3 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Youngsuk Oh, Scienfic Review Administrator, National Heart, Lung, and Blood Institute, Two Rockledge Centre, Room 7182, 6701 Rockledge Drive, Bethesda, MD 20817, 301–435–0273, *yoh@mail.nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Modified Hemoglobin Production.

Date: February 23, 2007.

Time: 8:30 a.m. to 3 p.m.

Agenda: To review and evaluate contract proposals.

Place: Embassy Suites Hotel Washington Covention Ctr, Washington, DC 20001.

Contact Person: Youngsuk Oh, Scienfitic Review Administrator, National Heart, Lung, and Blood Institute, Two Rockledge Centre, Room 7182, 6701 Rockledge Drive, Bethesda, MD 20817, 301–435–0273, *yoh@mail.nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Heart Failure Monitoring Clinical Trial.

Date: February 23, 2007.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Holly Patton, PhD, Scienfitic Review Administrator, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, Two Rockledge Centre, Room 7188, 6701 Rockledge Dr, Bethesda, MD 20892, 301–435–0280, *pattonh@nhlbi.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 8, 2007.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–100 Filed 1–11–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning

individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Oncological Sciences Integrated Review Group; Cancer Molecular Pathobiology Study Section.
Date: January 29–30, 2007.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Double Tree Hotel, 1515 Rhode Island Avenue, Washington, DC 20005.
Contact Person: Elaine Sierra-Rivera, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, 301–435–1779, *riverase@csr.nih.gov*.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Somatosensory and Chemosensory Systems Study Section.
Date: February 7–8, 2007.
Time: 8:30 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Adam's Mark Denver, 1550 Court Place, Denver, CO 80202.
Contact Person: Daniel R. Kenshalo, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, 301–435–1255, *kenshalod@csr.nih.gov*.

Name of Committee: Biology of Development and Aging Integrated Review Group, Development—1 Study Section.
Date: February 8–9, 2007.
Time: 8 a.m. to 3 p.m.
Agenda: To review and evaluate grant applications.
Place: Georgetown Suites, 1000 29th Street, NW., Washington, DC 20007.
Contact Person: Sherry L. Dupere, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3216, MSC 7843, Bethesda, MD 20892, (301) 435–1021, *duperes@csr.nih.gov*.

Name of Committee: Cardiovascular Sciences Integrated Review Group; Atherosclerosis and Inflammation of the Cardiovascular System Study Section.
Date: February 8–9, 2007.
Time: 8:30 a.m. to 1:30 p.m.
Agenda: To review and evaluate grant applications.
Place: Upham Hotel, 1404 De la Vina Street, Santa Barbara, CA 93101.
Contact Person: Larry Pinkus, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435–1214, *pinkusl@csr.nih.gov*.

Name of Committee: Cell Biology Integrated Review Group; Membrane Biology and Protein Processing Study Section.
Date: February 8–9, 2007.
Time: 8:30 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Melrose Hotel, 2430 Pennsylvania Avenue, NW., Washington, DC 20037.
Contact Person: Janet M. Larkin, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1102, MSC 7840, Bethesda, MD 20892, 310–435–1026, *larkinja@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Viral Pathogenesis.
Date: February 9, 2007.
Time: 1 p.m. to 3 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Fouad A. El-Zaatari, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, MSC 7808, Bethesda, MD 20814–9692, (301) 435–1149, *elzaataf@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Applications in Mechanisms of Emotion, Stress and Health.
Date: February 12, 2007.
Time: 12 p.m. to 2 p.m.
Agenda: To review and evaluate grant applications.
Place: One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.
Contact Person: Jane A. Doussard-Roosevelt, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435–4445, *doussarj@csr.nih.gov*.

Name of Committee: Cell Biology Integrated Review Group; Cellular Signaling and Dynamics Study Section.
Date: February 15–16, 2007.
Time: 8 a.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: Watergate Hotel, 2650 Virginia Avenue, NW., Washington, DC 20037.
Contact Person: Jonathan Arias, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7840, Bethesda, MD 20892, (301) 435–2406, *ariasj@csr.nih.gov*.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Genetic Variation and Evolution Study Section.
Date: February 15–16, 2007.
Time: 8 a.m. to 4 p.m.
Agenda: To review and evaluate grant applications.
Place: The River Inn, 924 25th Street, NW., Washington, DC 20037.
Contact Person: David J. Remondini, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2210, MSC 7890, Bethesda, MD 20892, 301–435–1038, *remondid@csr.nih.gov*.

Name of Committee: Immunology Integrated Review Group; Hypersensitivity, Autoimmune, and Immune-mediated Diseases Study Section.
Date: February 15–16, 2007.
Time: 8 a.m. to 4:30 p.m.
Agenda: To review and evaluate grant applications.
Place: M Street Hotel, 1400 M Street, NW., Washington, DC 20005.
Contact Person: Bahiru Gametchu, DVM, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4204, MSC 7812, Bethesda, MD 20892, 301–435–1225, *gametchb@csr.nih.gov*.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Developmental Brain Disorders Study Section.
Date: February 15–16, 2007.
Time: 8 a.m. to 2 p.m.
Agenda: To review and evaluate grant applications.
Place: Embassy Suites Hotel, 4300 Military Road, Washington, DC 20015.
Contact Person: Pat Manos, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, 301–435–1785, *manospa@csr.nih.gov*.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Adult Psychopathology and Disorders of Aging Study Section.
Date: February 15–16, 2007.
Time: 8:30 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Villa Florence Hotel, 225 Powell Street, San Francisco, CA 94102.
Contact Person: Dana Jeffrey Plude, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, 301–435–2309, *pluded@csr.nih.gov*.

Name of Committee: Immunology Integrated Review Group, Cellular and Molecular Immunology; A Study Section.
Date: February 15–16, 2007.
Time: 8:30 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Marina del Rey Hotel, 13534 Bali Way, Marina del Rey, CA 90292.
Contact Person: Samuel C. Edwards, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4200, MSC 7812, Bethesda, MD 20892, (301) 435–1152, *edwardss@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; MEDI Overflow Applications.
Date: February 15, 2007.
Time: 4 p.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: Bahia Resort Hotel, 998 W. Mission Bay Drive, San Diego, CA 92109.
Contact Person: Xiang-Ning Li, PhD, MD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217, MSC 7854, Bethesda, MD 20892, 301–435–1744, *lixiang@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Collaborative Applications in Adult Psychopathology and Disorders of Aging.
Date: February 16, 2007.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Villa Florence Hotel, 225 Powell Street, San Francisco, CA 94012.

Contact Person: Dana Jeffrey Plude, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, 301–435–2309, *pluded@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Innovative Biomedical Imaging and Technologies.

Date: February 17, 2007.

Time: 8 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 W. Mission Bay Drive, San Diego, CA 92109.

Contact Person: Xiang-Ning Li, MD, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5112, MSC 7854, Bethesda, MD 20892, 301–435–1744, *lixiang@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.486–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 8, 2007.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–102 Filed 1–11–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting.

Notice is hereby given of a change in the meeting of the Enabling Bioanalytical and Biophysical Technologies Study Section, January 31, 2007, 8:30 a.m. to February 1, 2007, 5 p.m., Courtyard Marriott, 299 Second Street, San Francisco, CA 94105 which was published in the **Federal Register** on December 5, 2006, 71 FR 70522–70523.

The meetings will be held February 1, 2007, to February 2, 2007. The meeting time and location remain the same. The meeting is closed to the public.

Dated: January 8, 2007.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–103 Filed 1–11–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Independent Evaluation of the Community Mental Health Services Block Grant Program—NEW

The Substance Abuse and Mental Health Services Administration (SAMHSA), the Center for Mental Health Services (CMHS) administers the Community Mental Health Services Block Grant (CMHS BG). The Community Mental Health Services Block Grant was funded by Congress to develop community-based systems of care for adults with serious mental illness (SMI) and children with severe emotional disorders (SED), and has been the largest Federal program dedicated to improving community mental health services. States have latitude in determining how to spend their funds to support services for adults with SMI and children with SED. The only requirements outlined in the authorizing legislation for State receipt of CMHS BG funds are provisions to increase children's services, create a State mental health planning council, and to develop a State mental health plan to be submitted to the Secretary of Health and Human Services (HHS). The State mental health planning council is to comprise various State constituents including providers, administrators, and mental health services consumers. Each State plan must:

- Provide for the establishment and implementation of an organized community-based system of care for individuals with mental illness.
- Estimate the incidence and prevalence of adults with SMI and children with SED within the State.
- Provide for a system of integrated services appropriate for the multiple needs of children.
- Provide for outreach to and services for rural and homeless populations.
- Describe the financial and other resources necessary to implement the plan and describe how the CMHS BG funds are to be spent.

In addition, Congress included a maintenance-of-effort (MOE) requirement that a State's expenditures for community mental health services be no less than the average spent in the two preceding fiscal years.

The CMHS BG received an adequate rating on the OMB PART in 2003. Clearly in the follow up period to that assessment, one of the critical areas that must be addressed is the expectation that an independent and objective evaluation of the program is to be carried out initially and at regular intervals. In addition, the program evaluation has been designed to be of high quality, sufficient scope and unbiased (with appropriate documentation for each of these elements). In fact it is in addressing an evaluation of the program that critical elements of accountability and program performance are also identified and initially assessed. The rigor of the evaluation is seen in how it addresses the effectiveness of the program's impact with regard to its mission and long term goals. By legislative design the CMHS BG Program has previously focused on legislative compliance. Now it addresses the impact of the program nationally, over time, with a view to coming to terms with identified program deficiencies and the corresponding impact of proposed changes.

In this evaluation, a multi-method evaluation approach is being used to examine Federal and State performance with regard to the CMHS BG and its identified goals. This approach emphasizes a qualitative and quantitative examination of both the CMHS BG process (e.g., activities and outputs in the logic model) and system-level outcomes whereby Federal and State stakeholder perspectives on the CMHS BG, as captured through semi-

structured interviews and surveys, are corroborated and compared to the considerable amount of already-collected source documents provided by States and CMHS (e.g., State plans, implementation reports, review summaries and monitoring site visit reports). More specifically, data collection will be conducted using four primary strategies: interviews and surveys of key stakeholders, data abstraction from source documents (i.e., CMHS BG applications and implementation reports), secondary data analysis (e.g., analysis of Uniform Reporting System (URS) data and National Outcome Measures (NOMS), and case studies highlighting important themes and issues relating to State CMHS BG implementation.

This evaluation is also seeking to measure the effectiveness of the CMHS BG through a variety of infrastructure indicators and NOMS measures. Infrastructure refers to the resources, systems, and policies that support the nation's public mental health service delivery system, and is a potential contributor to significant State behavioral health system outcomes. Examples of infrastructure include staff training, consumer involvement in the State mental health system, policy changes, and service availability. Outcomes related to infrastructure and the NOMS were included in the program logic model that has been developed and are expected to be examined through the data collection strategies listed above.

Infrastructure indicators that can be measured in this evaluation, for which some form of data can be collected include:

- Range of available services within a State
- Capacity (# of persons served)
- Specialized services (such as co-occurring disorders)
- Number of persons served by evidence-based practices (EBPs)
- Staff credentialing (identify patterns)
- Program accreditation (as a quality marker)
- Staff/workforce development (TA & training available for State staff)
- Connections with other agencies (*e.g.*, MOUs, joint funding, joint appointments)
- Policy changes initiated
- Policy changes completed
- Consumer involvement

Two data collection strategies will be used for this evaluation: Two (2) open-ended interviews and four (4) web-based surveys. Interviews will be conducted with Federal staff involved in the administration of the CMHS BG and State staff from all States and Territories involved in their State's implementation of the CMHS BG program. The two interview guides, one for Federal staff and one for State staff, range from 54 to 94 open-ended questions. The Federal staff interview is expected to take one hour to complete while the State staff interview is expected to take two hours on average to complete, and can be done over two sessions. Because of the relatively small number of Federal and State staff participating in the evaluation, interviews are an optimal data collection strategy to gather the extensive qualitative data needed for the evaluation while minimizing reporting burden. Federal staff stakeholders will be interviewed in person due to their close proximity to the interviewers and State staff stakeholder interviews will be conducted via conference call. State Mental Health Agency (SMHA) Commissioners will select those State staff who are knowledgeable about the CMHS BG for participation in the interviews. It is anticipated that, at a minimum, a State Planner, State Data Analyst, and the SMHA Commissioner will participate.

The four (4) web-based surveys will be distributed nationally to State Planning Council Chairs, State Planning Council Members, CMHS BG Regional Reviewers, and CMHS BG Monitoring Site Visitors. The web-based surveys will be tailored so that each of the four different stakeholder groups will receive survey questions designed to capture their specific knowledge of and experience with the CMHS BG. It is estimated that any one individual stakeholder will require one hour to complete their own survey, which contains a range of 22 to 42 mostly fill-in-the blank type questions. Each member of the four major stakeholder groups will submit their responses to the survey online over a three-week period.

Table 1 summarizes the estimate of the total time burden to Federal and State staff stakeholders resulting from the interviews. Table 2 summarizes the estimate of the total time burden to Planning Council members, Regional Reviewers, and Monitoring Site Visitors resulting from completion of the web-based surveys. Table 3 summarizes the total reporting burden for all data collection strategies.

TABLE 1.—ESTIMATED REPORTING BURDEN OF INTERVIEWS

Respondent	Number of respondents	Average hours per interview	Estimated total burden (hours)
State Mental Health Agency Commissioner	59	2	118
State Planners	59	2	118
State Data Analysts	59	2	118
Federal CMHS Block Grant Staff	26	1	26
Total Burden	203	.....	380

TABLE 2.—ESTIMATED REPORTING BURDEN OF WEB-BASED SURVEYS

Respondent	Number of respondents	Average hours per survey	Estimated total burden (hours)
Planning Council Members	1,700	1	1,700
Regional Block Grant Reviewers	35	1	35
Monitoring Site Visitors	28	1	28
Total Burden	1,763	.....	1,763

TABLE 3.—ESTIMATED REPORTING BURDEN OF ALL DATA COLLECTION STRATEGIES

Data collection strategy	Estimated total burden (hours)
Interviews	380
Web-based Surveys	1,763
Total Burden	2,143

This **Federal Register** Notice is focused on the interviews and surveys that will be administered to the CMHS BG stakeholders as those methods of data collection require OMB approval. It is anticipated that in future independent evaluations of the CMHS BG Program focus will be given to the NOMS and their implications for program performance and goals.

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 5, 2007.

Elaine Parry,

Acting Director, Office of Program Services.

[FR Doc. E7–310 Filed 1–11–07; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Immigration and Customs Enforcement

Agency Information Collection Activities: Extension of an Existing Information Collection; Comment Request.

ACTION: 30-Day Notice of Information Collection under Review: Immigration Bond; Form I–352, OMB Control Number 1653–0022.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (USICE) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on October 23, 2006, Vol. 71. No. 204 62117–8, allowing for a 60-day public comment period. No comments were received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until February 12, 2007. 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 Department of Homeland Security (DHS). USICE, Office of Asset Management, Records Branch 425 I St NW., room 1122, Washington, DC 20536. Comments may also be submitted to ICE via facsimile to 202–514–1867 or via e-mail at *ICERecordsbranch@dhs.gov.* Any comments should also be submitted to the OMB Desk Officer by e-mail at *kastrich@omb.eop.gov* or faxed to 202–395–6974.

When submitting comments by e-mail please make sure to add OMB Control Number 1653–0022. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate 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) Evaluate the accuracy of the agencies estimate of the burden of the 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 currently approved information collection.

(2) *Title of the Form/Collection:* Immigration Bond.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* I–352. U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals and Households. This information collection provides a uniform method for applicants to apply for refugee status and contains the information needed in order to adjudicate such applications.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 30,000 responses at approximately 30 minutes per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 15,000 annual burden hours.

If additional information is required contact: ICE Records Management Branch via Facsimile 202–514–1867 or via e-mail at *ICERecordsbranch@dhs.gov.*

Dated: January 9, 2007.

Ricardo Lemus,

Chief, Records Management Branch, U.S. Immigration and Customs Enforcement, Department of Homeland Security.

[FR Doc. E7–343 Filed 1–11–07; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

Immigration and Customs Enforcement

Agency Information Collection Activities: Extension of an Existing Information Collection; Comment Request

ACTION: *30-Day Notice of Information Collection Under Review:* Data Relating to Beneficiary of Private Bill; Form G–79A, OMB Control Number 1653–0026.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (USICE) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on October 23, 2006, at 71 FR 62116, allowing for a 60-day public comment period. No comments were received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until February 12, 2007. 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 Department of Homeland Security (DHS), USICE, Office of Asset Management, Records Branch 425 I St., NW., Room 1122, Washington, DC 20536. Comments may also be submitted to ICE via facsimile to 202–

514–1867 or via e-mail at *ICERecordsbranch@dhs.gov.* Any comments should also be submitted to the OMB Desk Officer by e-mail at *kastrich@omb.eop.gov* or faxed to 202–395–6974.

When submitting comments by e-mail please make sure to add OMB Control Number 1653–0026. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate 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) Evaluate the accuracy of the agency's estimate of the burden of the 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 information collection.

(2) *Title of the Form/Collection:* Data Relating to Beneficiary of Private Bill.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* G–79A. U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals and Households. This information collection provides a uniform method for applicants to apply for refugee status and contains the information needed in order to adjudicate such applications.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 100 responses at approximately 1 hour per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 100 annual burden hours.

If additional information is required contact: ICE Records Management Branch via facsimile 202–514–1867 or via e-mail at *ICERecordsbranch@dhs.gov.*

Dated: January 9, 2007.

Ricardo Lemus,

Chief, Records Management Branch, U.S. Immigration and Customs Enforcement, Department of Homeland Security.

[FR Doc. E7–344 Filed 1–11–07; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5125–N–02]

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.

DATES: *Effective Date:* January 12, 2007.

FOR FURTHER INFORMATION CONTACT: Kathy Ezzell, Department of Housing and Urban Development, Room 7262, 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 the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: January 4, 2007.

Mark R. Johnston,

Deputy Assistant Secretary for Special Needs.

[FR Doc. 07–37 Filed 1–11–07; 8:45 am]

BILLING CODE 4210–67–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Draft Permit Conditions for Abatement Activities Using Raptors

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: We, the U.S. Fish and Wildlife Service, have drafted permit conditions to allow the use of raptors protected by the Migratory Bird Treaty Act for abatement activities. We will authorize the use of these raptors for this purpose under our special purpose permits. We are asking for comments on our draft permit conditions. Allowing the use of raptors to conduct abatement activities is consistent with ensuring the long-term conservation of these species and will serve a public need.

DATES: We will accept written comments until February 12, 2007.

ADDRESSES: *Mail:* U.S. Fish and Wildlife Service, Division of Migratory Bird Management, 4401 North Fairfax Drive, Mail Stop MBSP–4107, Arlington, VA 22203, or *E-mail: abatement@fws.gov*

FOR FURTHER INFORMATION CONTACT: Shauna Hanisch, Division of Migratory Bird Management, (see **ADDRESSES** section); via e-mail at: *Shauna_Hanisch@fws.gov*; by telephone: (703) 358–1714; or by facsimile: (703) 358–2217.

SUPPLEMENTARY INFORMATION:

Background

The U.S. Fish and Wildlife Service (FWS or Service) is the Federal agency with primary responsibility for managing migratory birds. Our authority is the Migratory Bird Treaty Act (MBTA) (16 U.S.C. 703 et seq.), which implements conventions with Great Britain (for Canada), Mexico, Japan, and the Soviet Union (Russia). Activities with migratory birds are prohibited unless specifically authorized by regulation. The MBTA authorizes us to issue regulations governing permits for migratory bird use. They are found in title 50, Code of Federal Regulations, parts 10, 13, 21, and 22.

We have implemented a series of migratory bird permit memoranda to ensure consistent implementation of our regulations and policies pertaining to migratory birds. Our latest memorandum in the series provides guidance for issuing Special Purpose permits (50 CFR 21.27) to authorize the possession and use of raptors protected by the MBTA to abate depredation problems. For purposes of this memorandum, ''abatement'' means the training and use of raptors to flush, haze, or take birds (or other wildlife where allowed) to mitigate depredation problems, including threats to human health and safety. Permit holders may be paid for providing abatement services. We developed this draft memorandum in response to growing

interest in the use of raptors to conduct commercial abatement activities. The Service has determined that authorizing such use is consistent with the MBTA and with the long-term conservation of raptor species. The Service seeks public comments on the draft permit conditions, which are presented below.

Applicants for a Special Use—Abatement (SPA) permit would use FWS Form 3–200–10f, the Migratory Bird Special Purpose—Miscellaneous application form. If we determine that the application meets our requirements, we will issue an SPA permit containing the proposed conditions set forth below. The first three conditions (A, B, and C) are standard for all Special Purpose permits. The remaining conditions (D through K) would be unique to abatement permits. It is about these conditions that we seek comment.

Special Purpose—Abatement Permit Conditions

A. General conditions set out in subpart D of 50 CFR 13, and specific conditions contained in Federal regulations cited in block 2 above, are hereby made a part of this permit. All activities authorized by this permit must be carried out in accord with and for the purposes described in the application submitted. Continued validity, or renewal, of this permit is subject to complete and timely compliance with all applicable conditions.

B. The validity of this permit is conditioned upon strict observance of all applicable State, local, or other Federal law.

C. Valid for use by permittee named above.

D. You are authorized to acquire, possess, and train up to [*specify number*] captive-bred raptors, in any species combination, to include hybrids from those species, of the following migratory bird species for the purpose of conducting abatement activities:

[*List species' common and scientific names.*]

All raptors must be captive-bred and must be marked on the metatarsus with a seamless numbered band issued by the U.S. Fish and Wildlife Service.

E. You may not take species protected under the MBTA unless such take is authorized under a Federal depredation order or a Federal depredation permit identifying you as a subpermittee. You do not need a Federal permit to flush or haze depredating birds, other than endangered or threatened species or bald and golden eagles. You do not need a Federal depredation permit to take species that the MBTA does not protect.

F. Under this permit, you may use a raptor held under your falconry permit for abatement. However, you may use a raptor held under this abatement permit for falconry only if it is transferred from your abatement permit to your falconry permit. If you use raptors to take depredating game birds in the context of falconry rather than abatement, you must comply with all applicable seasons and bag limits and may do so only in areas where the practice of falconry is authorized.

G. *Subpermittees:* Persons under your direct control or employed by you, or under contract to you for purposes authorized by this permit, may carry out the permitted activities provided they are, or have been, a General or Master Falconer (in accordance with 50 CFR 21.28).

H. You must submit FWS Form 3–186A (Migratory Bird Acquisition and Disposition Report) completed in accordance with the instructions on the form for each acquisition and disposition of a raptor.

I. If your raptor takes a migratory bird in the course of conducting abatement activities and that take is not authorized by a depredation permit or a depredation order, the bird must be left in the field, though the raptor may be allowed to feed on it in the field.

J. All facilities and equipment must meet standards described in 50 CFR 21.29, and all birds must be maintained under humane and healthful conditions at all times.

K. Acceptance of this permit authorizes us to inspect in accordance with 50 CFR 13.47.

Public Comments

Please submit comments to one of the addresses listed above in **ADDRESSES**. If you mail a comment, it must be on 8½-inch-by-11-inch paper. Before including your address, telephone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. You may inspect comments by appointment during normal business hours at the address in **ADDRESSES**.

Authority: The Migratory Bird Treaty Act, 16 U.S.C. 703–712.

Dated: December 20, 2006.

David M. Verhey,

Assistant Secretary, Fish and Wildlife.

[FR Doc. E7–353 Filed 1–11–07; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV–010–5870–EU; N–77382; 7–08807]

Notice of Realty Action: Direct (Non-Competitive) Sale of Reversionary Interest, Elko County, NV

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action, sale and release of reversionary interest in public land in West Wendover, Nevada.

SUMMARY: Reversionary interest held by the United States in the lands described in the Supplementary Information below has been determined suitable for direct sale and release to the City of West Wendover, Nevada, under the authority of Section 203 of the Federal Land Policy and Management Act of October 21, 1976 (FLPMA) (43 U.S.C.1713).

The lands are currently patented by the City of West Wendover, Nevada, but the purposes for which the land can be used is restricted by a reversionary clause in the patent under which the land was conveyed by the United States.

DATES: Comments regarding the proposed sale, and other pertinent documents, must be received by the Bureau of Land Management (BLM) on or before February 26, 2007.

ADDRESSES: Elko Field Office, Bureau of Land Management, 3900 E. Idaho St., Elko, NV 89801. More detailed information regarding the proposed sale and the land involved may be reviewed during normal business hours (7:30 a.m. to 4:30 p.m.) at the Elko Field Office.

FOR FURTHER INFORMATION CONTACT: Cathie Jensen, Supervisory Realty Specialist, at the above address, or (775) 753–0230 or by e-mail at *Cathie_Jensen@BLM.GOV.*

SUPPLEMENTARY INFORMATION: The purpose of the sale of the reversionary interests in the land is so the land, patented to the City of West Wendover, can be used for the purposes which will be the best and highest uses of the land and best meet the needs of the City of West Wendover without the threat of a reversion of the title for breach of patent conditions. The lands are not needed for Federal purposes and the United States has no present interest in the property. The action is consistent with Federal, state and local planning and zoning. The reversionary interest in this land will be offered by direct sale and release to the City of West Wendover for Fair Market Value which is $1,600,000.00. The reversionary interest in these lands

will not be offered for sale and release until 60 days after this notice.

The release, when issued, will be for the reversionary interest only. All other terms and conditions of the Patent No. 27–2003–0001 will continue to apply to the lands involved. For a period of 45 days following the publication of this notice in the **Federal Register**, interested parties may submit comments regarding the proposed conveyance or classification of the lands to the Elko Field Manager, at the above address. In the absence of timely objections, this proposal shall become the final decision of the Department of the Interior.

Pursuant to the terms and conditions of a patent dated October 28, 2002 issued pursuant to the Recreation and Public Purpose (R&PP) Act, as amended (43 U.S.C. 869–869–4), the United States retained and continues to hold a reversionary interest in the above described land. The City of West Wendover, Nevada proposes to change the use of the 81.065 acre parcel, from solely municipal and recreational use, to include commercial privately owned property to accommodate community expansion and commercial development. If the City of West Wendover, Nevada desires to transfer the title to, or control over, the land to a ''for profit'' entity, or if the land is devoted to a ''for profit'' use, the land (ownership), as stated in the Act, would revert to the United States because such would be inconsistent with the R&PP Act (43 U.S.C. 869–2(a)).

The City desires to change the use and control of the 81.065 acre parcel, from solely municipal and recreational use, to include commercial property to accommodate community expansion and commercial development. The City currently uses the land for fire station, police station, recreational ball field and park purposes which are appropriate uses under the R&PP Act. Direct sale procedures to the City are considered appropriate, in this case, as the 81.065 acre parcel of land described above has been patented to the City, and transfer of the Federal reversionary interest, if it were sanctioned, to any other entity would not protect existing equities of West Wendover, Nevada in the land. The sale would be conducted under the provisions found at 43 CFR 2711.3.3 (a)(1) and (2) for direct sales which state the following: Direct sales (without competition) may be utilized, when in the opinion of the authorized officer, a competitive sale is not appropriate and the public interest would best be served by a direct sale. Examples are, but are not limited to,: (1) A tract identified for transfer to State or local government or nonprofit organization; or (2) A tract identified for sale that is an integral part of a project or public importance and speculative bidding would jeopardize a timely completion and economic viability of the project. The purpose of the sale is so that the land may be used for the purposes which, in the opinion of the authorized officer, will be the best and highest uses of the land and best meet the needs of the City without the threat of a reversion of the title to the United States for violation of patent conditions. The sale is consistent with current BLM land use planning for the area.

Consequently, the City of West Wendover, Nevada has applied to the BLM to be released from the reverter by the purchase thereof pursuant to section 203 of the Federal Land Policy and Management Act of 1976 (Pub. L. 94–579), 43 U.S.C. 1713, and 43 CFR 2711.3.3 (a)(1). The reverter is identified as the R&PP Act reversionary interest of the United States in patent 27–2003–0001, pertaining to particular parcels described as follows:

Mount Diablo Meridian, Nevada

T. 33 N., R. 70 E.,
Section 16, lots 1, 4, 6, and 11;
S½SW¼NE¼NE¼,
S½SE¼SW¼SW¼NE¼,
NE¼SW¼SE¼SW¼NE¼,
S½SW¼SE¼SW¼NE¼, and
SE¼SE¼SW¼NE¼.

Containing 81.065 acres, more or less.

The City of West Wendover, Nevada would pay the fair market value of the reverter in the sum of $1,600,000.00, as determined by the BLM authorized officer having taken into account an appraisal, conducted in accordance with the applicable appraisal standards and that assumed the land, as patented pursuant to the R&PP Act, to be free and clear of the outstanding reversionary interest now held by the United States.

The reversionary interest is being offered for non-competitive (direct) sale and release to the City of West Wendover, Nevada, in accordance with the criterion prescribed in 43 CFR 2711.3–3(a)(1), namely, that the public interest would best be served by the sale and release to the local government. Authority for the sale and release of the reversionary interest is Section 203 of the Federal Land Policy and Management Act of October 21, 1976 (FLPMA) (43 U.S.C. 1713).

Direct sale procedures to the City of West Wendover, Nevada are considered appropriate, in this case, as the 81.065 acre parcel of land described above was patented previously to the City of West Wendover, Nevada, and transfer of the Federal reversionary interest, if it were sanctioned, to any other entity would not protect existing equities of the City of West Wendover, Nevada in the land. The direct sale is consistent with current BLM land use planning for the area. Currently the land involved is classified for lease/conveyance pursuant to the R&PP Act. Thus classification remains to be terminated effective prior to direct sale.

The release of the reversionary interest of the 81.065 acres will be made subject to the provisions of the Federal Land Policy and Management Act, the applicable regulations of the Secretary of the Interior, all valid existing rights, and the following:

1. A right-of-way for ditches or canals by the authority of the United States pursuant to the Act of August 30, 1890 (43 U.S.C. 945);

2. The terms and conditions of the United States patent 27–2003–0001, including but not limited to all mineral deposits in the land so patented, and to it, or persons authorized by it, the right to prospect for, mine, and remove such deposits from the same under applicable law regulations to be established by the Secretary of the Interior;

3. Those rights for federal highway purposes which have been reserved to the Federal Highway Administration, its successors and assigns, by right-of-way no. N–45133, pursuant to the section 501 of FLPMA (43 U.S.C. 1761); and N–57341.

4. Those rights for federal highway purposes which have been granted to the State of Nevada Department of Transportation, its successors and assigns, by right-of-way No. N–041037, pursuant to the Act of November 9, 1921 (042 Sat. 0261).

5. A right-of-way for railroad purposes granted to Union Pacific Railroad Company, its successors and assigns, by right-of-way No. CC–005090, pursuant to the Act of March 3, 1875 (18 Stat. 482, 43 U.S.C. 934–939).

6. Those rights for telephone line purposes which have been granted to Citizens Communications Company, its successors and assigns, by right-of-way. No. CC–01089A and N–61184, pursuant to section 501 of FLPMA (43 U.S.C.1761);

7. Those rights for telephone line purposes which have been granted to Beehive Telephone Company, Inc., its successors and assigns, by right-of-way No. E–001655 and N–47793, pursuant to section 501 of FLPMA (43 U.S.C. 1761);

8. Those rights for power line purposes which have been granted to Wells Rural Electric, its successors and assigns, by rights-of -way Nos. N–39920, N–53135, and N–61064, pursuant to section 501 of FLPMA (43 U.S.C. 1761);

9. Those rights for fiber optic cable purposes which have been granted to Sprint Communications Company, LP, its successors and assigns, by right-of-way No. N–42787, pursuant to section 501 of FLPMA;

10. Those rights for access road purposes which have been granted to Chevron USA, Inc., its successors and assigns, by right-of-way No. N–48016, pursuant to section 501 of FLPMA.

11. The purchaser, by accepting the release of the reversionary interest of the United States agrees to indemnify, defend, and hold the United States, its officers, agents or employees harmless from any costs, damages, claims, causes of action, penalties, fines, liabilities, and judgments of any kind arising from the past, present or future acts or omissions of the purchaser, its employees, agents, contractors, or lessees, or third-party arising out of or in connection with the purchaser's acceptance of the aforementioned release or purchaser's use and/or occupancy of the land involved resulting in: (1) Violations of Federal, State, and local laws and regulations that are now, or in the future become, applicable to real property; (2) Judgments, claims or demands of any kind assessed against the United States; (3) Cost, expenses, or damages of any kind incurred by the United States; (4) Releases or threatened releases of solid or hazardous waste(s) and/or hazardous substances(s), as defined by Federal or State environmental laws, off, on, into or under land, property, and other interests of the United States; (5) Other activities by which solids or hazardous substances or wastes, as defined by Federal and State environmental laws are generated, released, stored, used, or otherwise disposed of on the land involved, and any cleanup, response, remedial action or other actions related in any manner to said solid or hazardous substances or wastes; or (6) Natural resource damages as defined by Federal and State law. Patentee shall stipulate that it will be solely responsible for compliance with all applicable Federal, State, and local environmental and regulatory provisions, throughout the life of the facility, including any closure and/or post-closure requirements that may be imposed with respect to any physical plant and/or facility upon the land involved under any Federal, state, or local environmental laws or regulatory provisions. This covenant shall be construed as running with the land and may be enforced by the United States in a court of competent jurisdiction.

No warranty of any kind, express or implied, is given by the United States in connection of the sale or release of the reversionary interest. The Documentation of Land Use Conformance and National Environmental Policy Adequacy, map, and approved appraisal report covering the proposed sale, are available for review at the BLM, Elko Field Office at the address above.

For a period until February 26, 2007, interested parties may submit written comments to the Elko Field Office Manager at the above address. Facsimiles, telephone calls, and electronic mail will not be considered acceptable submissions by the authorized officer. Any adverse written comments will be reviewed by the State Director, who may sustain, vacate, or modify this proposed realty action and issue a final determination. In the absence of timely field objections this realty action will become the final determination of the Department of the Interior. Any written comments received during this process, as well as the commenter's name and address, will be available to the public in the administrative record and/or pursuant to a Freedom of Information Act request. You may indicate for the record that you do not wish to have your name and/or address made available to the public. Any determination by the BLM to release or withhold the names and/or address of those who comment will be made on a case-by-case basis. A request from a commenter to have their name/or address withheld from public release will be honored to the extent permissible by the law. The reversionary interest will not be offered for sale and release until March 13, 2007.

Authority: (43 CFR 2711.1–2).

Dated: January 5, 2007.

Helen Hankins,

Elko Field Manager.

[FR Doc. E7–429 Filed 1–11–07; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Notice of Proposed Information Collection for 1029–0115, 1029–0116 and 1029–0117

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing that the information collection requests for 30 CFR Part 773 (Requirements for permits and permit processing), Part 774 (Revision; Renewal; and Transfer, Assignment, or Sale of Permit Rights), and Part 778 (Permit Applications—Minimum Requirements for Legal, Financial, Compliance, and Related Information) have been forwarded to the Office of Management and Budget (OMB) for review and reauthorization. The information collection packages were previously approved and assigned clearance numbers 1029–0115 for 30 CFR Part 773, 1029–0116 for 30 CFR Part 774, and 1029–0117 for 30 CFR Part 778. This notice describes the nature of the information collection activities and the expected burdens.

DATES: OMB has up to 60 days to approve or disapprove the information collection but may respond after 30 days. Therefore, public comments should be submitted to OMB by February 12, 2007, in order to be assured of consideration.

ADDRESSES: Submit comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Department of Interior Desk Officer, by telefax at (202) 395–6566 or via e-mail to *OIRA_Docket@omb.eop.* Also, please send a copy of your comments to John A. Trelease, Office of Surface Mining Reclamation and enforcement, 1951 Constitution Ave., NW., Room 202–SIB, Washington, DC 20240, or electronically to *jtrelease@osmre.gov.*

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection requests and explanatory information, contact John A. Trelease at (202) 208–2783, or electronically at *jtrelease@osmre.gov.* You may also review the information collection requests online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. OSM has submitted requests to OMB to renew its approval for the collections of information for 30 CFR Part 773 (Requirements for permits and permit processing), Part 774 (Revision; Renewal; and Transfer, Assignment, or Sale of Permit Rights), and Part 778 (Permit Applications—Minimum

Requirements for Legal, Financial, Compliance, and Related Information). OSM is requesting a 3-year term of approval for these information collection activities.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for these collections of information are listed in 30 CFR 773.3, which is 1029–0115; in 30 CFR 774.9, which is 1029–0116; and in 30 CFR 778.8, which is 1029–0117.

As required under 5 CFR 1320.8(d), **Federal Register** notice soliciting comments on these collections of information was published on September 11, 2006 (71 FR 53476). No comments were received. This notice provides the public with an additional 30 days in which to comment on the following information collection activities:

Title: 30 CFR Part 773—Requirements for Permits and Permit Processing.

OMB Control Number: 1029–0115.

Summary: The collection activities for this part ensure that the public has the opportunity to review permit applications prior to their approval, and that applicants to permanent program permits or their associates who are in violation of the Surface Mining Control and Reclamation Act do not receive surface coal mining permits pending resolution of their violations.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: Applicants for surface coal mining and reclamation permits and State governments and Indian Tribes.

Total Annual Respondents: 4,431.

Total Annual Burden Hours: 34,650.

Total Non-wage Costs: $13,040.

Title: 30 CFR Part 774—Revisions; Renewals; and Transfer, Assignment, or Sale of Permit Rights.

OMB Control Number: 1029–0116.

Summary: Sections 506 and 511 of Public Law 95–87 provide that persons seeking permit revisions, renewals, transfer, assignment, or sale of their permit rights to coal mining activities submit relevant information to the regulatory authority to allow the regulatory authority to determine whether the applicant meets the requirements for the action anticipated.

Bureau Form Number: None.

Frequency of Collection: On occasion.

Description of Respondents: Surface coal mining permit applicants and State regulatory authorities.

Total Annual Responses: 6,577.

Total Annual Burden Hours: 63,905.

Title: 30 CFR Part 778—Permit Applications—Minimum Requirements for Legal, Financial, Compliance, and Related Information.

OMB Control Number: 1029–0117.

Summary: Section 507(b) of Public Law 95–87 provides that persons conducting coal mining activities submit to the regulatory authority all revelant information regarding ownership and control of the property affected, their compliance status and history. This information is used to ensure all legal, financial and compliance requirements are satisfied prior to issuance of a permit.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: Surface coal mining permit applicants and State regulatory authorities.

Total Annual Responses: 3,085.

Total Annual Burden Hours: 7,974.

Send comments on the need for the collection of information for the performance of the functions of the agency; the accuracy of the agency's burden estimates; ways to enhance the quality, utility and clarity of the information collection; and ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information, to the address listed above. Please refer to the appropriate OMB control number in all correspondence, 1029–0115 for Part 773, 1029–0116 for Part 774, and 1029–0117 for Part 778.

Dated: January 4, 2007.

John R. Craynon,

Chief, Division of Regulatory Support.

[FR Doc. 07–88 Filed 1–11–07; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; Correction

By Notice dated November 21, 2006, and published in the **Federal Register** on December 1, 2006, (71 FR 69590), Notice of Application, Hospira, Inc., 1776 North Centennial Drive, McPherson, Kansas 67460–1247, paragraph three should be corrected to read as follows: The company plans to import Remifentanil for use in dosage form manufacturing.

Dated: January 5, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7–309 Filed 1–11–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employment and Training Administration

Proposed Information Collection Request for Form MA 8–7, Transmittal for Unemployment Insurance Materials; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment and Training Administration is soliciting comments concerning the proposed extension of the Form MA 8–7, Transmittal for Unemployment Insurance Materials. A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice or by accessing: *http://www.doleta.gov/OMBCN/OMBControlNumber.cfm.*

DATES: Submit comments on or before March 13, 2007.

ADDRESSES: Send comments to Robert Johnston, Room S–4231, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; phone (202) 693–3005 (this is not a toll-free number); internet address *johnston.robert@dol.gov;* fax (202) 693–2874.

SUPPLEMENTARY INFORMATION:

I. Background

Department of Labor, Employment and Training Administration regulations, 20 CFR 601, Administrative Procedures, contains collection of information requirements at Sections

601.2 and 601.3. Section 601.2 requires states to submit copies of their unemployment compensation laws for approval by the Secretary of Labor so that the Secretary may determine the status of state laws. Section 601.3 requires states to ''submit all relevant state materials such as statutes, executive and administrative orders, legal opinions, rules, regulations, interpretations, court decisions, etc.'' These materials are used by the Secretary to certify to the Secretary of Treasury whether employers in the state qualify for tax credits under Sections 3303 and 3304 of the Federal Unemployment Tax Act, and if the state qualifies for grants for the administration of their unemployment compensation laws by meeting the conditions found in Section 303 of the Social Security Act. If this information is not available, the Secretary cannot make such certifications. To facilitate transmittal of required material, the Department prescribes the use of Form MA 8–7, Transmittal for Unemployment Insurance Materials. This simple check off form is used by the states to identify material being transmitted to the Department of Labor/Employment Training Administration and allows the material to be routed to appropriate staff for prompt action. States could not be certified if this information was not collected and Form MA 8–7 greatly facilitates its receipt.

II. Desired Focus of Comments

Currently, the Employment and Training Administration is soliciting comments concerning the proposed extension collection of the MA 8–7, Transmittal for Unemployment Insurance Materials. The Department of Labor is particularly interested in comments which:

- 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;
- 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;
- Enhance the quality, utility, and clarity of the information to be collected; and
- 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 submissions of responses.

A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed above in the addressee section of this notice.

III. Current Actions

Type of Review: Extension.
Agency: Employment and Training Administration.
Title: Transmittal for Unemployment Insurance Materials.
OMB Number: 1205–0222.
Agency Number: MA 8–7.
Affected Public: State Governments.
Cite/Reference/Form/etc: Social Security Act, Section 303(a)(6).
Total Respondents: 53.
Frequency: As needed.
Total Responses: 600.
Average Time per Response: 1 minute.
Estimated Total Burden Hours: 10 hours.
Total Burden Cost (capital/startup): None.
Total Burden Cost (operating/maintaining): None

Comments submitted in response to this comment request will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: January 4, 2007.

Cheryl Atkinson,

Administrator, Office of Workforce Security.

[FR Doc. E7–352 Filed 1–11–07; 8:45 am]

BILLING CODE 4510–30–P

OFFICE OF NATIONAL DRUG CONTROL POLICY

Paperwork Reduction Act; 30-Day Notice

AGENCY: Office of National Drug Control Policy.

The Office of National Drug Control Policy (ONDCP) proposes the collection of information concerning arrestee drug use. ONDCP hereby invites interested persons to submit comments to the Office of Management and Budget (OMB) regarding any aspect of this proposed effort.

Type of Information Collection: New collection.
Title: Arrestee Drug Abuse Monitoring (ADAM II) Program Questionnaire.
Use: The information will support statistical trend analysis.
Frequency: Ten sites will each conduct two cycles of surveys from 250 arrestees per cycle.
Annual Number of Respondents: 5000.
Total Annual Responses: 5000.
Average Burden per Response: 20 minutes.
Total Annual Hours: 1667.

Send comments to John Kraemer, OMB Desk Officer for ONDCP, New Executive Office Building, Room 10235, Washington, DC 20503. Comments must be received within 30 days. Request additional information by facsimile transmission to (202) 395–5598, attention: Robert Cohen, ONDCP, Office of Planning and Budget.

Dated: January 9, 2007.

Daniel R. Petersen,

Assistant General Counsel.

[FR Doc. E7–342 Filed 1–11–07; 8:45 am]

BILLING CODE 3180–02–P

NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Proposed Collection: Comment Request

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection request to OMB and solicitation of public comment.

SUMMARY: The NRC is preparing a submittal to OMB for review of continued approval of information collections under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information Pertaining to the Requirement To Be Submitted

1. *The title of the information collection:* NRC Forms 540 and 540A, ''Uniform Low-Level Radioactive Waste Manifest (Shipping Paper) and Continuation Page;'' NRC Forms 541 and 541A, ''Uniform Low-Level Radioactive Waste Manifest, Container and Waste Description, and Continuation Page;'' NRC Forms 542 and 542A, ''Uniform Low-Level Radioactive Waste Manifest, Index and Regional Compact Tabulation.''
2. *Current OMB approval numbers:* 3150–0164 for NRC Forms 540 and 540A; 3150–0166 for NRC Forms 541 and 541A; and 3150–0165 for NRC Forms 542 and 542A.
3. *How often the collection is required:* Forms are used by shippers whenever radioactive waste is shipped. Quarterly or less frequent reporting is made to NRC depending on specific license conditions.

4. *Who is required or asked to report:* All NRC-licensed low-level waste facilities. All generators, collectors, and processors of low-level waste intended for disposal at a low-level waste facility must complete the appropriate forms.

5. *The estimated number of annual respondents:*

NRC Form 540 and 540A: 2,500 licensees.

NRC Form 541 and 541A: 2,500 licensees.

NRC Form 542 and 542A: 22 licensees.

6. *The number of hours needed annually to complete the requirement or request:*

NRC Form 540 and 540A: 10,050 (.75 hours per response).

NRC Form 541 and 541A: 44,341 (3.3 hours per response).

NRC Form 542 and 542A: 567 (.75 hours per response).

7. *Abstract:* NRC Forms 540, 541, and 542, together with their continuation pages, designated by the ''A'' suffix, provide a set of standardized forms to meet Department of Transportation (DOT), NRC, and State requirements. The forms were developed by NRC at the request of low-level waste industry groups. The forms provide uniformity and efficiency in the collection of information contained in manifests which are required to control transfers of low-level radioactive waste intended for disposal at a land disposal facility. NRC Form 540 contains information needed to satisfy DOT shipping paper requirements in 49 CFR Part 172 and the waste tracking requirements of NRC in 10 CFR Part 20. NRC Form 541 contains information needed by disposal site facilities to safely dispose of low-level waste and information to meet NRC and State requirements regulating these activities. NRC Form 542, completed by waste collectors or processors, contains information which facilitates tracking the identity of the waste generator. That tracking becomes more complicated when the waste forms, dimensions, or packagings are changed by the waste processor. Each container of waste shipped from a waste processor may contain waste from several different generators. The information provided on NRC Form 542 permits the States and Compacts to know the original generators of low-level waste, as authorized by the Low-Level Radioactive Waste Policy Amendments Act of 1985, so they can ensure that waste is disposed of in the appropriate Compact.

Submit, by March 13, 2007, Comments That Address the Following Questions

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the draft supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O–1 F21, Rockville, MD 20852. OMB clearance requests are available at the NRC worldwide Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/index.html*. The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions about the information collection requirements may be directed to the NRC Clearance Officer, Margaret A. Janney, U.S. Nuclear Regulatory Commission, T–5 F53, Washington, DC 20555–0001, by telephone at 301–415–7245, or by Internet electronic mail to *INFOCOLLECTS@NRC.GOV*.

Dated at Rockville, Maryland, this 8th day of January 2007.

For the Nuclear Regulatory Commission.

Margaret A. Janney,

NRC Clearance Officer, Office of Information Services.

[FR Doc. E7–325 Filed 1–11–07; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–400]

Notice of Acceptance for Docketing of the Application, for Facility Operating License No. NPF–63 for an Additional 20-Year Period; Carolina Power & Light Company, Shearon Harris Nuclear Power Plant, Unit 1

The U.S. Nuclear Regulatory Commission (NRC or the Commission) is considering an application for the renewal of operating license NPF–63, which authorizes the Carolina Power & Light Company, doing business as Progress Energy Carolinas, Inc., to operate the Shearon Harris Nuclear Power Plant, (HNP), Unit 1, at 2900 megawatts thermal. The renewed license would authorize the applicant to operate the HNP, Unit 1, for an additional 20 years beyond the period specified in the current license. HNP, Unit 1, is located in Wake County, North Carolina, and its current operating license expires on October 24, 2026.

On November 16, 2006, the Commission's staff received an application from Carolina Power & Light Company, to renew operating license NPF–63 for HNP, Unit 1, pursuant to Title 10 of the Code of Federal Regulations (CFR) Part 54. A notice of receipt and availability of the license renewal application (LRA) was published in the **Federal Register** on December 11, 2006 (71 FR 71586).

The Commission's staff has reviewed the LRA for its acceptability and has determined that Carolina Power & Light Company has submitted sufficient information in accordance with 10 CFR Sections 54.19, 54.21, 54.22, 54.23, and 51.53(c), and that the application is acceptable for docketing. The Commission will retain the current Docket No. 50–400, for operating license NPF–63. The docketing of the renewal application does not preclude requests for additional information as the review proceeds, nor does it predict whether the Commission will grant or deny the license.

The license renewal process proceeds along two tracks, one for review of safety issues, pursuant to 10 CFR Part 54 and another for environmental issues, pursuant to 10 CFR Part 51. An applicant must provide NRC with an evaluation of the technical aspects of plant aging and describe the aging management programs and activities that will be relied on to manage aging. In addition, in order to support plant operation for the additional 20 years, the applicant must prepare an evaluation of the potential impact on the environment. The NRC reviews the application, documents its reviews in a safety evaluation report and a supplemental environmental impact statement, and performs verification inspections at the applicant's facility. If the NRC issues a renewed license, the licensee must continue to comply with all existing regulations, license conditions, orders, and commitments associated with the current operating license as well as those additional activities required as a result of license renewal. The licensee's activities continue to be subject to NRC oversight during the period of extended operation.

Before issuance of the requested renewed license, the NRC will have made the findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules

and regulations. In accordance with 10 CFR 54.29, the NRC may issue a renewed license on the basis of its review if it finds that actions have been identified and have been or will be taken with respect to: (1) Managing the effects of aging during the period of extended operation on the functionality of structures and components that have been identified as requiring aging management review; and (2) time-limited aging analyses that have been identified as requiring review, such that there is reasonable assurance that the activities authorized by the renewed license will continue to be conducted in accordance with the current licensing basis (CLB), and that any changes made to the plant's CLB will comply with the Act and the Commission's regulations. In addition, the Commission must find that applicable requirements of Subpart A of 10 CFR Part 51 have been satisfied, and that matters raised under 10 CFR 2.335 have been addressed.

Notice of Opportunity for Hearing and Notices relating to the environmental review will be published at a later date.

In accordance with 10 CFR 51.53(c) and 10 CFR 54.23, Carolina Power & Light Company prepared and submitted the environmental report (ER) as part of the LRA. The LRA and the ER are publicly available at the NRC's PDR, located at One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, or from ADAMS. The ADAMS accession numbers for the LRA and the ER are ML063350270 and ML063350276, respectively. The public may also view the LRA and the ER on the Internet at *http://www.nrc.gov/reactors/operating/licensing/renewal/applications.html*. In addition, the LRA and the ER are available to the public near HNP, Unit 1, at the Eva. H. Perry Library, 2100 Shepherd's Vineyard Drive, Apex, North Carolina 27502.

Dated at Rockville, Maryland, this 8th day of January, 2007.

For the Nuclear Regulatory Commission.

Pao-Tsin Kuo,

Acting Director, Division of License Renewal, Office of Nuclear Reactor Regulation.

[FR Doc. E7–324 Filed 1–11–07; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF MANAGEMENT AND BUDGET

Discount Rates for Cost-Effectiveness Analysis of Federal Programs

AGENCY: Office of Management and Budget.

ACTION: Revisions to Appendix C of OMB Circular A–94.

SUMMARY: The Office of Management and Budget revised Circular A–94 in 1992. The revised Circular specified certain discount rates to be updated annually when the interest rate and inflation assumptions used to prepare the budget of the United States Government were changed. These discount rates are found in Appendix C of the revised Circular. The updated discount rates are shown below. The discount rates in Appendix C are to be used for cost-effectiveness analysis, including lease-purchase analysis, as specified in the revised Circular. They do not apply to regulatory analysis.

DATES: The revised discount rates are effective immediately and will be in effect through December 2007.

FOR FURTHER INFORMATION CONTACT: Robert B. Anderson, Office of Economic Policy, Office of Management and Budget, (202) 395–3381.

James D. Foster,

Associate Director for Economic Policy, Office of Management and Budget.

Appendix C—Discount Rates for Cost-Effectiveness, Lease Purchase, and Related Analyses (OMB Circular No. A–94)

Revised December 2006.

Effective Dates. This appendix is updated annually around the time of the President's budget submission to Congress. This version of the appendix is valid for calendar year 2007. A copy of the updated appendix can be obtained in electronic form through the OMB home page at *http://www.whitehouse.gov/omb/circulars/a094/a94_appx-c.html,* the text of the main body of the Circular is found at *http://www.whitehouse.gov/omb/circulars/a094/a094.html,* and a table of past years' rates is located at *http://www.whitehouse.gov/omb/circulars/a094/DISCHIST–2007.pdf.* Updates of the appendix are also available upon request from OMB's Office of Economic Policy (202–395–3381).

Nominal Discount Rates. A forecast of nominal or market interest rates for 2007 based on the economic assumptions for the 2008 Budget are presented below. These nominal rates are to be used for discounting nominal flows, which are often encountered in lease-purchase analysis.

NOMINAL INTEREST RATES ON TREASURY NOTES AND BONDS OF SPECIFIED MATURITIES

[In percent]

3-Year	5-Year	7-Year	10-Year	20-Year	30-Year
4.9	4.9	4.9	5.0	5.1	5.1

Real Discount Rates. A forecast of real interest rates from which the inflation premium has been removed and based on the economic assumptions from the 2008 Budget is presented below. These real rates are to be used for discounting constant-dollar flows, as is often required in cost-effectiveness analysis.

REAL INTEREST RATES ON TREASURY NOTES AND BONDS OF SPECIFIED MATURITIES

[In percent]

3-Year	5-Year	7-Year	10-Year	20-Year	30-Year
2.5	2.6	2.7	2.8	3.0	3.0

Analyses of programs with terms different from those presented above may use a linear interpolation. For example, a four-year project can be evaluated with a rate equal to the average of the three-year and five-year rates. Programs with durations longer

than 30 years may use the 30-year interest rate.

[FR Doc. E7–308 Filed 1–11–07; 8:45 am]

BILLING CODE 3110–01–P

PENSION BENEFIT GUARANTY CORPORATION

Required Interest Rate Assumption for Determining Variable-Rate Premium for Single-Employer Plans; Interest on Late Premium Payments; Interest on Underpayments and Overpayments of Single-Employer Plan Termination Liability and Multiemployer Withdrawal Liability; Interest Assumptions for Multiemployer Plan Valuations Following Mass Withdrawal

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of interest rates and assumptions.

SUMMARY: This notice informs the public of the interest rates and assumptions to be used under certain Pension Benefit Guaranty Corporation regulations. These rates and assumptions are published elsewhere (or can be derived from rates published elsewhere), but are collected and published in this notice for the convenience of the public. Interest rates are also published on the PBGC's Web site (*http://www.pbgc.gov*).

DATES: The required interest rate for determining the variable-rate premium under part 4006 applies to premium payment years beginning in January 2007. The interest assumptions for performing multiemployer plan valuations following mass withdrawal under part 4281 apply to valuation dates occurring in February 2007. The interest rates for late premium payments under part 4007 and for underpayments and overpayments of single-employer plan termination liability under part 4062 and multiemployer withdrawal liability under part 4219 apply to interest accruing during the first quarter (January through March) of 2007.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion, Manager, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION:

Variable-Rate Premiums

Section 4006(a)(3)(E)(iii)(II) of the Employee Retirement Income Security Act of 1974 (ERISA) and § 4006.4(b)(1) of the PBGC's regulation on Premium Rates (29 CFR part 4006) prescribe use of an assumed interest rate (the ''required interest rate'') in determining a single-employer plan's variable-rate premium. Pursuant to the Pension Protection Act of 2006, for premium payment years beginning in 2006 or 2007, the required interest rate is the ''applicable percentage'' (currently 85 percent) of the annual rate of interest determined by the Secretary of the Treasury on amounts invested conservatively in long-term investment grade corporate bonds for the month preceding the beginning of the plan year for which premiums are being paid (the ''premium payment year''). Thus, the required interest rate to be used in determining variable-rate premiums for premium payment years beginning in January 2007 is 4.89 percent (*i.e.*, 85 percent of the 5.75 percent composite corporate bond rate for December 2006 as determined by the Treasury).

On December 2, 2005, the Internal Revenue Service published proposed regulations containing updated mortality tables for determining current liability under section 412(l)(7) of the Code and section 302(d)(7) of ERISA for plan years beginning on or after January 1, 2007, *http://www.irs.gov/pub/irs-regs/12498805.pdf*. If these regulations are finalized and effective for plan years beginning on or after January 1, 2007, the required interest rate to be used in determining variable-rate premiums would be 100 percent (instead of 85 percent) of the composite corporate bond rate. If the required interest rate for premium payment years beginning in January 2007 changes, the PBGC will promptly publish a **Federal Register** notice with the new rate.

The following table lists the required interest rates to be used in determining variable-rate premiums for premium payment years beginning between February 2006 and January 2007.

For premium payment years beginning in:	The required interest rate is:
February 2006	4.80
March 2006	4.87
April 2006	5.01
May 2006	5.25
June 2006	5.35
July 2006	5.36
August 2006	5.36
September 2006	5.19
October 2006	5.06
November 2006	5.05
December 2006	4.90
January 2007	4.89

Late Premium Payments; Underpayments and Overpayments of Single-Employer Plan Termination Liability

Section 4007(b) of ERISA and § 4007.7(a) of the PBGC's regulation on Payment of Premiums (29 CFR part 4007) require the payment of interest on late premium payments at the rate established under section 6601 of the Internal Revenue Code. Similarly, § 4062.7 of the PBGC's regulation on Liability for Termination of Single-Employer Plans (29 CFR part 4062) requires that interest be charged or credited at the section 6601 rate on underpayments and overpayments of employer liability under section 4062 of ERISA. The section 6601 rate is established periodically (currently quarterly) by the Internal Revenue Service. The rate applicable to the first quarter (January through March) of 2007, as announced by the IRS, is 8 percent.

The following table lists the late payment interest rates for premiums and employer liability for the specified time periods:

From—	Through—	Interest rate (percent)
4/1/00	3/31/01	9
4/1/01	6/30/01	8
7/1/01	12/31/01	7
1/1/02	12/31/02	6
1/1/03	9/30/03	5
10/1/03	3/31/04	4
4/1/04	6/30/04	5
7/1/04	9/30/04	4
10/1/04	3/31/05	5
4/1/05	9/30/05	6
10/1/05	6/30/06	7
7/1/06	3/31/07	8

Underpayments and Overpayments of Multiemployer Withdrawal Liability

Section 4219.32(b) of the PBGC's regulation on Notice, Collection, and Redetermination of Withdrawal Liability (29 CFR part 4219) specifies the rate at which a multiemployer plan is to charge or credit interest on underpayments and overpayments of withdrawal liability under section 4219 of ERISA unless an applicable plan provision provides otherwise. For interest accruing during any calendar quarter, the specified rate is the average quoted prime rate on short-term commercial loans for the fifteenth day (or the next business day if the fifteenth day is not a business day) of the month preceding the beginning of the quarter, as reported by the Board of Governors of the Federal Reserve System in Statistical Release H.15 (''Selected Interest Rates''). The rate for the first

quarter (January through March) of 2007 (*i.e.*, the rate reported for December 15, 2006) is 8.25 percent.

The following table lists the withdrawal liability underpayment and overpayment interest rates for the specified time periods:

From—	Through—	Interest rate (percent)
7/1/00	3/31/01	9.50
4/1/01	6/30/01	8.50
7/1/01	9/30/01	7.00
10/1/01	12/31/01	6.50
1/1/02	12/31/02	4.75
1/1/03	9/30/03	4.25
10/1/03	9/30/04	4.00
10/1/04	12/31/04	4.50
1/1/05	3/31/05	5.25
4/1/05	6/30/05	5.50
7/1/05	9/30/05	6.00
10/1/05	12/31/05	6.50
1/1/06	3/31/06	7.25
4/1/06	6/30/06	7.50
7/1/06	9/30/06	8.00
10/1/06	3/31/07	8.25

Multiemployer Plan Valuations Following Mass Withdrawal

The PBGC's regulation on Duties of Plan Sponsor Following Mass Withdrawal (29 CFR part 4281) prescribes the use of interest assumptions under the PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044). The interest assumptions applicable to valuation dates in February 2007 under part 4044 are contained in an amendment to part 4044 published elsewhere in today's **Federal Register**. Tables showing the assumptions applicable to prior periods are codified in appendix B to 29 CFR part 4044.

Issued in Washington, DC, on this 9th day of January 2007.

Vincent K. Snowbarger,

Interim Director, Pension Benefit Guaranty Corporation.

[FR Doc. E7–337 Filed 1–11–07; 8:45 am]

BILLING CODE 7709–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

New Information Collection:

Study of Marketing and Delivery of Financial Products to Individual Investors, OMB Control No. 3235-xxxx; SEC File No. 270–561.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this collection of information to the Office of Management and Budget for approval.

The Commission has engaged an outside contractor to undertake a study that will involve collecting, categorizing, and analyzing empirical data regarding the marketing, sale and delivery of financial products, accounts, programs and services offered to individual investors by broker-dealers and investment advisers. The contractor's findings will be summarized in a report for the Commission.

Participation in the study will be voluntary. Information collected during the study will not be kept confidential, except that the identity of a study participant, and information that would identify a participant to anyone outside the study will not be disclosed without the participant's consent, except as required by law. Participants in the study are expected to include broker-dealers, investment advisers, individual investors, investor advocates and industry groups. We estimate that there would be approximately 330 participants in the study at an estimated 1.5 hours for a total annual burden of approximately 500 hours.

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 control number.

Written comments regarding the above information should be directed to the following persons: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington DC 20503 or send an e-mail to *David_Rostker@omb.eop.gov*; and (ii) R. Corey Booth, Director/Chief Information Officer, Securities and Exchange Commission, C/O Shirley Martinson 6432 General Green Way, Alexandria, VA 22312; or send an e-mail to: *PRA_Mailbox@sec.gov*. Comments must be submitted to OMB within 30 days of this notice.

January 3, 2007.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–300 Filed 1–11–07; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: U.S. Securities and Exchange Commission, Office of Filing and Information Services, Washington, DC 20549.

Extension:

Rule 35d–1; SEC File No. 270–491; OMB Control No. 3235–0548.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''Act'') the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

Rule 35d–1 (17 CFR 270.35d–1) under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) generally requires that investment companies with certain names invest at least 80% of their assets according to what their names suggests. The rule provides that an affected investment company must either adopt this 80% requirement as a fundamental policy or adopt a policy to provide notice to shareholders at least 60 days prior to any change in its 80% investment policy. This preparation and delivery of the notice to existing shareholders is a collection of information within the meaning of the Act.

The Commission estimates that there are 7,200 open-end and closed-end management investment companies and series that have descriptive names that are governed by the rule. The Commission estimates that of these 7,200 investment companies, approximately 24 provide prior notice to their shareholders of a change in their investment policies per year. The Commission estimates that the annual burden associated with the notice requirement of the rule is 20 hours per affected investment company or series. The total burden hours for Rule 35d–1 is 480 per year in the aggregate (24 responses x 20 hours per response). Estimates of average burden hours are made solely for the purposes of the Act, and are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules and forms.

The collection of information under Rule 35d–1 is mandatory. The information provided under Rule 35d–1 is not kept confidential. 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 control number.

General comments regarding the above information should be directed to the following persons: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or e-mail to *David_Rostker@omb.eop.gov*; and (ii) R. Corey Booth, Director/Chief Information Officer, Securities and Exchange Commission, C/O Shirley Martinson 6432 General Green Way, Alexandria, VA, 22312; or send an e-mail to: *PRA_Mailbox@sec.gov*. Comments must be submitted to OMB within 30 days of this notice.

January 3, 2007.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–301 Filed 1–11–07; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension:

Rule 15c2–12; SEC File No. 270–330; OMB Control No. 3235–0372.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

• Rule 15c2–12 Disclosure requirements for municipal securities

Rule 15c2–12 (17 CFR 240.15c2–12), under the Securities Exchange Act of 1934 (15 U.S.C. 78 *et. seq.*), requires underwriters of municipal securities: (1) To obtain and review a copy of an official statement deemed final by an issuer of the securities, except for the omission of specified information; (2) in non-competitively bid offerings, to make available, upon request, the most recent preliminary official statement, if any; (3) to contract with the issuer of the securities, or its agent, to receive, within specified time periods, sufficient copies of the issuer's final official statement to comply both with this rule and any rules of the MSRB; (4) to provide, for a specified period of time, copies of the final official statement to any potential customer upon request; (5) before purchasing or selling municipal securities in connection with an offering, to reasonably determine that the issuer or other specified person has undertaken, in a written agreement or contract, for the benefit of holders of such municipal securities, to provide certain information about the issue or issuer on a continuing basis to a nationally recognized municipal securities information repository; and (6) to review the information the issuer of the municipal security has undertaken to provide prior to recommending a transaction in the municipal security.

These disclosure and recordkeeping requirements will ensure that investors have adequate access to official disclosure documents that contain details about the value and risks of particular municipal securities at the time of issuance while the existence of compulsory repositories will ensure that investors have continued access to terms and provisions relating to certain static features of those municipal securities. The provisions of Rule 15c2–12 regarding an issuer's continuing disclosure requirements assist investors by ensuring that information about an issue or issuer remains available after the issuance.

Municipal offerings of less than $1 million are exempt from the rule, as are offerings of municipal securities issued in large denominations that are sold to no more than 35 sophisticated investors, have short-term maturities, or have short-term tender or put features. It is estimated that approximately 12,000 brokers, dealers, municipal securities dealers, issuers of municipal securities, and nationally recognized municipal securities information repositories will spend a total of 123,850 hours per year complying with Rule 15c2–12.

There is no specific retention period applied by Rule 15c2–12 for the recordkeeping requirement contained in Rule 15c2–12. The retention period is determined by private agreement between a nationally recognized municipal securities information repository and the issuer.

The recordkeeping requirement is mandatory to ensure that investors have access to information about the issuer and particular issues of municipal securities. This rule does not involve the collection of confidential information. Please note that 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 control number.

General Comments regarding the estimated burden hours should be directed to the following persons: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or by sending an e-mail to: *David_Rostker@omb.eop.gov*; and (ii) R. Corey Booth, Director/Chief Information Officer, Securities and Exchange Commission, c/o Shirley Martinson, 6432 General Green Way, Alexandria, VA 22312 or send an e-mail to: *PRA_Mailbox@sec.gov*. Comments must be submitted to OMB within 30 days of this notice.

January 3, 2007.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–302 Filed 1–11–07; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submissions for OMB Review; Comment Request

Upon written request; copies available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extensions:

Rule 14f–1; OMB Control No. 3235–0108; SEC File No. 270–127.

Rule 12g3–2; OMB Control No. 3235–0119; SEC File No. 270–104.

Rule 13e–1; OMB Control No. 3235–0305; SEC File No. 270–255.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget these requests for extension of the previously approved collections of information discussed below.

Rule 14f–1 (17 CFR 240.14f–1) requires issuers to disclose a change in a majority of the directors of the issuer. The information filed under Rule 14f–1 must be filed with the Commission and is publicly available. We estimate that it takes approximately 18 burden hours to provide the information required under Rule 14f–1 and that the information is filed by 44 respondents for a total annual burden of 792.

Rule 12g3–2 (17 CFR 240.12g3–2) provides an exemption from Section 12(g) of the Act (15 U.S.C. 78l(g)) for foreign private issuers. Rule 12g3–2 is designed to provide investors in foreign securities with information about such securities and the foreign issuer. The information filed under Rule 12g3–2 must be filed with the Commission and is publicly available. We estimate that it takes approximately one hour to provide the information required under Rule 12g3–2 and that the information is filed by 1,800 foreign issuers for a total annual reporting burden of 1,800 hours.

Rule 13e–1 (17 CFR 240.13e–1) makes it unlawful for an issuer who has received notice that it is the subject of a tender offer made under Section 14(d)(1) of the Act (15 U.S.C. 78n(d)(1)) and which has commenced under Rule 14d–2 (17 CFR 240.14d–2) to purchase any of its equity securities during the tender offer unless it first files a statement with the Commission containing information required by the Rule. This rule is in keeping with the Commission's statutory responsibility to prescribe rules and regulations that are necessary for the protection of investors. Public companies are the respondents. We estimate that it takes approximately 10 burden hours per response to provide the information required under Rule 13e–1 and that the information is filed by 20 respondents. We estimate that 25% of the 10 hours per response (2.5 hours) is prepared by the company for a total annual reporting burden of 50 hours (2.5 hours per response × 20 responses).

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 control number.

Written comments regarding the above information should be directed to the following persons: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or send an e-mail to *David_Rostker@omb.eop.gov;* and (ii) R. Corey Booth, Director/Chief Information Officer, Securities and Exchange Commission, C/O Shirley Martinson 6432 General Green Way, Alexandria, VA 22312; or send an e-mail to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: January 3, 2007.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–303 Filed 1–11–07; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submissions for OMB Review; Comment Request

Upon written request; copies available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extensions:

Industry Guides: OMB Control No. 3235–0069 and SEC File No. 270–069.

Notice of Exempt Roll-Up Preliminary Communication: OMB Control No. 3235–0452 and SEC File No. 270–396.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget these requests for extension of the previously approved collections of information discussed below.

Industries Guides are used by registrants in certain specified industries as disclosure guidelines to be followed in disclosing information to investors in Securities Act (15 U.S.C. 77a *et seq.*) and Exchange Act (15 U.S.C. 78a *et seq.*) registration statements and certain other Exchange Act filings. The information filed with the Commission using the Industry Guides permits verification of compliance with securities law requirements and assures the public availability and dissemination of such information. The information required by the Industry Guides is filed on occasion and is mandatory. All information is provided to the public. The Commission estimates for administrative purposes only that the total annual burden with respect to the Industry Guides is one hour. The Industry Guides do not directly impose any disclosure burden.

A Notice of Exempt Preliminary Roll-Up Communication (''Notice'') (240.14a–104) provides information regarding ownership interests and any potential conflicts of interest to be included in statements submitted by or on behalf of a person pursuant to Section 240.14a–2(b)(4) and Section 240.14a–6(n). The Notice is filed on occasion and the information required is mandatory. All information is provided to the public upon request. The Notice takes approximately .25 hours per response and is filed by 4 respondents for a total of one annual burden hour.

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 control number.

Written comments regarding the above information should be directed to the following persons: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or send an e-mail to *David_Rostker@omb.eop.gov;* and (ii) R. Corey Booth, Director/Chief Information Officer, Securities and Exchange Commission, C/O Shirley Martinson, 6432 General Green Way, Alexandria, VA 22312; or send an e-mail to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: January 3, 2007.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–304 Filed 1–11–07; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: [To be Published].

STATUS: Closed Meeting.

PLACE: 100 F Street, NE., Washington, DC

ANNOUNCEMENT OF ADDITIONAL MEETING: Additional Meeting (Week of January 8, 2007).

A Closed Meeting has been scheduled for Thursday, January 11, 2007 at 10 a.m.

Commissioners and certain staff members who have an interest in the matter will attend the Closed Meeting.

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)(5), (7), (9)(B) and (10) and 17 CFR 200.402(a)(5), (7), (9)(ii) and (10) permit consideration of the scheduled matter at the Closed Meeting.

Commissioner Campos as duty officer, voted to consider the item listed for the closed meeting in closed session, and determined that no earlier notice thereof was possible.

The subject matter of the Closed Meeting scheduled for Thursday, January 11, 2007 will be: Institution and settlement of injunctive action.

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) 551–5400.

Dated: January 9, 2007.

Nancy M. Morris,

Secretary.

[FR Doc. 07–113 Filed 1–9–07; 4:03 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55049; File No. SR–OPRA–2006–02]

Options Price Reporting Authority; Order Approving an Amendment to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information To Provide That Classes of Foreign Currency Options Newly Introduced for Trading by Any of the Parties to the Plan Be Treated Under the Provision ''Special Temporary Provision for Newly Traded FCO Securities'' During a Temporary Period Ending on December 31, 2007

January 5, 2007.

On November 17, 2006, the Options Price Reporting Authority (''OPRA'') submitted to the Securities and Exchange Commission (''Commission''), pursuant to Section 11A of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 608 thereunder,[2] an amendment to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information (''OPRA Plan'').[3] The proposed OPRA Plan amendment would provide that classes of Foreign Currency Options (''FCO Securities'' or ''FCOs''), newly introduced for trading in the securities markets maintained by any of the parties to the OPRA Plan, will be treated by OPRA under the provision ''Special Temporary Provision for Newly Traded FCO Securities'' during a temporary period ending no later than December 31, 2007. Notice of the proposal was published in the **Federal Register** on December 11, 2006.[4] The Commission received no comment letters on the proposed OPRA Plan amendment. This order approves the proposal.

Under the terms of the OPRA Plan, subject to the exception described in Section VIII(c)(iii), FCOs traded on any of the exchanges that are parties to the Plan are ordinarily assigned to a separate ''FCO service'' rather than OPRA's ''basic service'' to which equity and index options are assigned. As a result, subject to the exception described below, separate fees and charges are imposed for access to the FCO service, and all revenues and expenses pertaining to the FCO service are allocated to a separate ''FCO Accounting Center'' established under Section VIII(c) of the OPRA Plan.

To date, FCOs have been traded only on the Phlx. In late 2005, at the request of the Phlx and with the Commission's approval, OPRA amended Section VIII(c) of the ORPA Plan by adding a new subparagraph (iii) thereto, which provides that during a temporary period ending on December 31, 2007, new classes of FCO Securities introduced for trading on the Phlx (such classes are defined as ''New FCO Securities'') will be included in OPRA's basic service and not in its FCO service.[5] The effect of the amendment is to treat New FCO Securities as if they were equity options and not FCO Securities, with the result that during the period when subparagraph (c)(iii) of Section VIII is in effect, access to market information pertaining to New FCO Securities is not subject to the separate fees and charges that apply to OPRA's FCO service, and revenues and expenses pertaining to market information pertaining to New FCO Securities are not allocated to OPRA's FCO accounting center but instead are allocated to its basic accounting center.

The ISE recently advised OPRA that it intends to commence trading in certain classes of FCOs and that none of the FCOs it intends to trade will be fungible with classes of FCOs traded on the Phlx. Since by its terms Section VIII(c)(iii) of the OPRA Plan currently applies to new classes of FCOs that are listed on the Phlx, in response to the ISE's request, OPRA proposes to amend that section to make it apply to all classes of FCOs newly listed by any exchange that is a party to the OPRA Plan while that section remains in effect. This will assure that all classes of newly listed FCOs will be treated the same by being included in OPRA's basic service, rather than in its FCO service regardless of the exchange on which those classes are traded.

After careful review, the Commission finds that the proposed OPRA Plan amendment is consistent with the requirements of the Act and the rules and regulations thereunder.[6] The Commission finds that the proposed OPRA Plan amendment is consistent with Section 11A of the Act [7] and Rule 608 thereunder [8] in that it is appropriate in the public interest, for the protection of investors and the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system. Specifically, the Commission finds that it is appropriate generally and consistent with OPRA's prior filing [9] to amend the language of the OPRA Plan to temporarily accommodate any of the parties to the OPRA Plan that are maintaining classes of FCO Securities newly introduced for trading in the securities markets and to treat such new FCO Securities under the provision ''Special Temporary Provision for Newly Traded FCO Securities'' during a temporary period ending no later than December 31, 2007.

It is therefore ordered, pursuant to Section 11A of the Act,[10] and Rule 608 thereunder,[11] that the proposed OPRA Plan amendment (SR–OPRA–2006–02) be, and it hereby is, approved on a temporary basis, until December 31, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–313 Filed 1–11–07; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78k–1.

[2] 17 CFR 242.608.

[3] The OPRA Plan is a national market system plan approved by the Commission pursuant to Section 11A of the Act and Rule 608 thereunder (formerly Rule 11Aa3–2). *See* Securities Exchange Act Release No. 17638 (March 18, 1981), 22 S.E.C. Docket 484 (March 31, 1981). The full text of the OPRA Plan is available at *http://www.opradata.com.*

The OPRA Plan provides for the collection and dissemination of last sale and quotation information on options that are traded on the participant exchanges. The six participants to the OPRA Plan are the American Stock Exchange LLC, the Boston Stock Exchange, Inc., the Chicago Board Options Exchange, Incorporated, the International Securities Exchange, LLC (''ISE''), the NYSE Arca, Inc., and the Philadelphia Stock Exchange, Inc. (''Phlx'').

[4] *See* Securities Exchange Act Release No. 54870 (December 5, 2006), 71 FR 71597.

[5] *See* Securities Exchange Act Release No. 52901 (December 6, 2005), 70 FR 74061 (December 14, 2005) (SR–OPRA–2005–03).

[6] In approving this proposed OPRA Plan Amendment, the Commission has considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[7] 15 U.S.C. 78k–1.

[8] 17 CFR 242.608.

[9] *See supra* note 5.

[10] 15 U.S.C. 78k–1.

[11] 17 CFR 242.608.

[12] 17 CFR 200.30–3(a)(29).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55052; File No. SR–NASDAQ–2006–047]

Self-Regulatory Organization; the NASDAQ Stock Market LLC; Order Approving Proposed Rule Change To Modify Its Listing Rules in the Case of a Reverse Merger

January 5, 2007.

On November 13, 2006, The NASDAQ Stock Market LLC (''Nasdaq'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b-4 thereunder,[2] a proposed rule change to clarify the process an issuer must follow when applying for initial listing in connection with a reverse merger. The proposed rule change was published for comment in the **Federal Register** on December 6, 2006.[3] The Commission received no comments regarding the proposal.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[4] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[5] which requires that the rules of an exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national securities system, and, in general, to protect investors and the public interest.

Nasdaq proposes to amend Nasdaq Rule 4340(a) and related interpretive material to state that an issuer must apply for initial listing prior to consummating a transaction whereby the issuer combines with an entity that is not listed on Nasdaq, resulting in a change of control of the issuer and potentially allowing the non-Nasdaq entity to obtain a ''backdoor listing'' on Nasdaq (''Reverse Merger'').

Current Nasdaq Rule 4340(a) states that an issuer must apply for initial listing ''following'' a Reverse Merger. Nasdaq proposes to replace the word ''following'' with the phrase ''in connection with'' and require the issuer to ''submit an application for the post-transaction entity with sufficient time to allow Nasdaq to complete its review before the transaction is completed.'' Because the entity resulting from the Reverse Merger could be substantially different from the one originally approved for Nasdaq listing, it is reasonable and consistent with the Act for Nasdaq to conduct a de novo listing review of the new entity and, for the new entity to keep the listing, to require sufficient time to complete the review before the Reverse Merger is completed. The Commission believes that this proposal is reasonably designed to enhance the transparency and integrity of the listing process.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[6] that the proposed rule change (SR–NASDAQ–2006–047) be, and it hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[7]

Nancy M. Morris,

Secretary.

[FR Doc. E7–311 Filed 1–11–07; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 54825 (November 28, 2006), 71 FR 70818.

[4] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[5] 5 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78s(b)(2).

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55042; File No. SR–NASDAQ–2006–055]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change as Amended by Amendment No. 1 To Temporarily Adjust Tier Volume Limits

January 4, 2007.

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 December 15, 2006, The NASDAQ Stock Market LLC (''Nasdaq'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been substantially prepared by Nasdaq. On December 21, 2006, the Exchange submitted Amendment No. 1 to the proposed rule change. The order provides notice of the proposed rule change as modified by Amendment No. 1 and approves the proposed rule change, as amended, on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes to reduce, for the month of November 2006, the average daily volume tiers in Nasdaq-listed securities contained in Nasdaq Rule 7018(a) to qualify for certain fee and rebate levels. The text of the proposed rule change is available at Nasdaq, the Commission's Public Reference Room, and *http://nasdaq.complinet.com/file_store/pdf/rulebooks/SR–NASDAQ–2006–055.pdf.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq 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 III below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq is proposing to reduce, for the month of November 2006, the average daily volume tiers for trading and routing in Nasdaq-listed securities contained in Nasdaq Rule 7018(a) to qualify for certain fee and rebate levels. Currently, in order to qualify for a per-share execution fee of $0.0028, members must have an average daily volume through Nasdaq facilities in all securities during a particular month of (i) more than 30 million shares of liquidity provided, and (ii) more than 50 million shares of liquidity accessed and/or routed. For the month of November 2006, Nasdaq is proposing to reduce those qualification volume tiers to 27 million shares and 47 million shares, respectively. In addition, Nasdaq is also reducing for the month of November 2006 the monthly average daily volume tier required to obtain the $0.0025 credit rebate from its current 30 million share level to 27 million shares. For routed orders, to qualify for a fee of the greater of (a) $0.0028 per share executed or (b) a pass-through of all applicable access fees charged by electronic communications networks that charge

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

more than $0.003 per share executed, a firm must have an average daily volume through Nasdaq facilities in all securities during the month of (y) more than 30 million shares of liquidity provided, and (z) more than 50 million shares of liquidity access and/or routed.

For the month of November 2006, Nasdaq is proposing to reduce the 30 million fee qualification volume tiers described above to 27 million shares, and the 50 million fee qualification volume tiers described above to 47 million shares. In addition, Nasdaq is also reducing for the month of November 2006, the monthly average daily volume tier required to obtain the $0.0025 credit rebate from its current 30 million share level to 27 million shares.

The reduction is designed to respond to certain processing issues associated with Nasdaq's implementation of its new single-book execution facility that can result in inhibiting the ability of users to submit orders to the system and thus not reach their usual levels of participation that would historically entitle them to the most competitive fee and rebate levels. Nasdaq believes that a temporary reduction of the qualification tiers is appropriate while both Nasdaq and its users gain more familiarity with the new single-book trading environment. Nasdaq notes that a similar reduction in tier levels is currently in effect for the month of December 2006,[3] and this filing merely makes the December tier levels retroactive to November 2006.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[4] in general, and with Section 6(b)(4) of the Act,[5] in particular, in that the proposal provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq 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

Written comments were neither solicited nor received.

III. 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. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2006–055 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2006–055. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). 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 also will be available for inspection and copying at the principal office of Nasdaq. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2006–055 and should be submitted on or before February 2, 2007.

IV. Commission's Finding and Order Granting Accelerated Approval of the Proposed Rule Change

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[6] Specifically, the Commission finds that approval of the proposed rule change is consistent with Section 6(b)(4)[7] of the Act because the proposal provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using the facilities of Nasdaq.

The Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[8] for approving the proposed rule change prior to the thirtieth day after the date of publication of the notice in the **Federal Register**. Nasdaq stated that the reduction is intended to address processing issues related to Nasdaq's implementation of its single-book trading environment. The Commission notes that the proposal represents a fee reduction for system users and also notes that the proposal is limited in duration. Therefore, the Commission finds that accelerated approval of the proposal is appropriate and should permit Nasdaq to extend the benefits of the reduction to its users for the month of November.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (SR–NASDAQ–2006–055) is hereby approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–312 Filed 1–11–07; 8:45 am]

BILLING CODE 8011–01–P

[3] *See* Securities Exchange Act Release No. 54933 (Dec. 13, 2006), 71 FR 76404 (Dec. 20, 2006) (SR–NASDAQ–2006–051).

[4] 15 U.S.C. 78f.

[5] 15 U.S.C. 78f(b)(4).

[6] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[7] 15 U.S.C. 78f(b)(4).

[8] 15 U.S.C. 78s(b)(2).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55047; File No. SR–OCC–2006–21]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of a Proposed Rule Change Relating to Membership Requirements

January 5, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934,[1] notice is hereby given that on November 15, 2006, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared primarily by OCC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change would modify certain OCC By-Laws and Rules relating to membership requirements.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC 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. OCC has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.[2]

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of this rule change is to modify certain By-Laws and Rules relating to membership requirements in order to improve their effectiveness or otherwise clarify their meaning.

1. Interpretation and Policy .03

Interpretation and Policy .03 to Article V, Section 1, of OCC's By-Laws currently requires applicants for membership to employ two key operations employees on a full-time basis. This requirement is intended to ensure that an applicant maintains sufficient staff to fulfill its obligations as a clearing member. However, several recent applicants for clearing membership have had difficulty meeting this requirement because their entire staff was employed by an affiliate of the applicant (*i.e.*, a parent or related organization) rather than by the applicant itself. While these applicants entered into employee leasing arrangements in order to comply with OCC's policy, OCC decided to reevaluate the policy in light of the fact that it had proved burdensome to a number of applicants.

OCC understands that it is not uncommon for some entities of an affiliated corporate group to outsource certain or all functions to another entity of the corporate group and let the latter be the sole employer of the people who perform those functions. In situations of that nature, OCC has concluded that there is not the same reason to be concerned about whether the applicant will have adequate staffing as in cases where the applicant relies on an unaffiliated third party for staffing. OCC therefore wishes to modify its policy in order to provide greater flexibility to recognize this alternative employment structure. Accordingly, OCC proposes to amend Interpretation and Policy .03 to Article V, Section 1, to permit the Membership/Risk Committee (''Committee'') to waive the requirement that an applicant employ two key operations employees on a full-time basis if the daily operations of the applicant are conducted by staff employed on a full-time basis by an entity affiliated with such applicant. OCC believes that the Committee's authority to waive such requirement is consistent with its existing authority to waive the requirement that an applicant employ at least one full-time person who is registered as a ''Limited Principal—Financial and Operations'' or comparable registration requirement, as applicable.

2. Rule 309

OCC proposes to amend Rule 309 to clarify that if an operationally capable clearing member proposes to become a managed clearing member (*i.e.*, outsource certain of its obligations as a clearing member to another clearing member [''managing clearing member'']), the applicant must obtain prior approval from the Committee. Currently, Interpretation and Policy .04 primarily contemplates the use of facilities management agreements by applicants for membership rather than existing clearing members. Nonetheless, OCC has always interpreted its By-Laws and Rules as requiring prior Committee review and approval of all facilities management agreements, including those proposed to be entered into by operationally capable clearing members. The proposed amendment to Rule 309 makes this interpretation explicit.

3. Rule 901

OCC proposes to amend Rule 901 to provide that a clearing member's appointment of another clearing member or CDS Clearing and Depository Services Inc. (''CDS'')[3], as applicable, for purposes of effecting settlements of exercised or matured cleared securities may not be terminated until after the 30th calendar day following notice to OCC of such termination.[4] Currently, clearing members are required to provide three business days notice of terminating such appointments. However, three business days might be insufficient for OCC to determine whether or not the clearing member has made appropriate alternative settlement arrangements. Accordingly, OCC proposes to change the notice period to be consistent with the notice period required to advise OCC of the termination of a facilities management agreement.[5]

OCC believes that the proposed change is consistent with Section 17A of the Act[6] because it amends certain rule provisions relating to membership requirements in order to improve their effectiveness or otherwise clarify their meaning and thereby promotes the prompt and accurate clearance and settlement of derivative contracts and transactions.

B. Self-Regulatory Organization's Statement on Burden on Competition

OCC does not believe that the proposed rule change would impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

OCC has not solicited or received written comments with respect to the proposed rule change.

[1] 15 U.S.C. 78s(b)(1).

[2] The Commission has modified the text of the summaries prepared by OCC.

[3] CDS is the successor organization to Canadian Depository for Securities Ltd. The By-Law definition of CDS has been amended to reflect this organizational change.

[4] OCC surveyed appointed clearing members that effect NSCC settlements for nonaffiliated clearing members as well as CDS to ascertain their views regarding the proposed change in the notice period for terminating such appointments. There were no objections to the proposed change.

[5] Conforming changes have been made to the related appointment forms, which are attached as Exhibits 5A and 5B to the proposed rule filing.

[6] 15 U.S.C. 78q–1.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five 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 ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve such proposed rule change or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File No. SR–OCC–2006–21 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–OCC–2006–21. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 100 F Street, NE., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at OCC's principal office and on OCC's Web site at *http://www.theocc.com/publications/rules/proposed_changes/proposed_changes.jsp*. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submission should refer to File No. SR–OCC–2006–21 and should be submitted on or before February 2, 2007.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[7]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–305 Filed 1–11–07; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

Interest Rates

The Small Business Administration publishes an interest rate called the optional ''peg'' rate (13 CFR 120.214) on a quarterly basis. This rate is a weighted average cost of money to the government for maturities similar to the average SBA direct loan. This rate may be used as a base rate for guaranteed fluctuating interest rate SBA loans. This rate will be 4.875 (4⅞) percent for the January-March quarter of FY 2007.

Janet A. Tasker,

Acting Associate Administrator for Financial Assistance.

[FR Doc. E7–296 Filed 1–11–07; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Aviation Proceedings, Agreements Filed the Week Ending December 29, 2006

The following Agreements were filed with the Department of Transportation under the Sections 412 and 414 of the Federal Aviation Act, as amended (49 U.S.C. 1382 and 1384) and procedures governing proceedings to enforce these provisions. Answers may be filed within 21 days after the filing of the application.

Docket Number: OST–2006–26768.

Date Filed: December 28, 2006.

Parties: Members of the International Air Transport Association.

Subject:

Mail Vote 525—Resolution 010i, TC23/123 Europe-Japan Korea, Special Passenger Amending Resolution from Korea (Rep. of) to Europe.

Intended effective date: 15 January 2007.

Barbara J. Hairston,

Supervisory Docket Officer, Docket Operations, Alternate Federal Register Liaison.

[FR Doc. E7–360 Filed 1–11–07; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Public Notice of Waiver of Aeronautical Land-Use Assurance—Hallock Municipal Airport, Hallock, MN

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of intent of waiver with respect to land.

SUMMARY: The Federal Aviation Administration (FAA) is considering a proposal to change a portion of the airport from aeronautical use to non-aeronautical use and to authorize the sale and/or conversion of the airport property. The proposal consists of two parcels of land containing a total of 4.18 acres located on the north side of the airport along County Road 13. There are no impacts to the airport by allowing the airport to dispose of the property.

These parcels were originally acquired under Grant No. FAAP–01 in 1964. The parcels were acquired for a runway that has since been abandoned and replaced by a new primary runway in a different location. The land comprising these parcels is, therefore, no longer needed for aeronautical purposes and the airport owner wishes to sell at 4.0 acre parcel for an agricultural implement dealership and convert 0.18 acres of another parcel for use as a city wastewater lift station site. The income from the sale/conversion of these parcels will be reinvested in the airport for extending the useful life of the runway pavement.

Approval does not consistute a commitment by the FAA to financially assist in the disposal of the subject airport property nor a determination of eligibility for grant-in-aid funding from the FAA. The disposition of proceeds from the disposal of the airport property will be in accordance with FAA's Policy and Procedures Concerning the Use of Airport Revenue, published in the **Federal Register** on February 16, 1999. In accordance with section 47107(h) of

[7] 17 CFR 200.30–3(a)(12).

title 49, United States Code, this notice is required to be published in the **Federal Register** 30 days before modifying the land-use assurance that requires the property to be used for an aeronautical purpose.

DATES: Comments must be received on or before February 12, 2007.

ADDRESSES: Send comments on this document to Mr. Gordon L. Nelson, Program Manager, Federal Aviation Administration, Minneapolis Airports District Office, 6020 28th Avenue South, Room 102, Minneapolis, MN 55450–2706.

FOR FURTHER INFORMATION CONTACT: Mr. Henry Noel, City Administrator, 163 South 3rd Street, Hallock, MN 56728, telephone (218) 843–2737; or Mr. Gordon L. Nelson, Program Manager, Federal Aviation Administration, Minneapolis Airports District Office, 6020 28th Avenue South, Room 102, Minneapolis, MN 55450–2706, telephone (612) 713–4358/FAX (612) 713–4364. Documents reflecting this FAA action may be reviewed at the above locations.

SUPPLEMENTARY INFORMATION: Following are legal descriptions of the property located in Kittson County, MN:

(1) That part of Section 24, T161N, R49W described as follows: Commending at an iron monument at the NW corner of said Section 24; thence South 89 degrees 40 minutes 33 seconds East, assumed bearing, along the north line of said Section 24 a distance of 2523.77 feet; thence South 27 degrees 29 minutes 58 seconds East, a distance of 33.72 feet to an iron pipe monument; being the point of beginning of the tract to be described; thence North 89 degrees 40 minutes 34 seconds East, parallel with north line of said Section 24 a distance of 400 feet to an iron pipe monument; thence South 22 degrees 18 minutes 25 seconds East, parallel with and 40 feet perpendicular to the westerly right-of-way line of Burlington Northern, Inc. railroad, a distance of 437.34 feet to an iron pipe monument; thence South 67 degrees 41 minutes 37 seconds West 317.57 feet to an iron pipe monument; thence North 27 degrees 29 minutes 58 seconds West 589.49 feet to the point of beginning, containing 4.00 acres, more or less.

(2) That part of the NE¼ of the NW¼ of Section 24, T161N, R49W bounded as follows: Beginning on the north line of said Section 24 at a point which lies 557.00 feet west of the northeast corner of the NW¼ being the point of beginning of the tract to be described; thence South 0 degrees 19 minutes 27 seconds West, assumed bearing, along a line perpendicular to said section line a distance of 172.82 feet; thence North 27 degrees 22 minutes 40 seconds West, a distance of 195.19 feet to the north line of said Section 24, thence South 89 degrees 40 minutes 33 seconds East, a distance of 90.74 feet along the north line of said section back to the point of beginning, containing 0.18 acres, more or less.

Dated: Issued in Minneapolis, MN, on December 11, 2006.

Robert A. Huber,

Manager, Minneapolis Airports District Office, FAA, Great Lakes Region.

[FR Doc. 07–34 Filed 1–11–07; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Ninth Meeting: RTCA Special Committee 203/Minimum Performance Standards for Unmanned Aircraft Systems and Unmanned Aircraft

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of RTCA Special Committee 203, Minimum Performance Standards for Unmanned Aircraft Systems and Unmanned Aircraft.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of RTCA Special Committee 203, Minimum Performance Standards for Unmanned Aircraft Systems and Unmanned Aircraft.

DATES: The meeting will be held February 6–8, 2007, from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at RTCA, Inc., 1828 L Street, NW., Suite 805, Washington, DC 20036.

Note: Workgroup 3 will convene on Monday, February 5, 2007, from 1 p.m. to 4:30 p.m. Workgroup 1 will convene on Friday, February 9, 2007, from 8 a.m. to 12 p.m. and Workgroup 2 will convene Friday, February 9, 2007, from 8 a.m. to 5 p.m. Dress is Business Casual.

FOR FURTHER INFORMATION CONTACT: (1) RTCA Secretariat, 1828 L Street, NW., Suite 805, Washington, DC 20036; telephone (202) 833–9339; fax (202) 833–9434; web site *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92–463, 5 U.S.C., Appendix 2), notice is hereby given for a Special Committee 203 meeting. The agenda will include:

- February 6:
- Opening Plenary Session (Welcome and Introductory Remarks, Approval of Eight Plenary Summary)
- Review SC–203 Progress Since Eighth Plenary: Status from Workgroups 1, 2 and 3
- Resolve Final Review and Comment (FRAC) comments on draft document Guidance Material and Considerations for Unmanned Aircrafts Systems. (GM) document
- February 7:
- Continue resolution of FRAC comments on draft GM document
- February 8:
- Continue resolution of FRAC comments on draft GM document
- Achieve plenary consensus on draft GM document and forward to RTCA PMC for consideration.
- Closing Plenary Session (Action Item Review, Other Business, Date, Place and Time of Next Plenary, Adjourn)
- Time permitting convene WGs 1, 2 and 3.

Attendance is open to the interested public but limited to space availability. With the approval of the chairmen, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on January 4, 2007.

Francisco Estrada C.,

RTCA Advisory Committee.

[FR Doc. 07–94 Filed 1–11–07; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

Sunshine Act Meetings; Unified Carrier Registration Plan Board of Directors

AGENCY: Federal Motor Carrier Safety Administration.

TIME AND DATE: January 15, 2007, 1 p.m. to 5 p.m. and January 16, 2007, 8 a.m. to 12 p.m.

PLACE: Four Points by Sheraton Phoenix Metro Center, 10220 N. Metro Parkway East, Phoenix, AZ 85051.

STATUS: Open to public.

MATTERS TO BE CONSIDERED: An overview of the Unified Carrier Registration Plan and Agreement requirements set forth under section 4305 of the ''Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users,'' and the administrative functioning of the Board. In addition, the Board will continue its

work in developing and implementing the Unified Carrier Registration Plan and Agreement. The Board's Subcommittees, including the Industry Advisory Subcommittee, will also meet. Further, any action taken by the Board at the last Board meeting held on December 4 and 5, 2006, in Chicago, IL will be considered for ratification.

FOR FURTHER INFORMATION CONTACT: Mr. William Quade, (202)366–2172, Director, Office of Safety Programs, Federal Motor Carrier Safety Administration, or Mr. Bryan Price, (412) 395–4816, FMCSA Pennsylvania Division Office.

Dated: January 9, 2007.

John H. Hill,

Administrator.

[FR Doc. 07–116 Filed 1–10–07; 10:42 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 of the Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) received a request for a waiver of compliance with certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

City of Placentia, California

[Docket Number FRA–2006–24654]

The City of Placentia, California (City) and BNSF Railway Company (BNSF) have petitioned for a second extension to the waiver granted on June 21, 2006, in FRA Docket No. FRA–2006–24654. In the June 21, 2006 waiver, FRA agreed to extend the original deadline of June 24, 2006, set forth in 49 CFR 222.42 for continuation of an intermediate partial quiet zone until September 22, 2006. Subsequently, FRA received a waiver requesting an extension of September 22, 2006, to January 20, 2007, from the parties. FRA granted this extension on September 21, 2006. In this current request, the City and BNSF state that they will be unable to meet the January 20, 2007, deadline due to technical problems with the radio communications system that required the ordering of new radio equipment and the need to conduct a 30-day test period of the radio communications system. The City and BNSF seek to retain the current partial quiet zone in order to avoid disruption and confusion in the interim and state that safety will not be compromised.

Interested parties are invited to participate in these proceedings by submitting written views, data or comments. Each comment shall specifically set forth the basis upon which it is made and contain a concise statement of the interest of the commenter in the proceeding. FRA does not anticipate the need to schedule a public hearing in connection with this proceeding since the facts do not appear to warrant a hearing. If any interested party desires an opportunity to comment, they should notify FRA in writing within 15 days of the date of publication of this notice and specify the basis for their request.

All communications concerning these proceedings should identify the docket number set forth above and may be submitted by any of the following methods:

- *Web site: http://dms.dot.gov.* Follow the instructions for submitting comments on the DOT electronic docket site.
- *Fax:* 202–493–2251.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–0001.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays. to the Docket Clerk, DOT Docket Management Facility, Room PL–401 (Plaza Level), 400 7th Street, SW., Washington, DC 20590.

Communications received within 15 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. FRA reserves the right to grant temporary relief to avoid lapse of the existing partial quiet zone while the comment period is open, after consideration of any comments filed prior to the initial date of decision. All written communications concerning this proceeding are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are available for inspection and copying on the Internet at the docket facility's Web site: *http://dms.dot.gov.*

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Department of Transportation's complete Privacy Act Statement, which was published in the **Federal Register** on April 11, 2000 (Volume 65, Number 70; Pages 19477–78). The Privacy Act Statement may also be found at *http://dms.dot.gov.*

Issued in Washington, DC on January 9, 2007.

Michael Logue,

Deputy Associate Administrator, for Safety Compliance and Program Implementation.

[FR Doc. E7–319 Filed 1–11–07; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) received a request for a waiver of compliance with certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

New Jersey Transit Corporation

[Supplement to Waiver Petition Docket Number FRA–1999–6135]

As a supplement to New Jersey Transit Corporation's (NJ Transit) Petition for Approval of Shared Use and Waiver of Certain FRA Regulations (the original shared use waiver was granted by the FRA Railroad Safety Board on December 3, 1999, and a five year extension was granted by the FRA Railroad Safety Board on May 2, 2005), NJ Transit is making signal improvements between CP45 and CP70 in order to create an ''Extended Temporal Separation Mode'' of operation. This will allow NJ Transit and Conrail to safely share a limited and specific section of the River Line outside of the fixed-windows of temporal separation. NJ Transit submits that this request is consistent with the waiver process for Shared Use. *See Statement of Agency Policy Concerning Jurisdiction Over the Safety of Railroad Passenger Operations and Waivers Related to Shared Use of the Tracks of the General Railroad System by Light Rail and Conventional Equipment, 65 FR 42529 (July 10, 2000); see also Joint Statement of Agency Policy Concerning Shared Use of the Tracks of the General Railroad System by Conventional*

Railroads and Light Rail Transit Systems, 65 FR 42526 (July 10, 2000).

Currently, River Line passenger operations and Conrail operations are temporally-separated, with light rail having exclusive use of the shared track from 6 a.m. until 10 p.m. during the Passenger Period and Conrail maintaining exclusive rights at all other times during the Freight Period. NJ Transit is proposing to make signal improvements that will maintain temporal separation but provide for superior utilization of the existing infrastructure by expanding the Passenger Period and allow Conrail an increased operating flexibility. Specifically, the intent of these improvements is to: enable the provision of passenger service to Route 73 station in Pennsauken during the extended hours of 5:30 a.m. until 12 a.m.; provide additional flexibility and efficiencies for the operation of freight trains, specifically to enable Conrail to operate between Pavonia Yard and Minson Siding/Pennsauken Industrial Track under vitally enforced separation from light rail vehicles during all hours; provide positive train separation through the utilization of active trip stop transponders for light rail encroachment; and power derails for freight encroachment.

NJ Transit further submitted on December 15, 2006, a letter offering clarification and additional information to amend the original petition. First, NJ Transit is formally notifying the FRA that in September of 2004, NJ Transit and Conrail established two separate zones of temporal separation: Zone One from CP45 (Pennsauken) to CP269 (Bordentown), with exclusive Passenger Period from 6 a.m. until 10 p.m., which remains unchanged from the original Shared Use Waiver; Zone Two from CP269 (Bordentown) to CP329 (Trenton) features a revised Passenger Period that starts at 5:45 a.m. until 10 p.m.

Second, as part of the current proposed extended temporal separation between CP45 and CP70, there is potential for a new parallel operation between River Line light rail vehicles and Conrail freight equipment at track centerline distances that in some locations are less than 17-ft. NJ Transit is informing FRA that it will not install an Intrusion Detection System (IDS) in this area as was done previously at two other locations of the River Line. Instead, NJ Transit proposes to maintain an equivalent level of safety by restricting this section of River Line to one mode at a time by prohibiting River Line light rail vehicles from operating between CP45 and CP70 when a Conrail freight train has been authorized through this section.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communication concerning these proceedings should identify the appropriate docket number (e.g., Waiver Petition Docket Number FRA–1999–6135) and must be submitted to the Docket Clerk, DOT Docket Management Facility, Room PL–401 (Plaza Level), 400 7th Street, SW., Washington, D.C. 20590. Communications received within 30 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's Web site at *http://dms.dot.gov.*

Issued in Washington, DC on January 9, 2007.

Grady C. Cothen,

Deputy Associate Administrator, for Safety Standards and Program Development.

[FR Doc. E7–318 Filed 1–11–07; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA 2002006–25975; Notice 2]

American Honda Motor Co., Inc., Grant of Petition for Decision of Inconsequential Noncompliance

American Honda Motor Co., Inc. (Honda) has determined that the certification labels for certain Pilot trucks that it produced in 2006 do not comply with S5.3 of 49 CFR 571.120, Federal Motor Vehicle Safety Standard (FMVSS) No. 120, ''Tire selection and rims for motor vehicles other than passenger cars.'' Pursuant to 49 U.S.C. 30118(d) and 30120(h), Honda has petitioned for a determination that this noncompliance is inconsequential to motor vehicle safety and has filed an appropriate report pursuant to 49 CFR Part 573, ''Defect and Noncompliance Reports.'' Notice of receipt of a petition was published, with a 30-day comment period, on October 4, 2006, in the **Federal Register** (71 FR 58660). NHTSA received no comments.

Affected are a total of approximately 23,000 model year 2006 and 2007 Honda Pilot trucks produced between February 17, 2006 and August 10, 2006. S5.3.2 of FMVSS No. 120 requires that the vehicles shall show the size designation appropriate for the tires. The noncompliant vehicles have certification labels stating that the rim size is 6 inches, when in fact the rim size is 16 inches. Honda has corrected the problem that caused these errors so that they will not be repeated in future production.

Honda believes that the noncompliance is inconsequential to motor vehicle safety and that no corrective action is warranted. Honda presents the following basis for its petition. Most vehicle owners, dealers, and tire service technicians would refer to the vehicles' existing tires and/or the separate Tire Placard to determine the appropriate size for a replacement tire rather than to the Certification Label. If the vehicle owner, dealer or tire service technician read the incorrect rim size on the certification label, it would be obvious that a full size vehicle could not use 6 inch wheels. The owner's manual contains the correct rim size information. The correct rim size is cast into the wheel itself.

NHTSA agrees with Honda that the noncompliance is inconsequential to motor vehicle safety. It would be obvious that a full size vehicle could not be supported by 6 inch wheels. The correct size information is available in the owner's manual, and on the wheel itself, in order to determine the correct size for replacement wheels and tires.

In consideration of the foregoing, NHTSA has decided that the petitioner has met its burden of persuasion that the noncompliance described is inconsequential to motor vehicle safety. Accordingly, Honda's petition is granted and the petitioner is exempted from the obligation of providing notification of, and a remedy for, the noncompliance.

(Authority: 49 U.S.C. 30118, 30120; delegations of authority at CFR 1.50 and 501.8).

Issued on: January 8, 2007.

Daniel C. Smith,

Associate Administrator for Enforcement.

[FR Doc. E7–316 Filed 1–11–07; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34554 (Sub-No. 6)]

Union Pacific Railroad Company—Temporary Trackage Rights Exemption—BNSF Railway Company

BNSF Railway Company (BNSF), pursuant to a modified written trackage rights agreement entered into between BNSF and Union Pacific Railroad Company (UP), has agreed to extend the expiration date of the local trackage rights granted to UP [1] over BNSF's line of railroad extending from BNSF milepost 579.3 near Mill Creek, OK, to BNSF milepost 631.1 near Joe Junction, TX, a distance of approximately 51 miles.[2]

The transaction is scheduled to be consummated on January 28, 2007.

The purpose of this transaction is to modify the temporary trackage rights exempted in STB Finance Docket No. 34554 (Sub-No. 4) to further extend the expiration date to on or before December 31, 2007. The modified trackage rights will permit UP to continue to move loaded and empty ballast trains for use in its maintenance-of-way projects.

As a condition to this exemption, any employees affected by the trackage rights will be protected by the conditions imposed in *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate*, 360 I.C.C. 653 (1980).

This notice is filed under 49 CFR 1180.2(d)(7). If it 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 will not automatically stay the effectiveness of the exemption. Stay petitions must be filed by January 19, 2007 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 34554 (Sub-No. 6), must be filed with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Gabriel S. Meyer, 1400 Douglas Street, STOP 1580, Omaha, NE 68179.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov*.

Decided: January 4, 2007.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. E7–163 Filed 1–11–07; 8:45 am]

BILLING CODE 4915–01–P

[1] UP submits that the trackage rights being granted here are only temporary rights, but, because they are ''local'' rather than ''overhead'' rights, they do not qualify for the Board's class exemption for temporary trackage rights at 49 CFR 1180.2(d)(8). *See Railroad Consolidation Procedures*, 6 S.T.B. 910 (2003). Therefore, UP and BNSF concurrently have filed a petition for partial revocation of this exemption in STB Finance Docket No. 34554 (Sub-No. 7), *Union Pacific Railroad Company—Temporary Trackage Rights Exemption—BNSF Railway Company*, wherein UP and BNSF request that the Board permit the proposed local trackage rights arrangement described in the present proceeding to expire on or about December 31, 2007. That petition will be addressed by the Board in a separate decision.

[2] The original trackage rights granted in *Union Pacific Railroad Company—Trackage Rights Exemption—The Burlington Northern and Santa Fe Railway Company*, STB Finance Docket No. 34554 (STB served Oct. 7, 2004), also extended from BNSF milepost 579.3 near Mill Creek, OK, to BNSF milepost 631.1 near Joe Junction, TX. By decisions served on November 24, 2004, in STB Finance Docket No. 34554 (Sub-No. 1), on March 25, 2005, in STB Finance Docket No. 34554 (Sub-No. 3), and on March 23, 2006, in STB Finance Docket No. 34554 (Sub-No. 5), the Board granted exemptions to permit the trackage rights authorized in STB Finance Docket No. 34554 and extended in STB Finance Docket No. 34554 (Sub-No. 2), served on February 11, 2005, and in STB Finance Docket No. 34554 (Sub-No. 4), served on March 3, 2006, to expire. At the time of the last extension, it was anticipated by the parties that the rights would expire on or about December 31, 2006. However, this authority has not yet been exercised.

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–6 (Sub–No. 446X)]

BNSF Railway Company—Abandonment Exemption—in Beltrami Country, MN

BNSF Railway Company (BNSF) has filed a notice of exemption under 49 CFR 1152 Subpart F—*Exempt Abandonments* to abandon a 5.29-mile line of railroad between milepost 90.87 and milepost 95.15, including the 1.01-mile depot spur between milepost 94.78 and milepost 93.77, near Bemidji in Beltrami County, MN. The line traverses United States Postal Service Zip Code 56601.

BNSF has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic on the line; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental report), 49 CFR 1105.8 (historic report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on February 14, 2007, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by January 22, 2007. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by February 1, 2007 with: Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to BNSF's representative: Sidney L. Strickland, Jr., PLLC, 3050 K Street, NW., Suite 101, Washington, DC 20007.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

BNSF has filed environmental and historic reports which address the effects, if any, of the abandonment on the environment and historic resources. SEA will issue an environmental assessment (EA) by January 19, 2007. Interested persons may obtain a copy of the EA by writing to SEA (Room 500, Surface Transportation Board, Washington, DC 20423–0001) or by calling SEA, at (202) 565–1539. [Assistance for the hearing impaired is

[1] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis (SEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Service Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[2] Each OFA must be accompanied by the filing fee, which currently is set at $1,300. *See* 49 CFR 1002.2(f)(25).

available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.] Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), BNSF shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by BNSF's filing of a notice of consummation by January 12, 2008, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at ''*WWW.STB.DOT.GOV.*''

Decided: January 4, 2007.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. E7–229 Filed 1–11–07; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

January 8, 2006

The Department of the Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 11000, 1750 Pennsylvania Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before February 12, 2007 to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545–1559.

Type of Review: Extension.

Title: Revenue Procedures 98–46 and 97–44, LIFO Conformity Requirement.

Description: This document contains final regulations addressing the carry over of certain attributes, such as earnings and profits and foreign income tax accounts, when two corporations combine in a corporate reorganization or liquidation that is described in both section 367(b) and section 381 of the Internal Revenue Code.

Respondents: Businesses and other for-profit institutions.

Estimated Total Burden Hours: 100,000 hours.

OMB Number: 1545–1130.

Type of Review: Extension.

Title: Special Loss Discount Account and Special Estimated Tax Payments for Insurance Companies.

Form: 8816.

Description: Form 8816 is used by insurance companies claiming an additional deduction under IRC section 847 to reconcile their special loss discount and special estimated tax payments, and to determine their tax benefit associated with the deduction. The information is needed by the IRS to determine that the proper additional deduction was claimed and to insure the proper amount of special estimated tax was computed and deposited.

Respondents: Businesses and other for-profit institutions.

Estimated Total Burden Hours: 1,983 hours.

OMB Number: 1545–1706.

Title: Revenue Procedure 2000–42 Section 1503(d) Closing Agreement Requests.

Type of Review: Extension.

Description: Revenue Procedure 2000–42 informs taxpayers of the information they must submit to request a closing agreement under Reg. S1.1503–2(g)(2)(iv)(B)(2)(i) to prevent the recapture of dual consolidated losses (DCLs) upon the occurrence of certain triggering events.

Respondents: Businesses and other for-profit institutions.

Estimated Total Burden Hours: 2,000 hours.

OMB Number: 1545–0240.

Title: Claim for Refund of Income Tax Return Preparer Penalties.

Form: 6118.

Type of Review: Extension.

Description: Form 6118 is used by preparers to file for a refund of penalties incorrectly charged. The information enables the IRS to process the claim and have the refund issued to the tax return preparer.

Respondents: Individuals or Households.

Estimated Total Burden Hours: 9,300 hours.

OMB Number: 1545–1160.

Title: CO–93–90 (Final) Corporations; Consolidated Returns-Special Rules Relating To Dispositions and Deconsolidations of Subsidiary Stock.

Type of Review: Extension.

Description: These regulations prevent elimination of corporate-level tax because of the operation of the consolidated returns investment adjustment rules. Statements are required for dispositions of a subsidiary's stock for which losses are claimed, for basis reductions within 2 years of the stock's deconsolidation, and for elections by the common parent to retain the NOLs of a disposed subsidiary.

Respondents: Businesses and other for-profit institutions.

Estimated Total Burden Hours: 6,000 hours.

OMB Number: 1545–1724.

Title: REG–109481–99 (Final) Special Rules Under Section 417(a)(7) for Written Explanations Provided by Qualified Retirement Plans After Annuity Starting Dates.

Type of Review: Extension.

Description: The collection of information requirement in sections 1.417(e)–1(b)(3)(iv)(B) and 1.417(e)–1(b)(3)(v)(A) is required to ensure that a participant and the participant's spouse consent to a form of distribution from a qualified plan that may result in reduced periodic payments.

Respondents: Individuals or households.

Estimated Total Burden Hours: 12,500 hours.

OMB Number: 1545–1450.

Title: FI–59–91 (Final), Debt Instructions With Originals Issue Discount; Contingent Payments; Anti-Abuse Rule.

Type of Review: Extension.

Description: The regulations provide definitions, general rules, and reporting requirements for debt instruments that provide for contingent payments. The regulations also provide definitions, general rules, and recordkeeping requirements for integrated debt instruments.

Respondents: Businesses and other for-profit institutions.

Estimated Total Burden Hours: 89,000 hours.

OMB Number: 1545–1451.

Title: REG–248900–96 (Final), Definition of Private Activity Bonds.

Type of Review: Extension.

Form: 8082.

Description: Section 103 provides generally that interest on certain State or local bonds is excluded from gross income. However, under sections 103(b)(1) and 141, interest on private activity bonds (other than qualified bonds) is not excluded. The regulations provide rules, for purposes of section 141, to determine how bond proceeds

are measured and used and how debt service for those bonds is paid or secured.

Respondents: State, local, or tribal governments.

Estimated Total Burden Hours: 30,100 hours.

Clearance Officer: Glenn P. Kirkland, (202) 622–3428, Internal Revenue Service, Room 6516, 1111 Constitution Avenue, NW., Washington, DC 20224.

OMB Reviewer: Alexander T. Hunt, (202) 395–7316, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

Robert Dahl,

Treasury PRA Clearance Officer.

[FR Doc. E7–348 Filed 1–11–07; 8:45 am]

BILLING CODE 4810–01–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law No. 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Community Development Financial Institutions Fund (the Fund) of the Department of the Treasury is soliciting comments concerning a voluntary information collection effort involving all Fund Programs. The specific information collection relates to the voluntary collection of narrative descriptions of projects financed by Fund awardees and allocatees in response to the public's request for better and more narrative information on impact and best practices associated with all of the Fund's Programs. The purpose is to more fully describe and record the innovative approaches community development financial institutions (CDFIs) and community development entities (CDEs) use in revitalizing communities and serving families. Fund awardees and allocatees will be invited to submit narratives on one or more projects that they believe demonstrate best practices or high impact. The project description may be for a project previously reported to the Fund through the Community Investment Impact System (CIIS) or for a new project that has not yet been reported in CIIS. The Fund plans to use the descriptions in Fund publications and on the Fund's Web site to highlight the work of its awardees and allocatees.

DATES: Written comments should be received on or before March 13, 2007 to be assured of consideration.

ADDRESSES: Direct all comments to Bob Ibanez, Financial and Program Analyst, Community Development Financial Institutions Fund, U.S. Department of the Treasury, 601 13th Street, NW., Suite 200 South, Washington, DC 20005, Facsimile Number (202) 622–7754.

FOR FURTHER INFORMATION CONTACT: A draft of the information collection may be obtained from the Fund's Web site at *http://www.cdfifund.gov.* Requests for additional information should be directed to Bob Ibanez, Financial and Program Analyst, Community Development Financial Institutions Fund, U.S. Department of the Treasury, 601 13th Street, NW., Suite 200 South, Washington, DC 20005, or by phone to (202) 927–6232.

SUPPLEMENTARY INFORMATION:

Title: CDFI/CDE Project Profile Web Form.

Abstract: The voluntary collection of narrative descriptions of projects financed by Fund awardees and allocatees via the CDFI/CDE Project Profile Web Form is in response to the public's request for better and more narrative information on impact and best practices associated with all of the Fund's Programs. The purpose is to more fully describe and record the innovative approaches community development financial institutions (CDFIs) and community development entities (CDEs) use in revitalizing communities and serving families. Each best practice is generated by one or more of four CDFI Fund Programs:

1. Through the CDFI Program by directly investing in, supporting and training CDFIs that provide loans, investments, financial services and technical assistance to underserved populations and communities;

2. Through the New Markets Tax Credit (NMTC) Program by providing an allocation of tax credit authority to community development entities (CDEs) which enable them to attract investment from the private-sector and to reinvest these amounts in low-income communities;

3. Through the Bank Enterprise Award (BEA) Program by providing an incentive to banks to invest in their communities and in other CDFIs; and

4. Through the Native American CDFI Assistance (NACA) Program, by taking action to provide financial assistance, technical assistance, and training to Native CDFIs and other Native entities proposing to become or create Native CDFIs.

Current Actions: Currently designing and test marketing the CDFI/CDE Project Profile Web Form.

Type of review: New.

Affected Public: CDFIs and CDEs; including business or other for-profit institutions, nonprofit entities, and State, local and Tribal entities.

Estimated Number of Respondents: 100.

Estimated Annual Time per Respondent: 2.5 Hours.

Estimated Total Annual Burden Hours: 250 Hours.

Requests for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of technology.

Authority: 12 U.S.C. 4703, 4703 note, 4704, 4706, 4707, 4717; 12 CFR part 1805; Consolidated Appropriations Act of 2001, Pub. L. No. 106–554; 31 U.S.C. 321.

Dated: January 4, 2007.

Peter Dugas,

Acting Director, Community Development Financial Institutions Fund.

[FR Doc. E7–354 Filed 1–11–07; 8:45 am]

BILLING CODE 4810–70–P

Corrections

Federal Register

Vol. 72, No. 8

Friday, Jnauary 12, 2007

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.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54995; File No. SR–Amex–2006–77]

Self-Regulatory Organizations; American Stock Exchange, LLC; Notice of Filing of Proposed Rule Change and Amendment No. 1 Thereto to Amend Rules 918 and 918—Ante Regarding Trading Rotations, Halts and Suspensions

Correction

In notice document E6–22398 beginning on page 78474 in the issue of Friday, December 29, 2006, make the following correction:

On page 78474, in the second column, footnote 31 should be footnote 3.

[FR Doc. Z6–22398 Filed 1–11–07; 8:45 am]

BILLING CODE 1505–01–D

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55002; File No. SR–NYSEArca–2006–32]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change to Trade Various iShares® MSCI Index Funds Pursuant to Unlisted Trading Privileges

Correction

In notice document E6–22402 beginning on page 78503 in the issue of Friday, December 29, 2006, make the following correction:

On page 78504, in the third column, footnote 87 should be footnote 8.

[FR Doc. Z6–22402 Filed 1–11–07; 8:45 am]

BILLING CODE 1505–01–D

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54979; File No. SR–NFA–2006–05]

Self-Regulatory Organization; National Futures Association; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change and Amendment No. 1 Thereto Relating to the Interpretive Notice Regarding Automated Order-Routing Systems

Correction

In notice document E6–22657 beginning on page 813 in the issue of Monday, January 8, 2007, make the following correction:

On page 813, in the second column, footnote 21 should be footnote 2.

[FR Doc. Z6–22657 Filed 1–11–07; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Friday,
January 12, 2007

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 211, 226, 300, et al.

Use of Materials Derived from Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 211, 226, 300, 500, 530, 600, 895, and 1271

[Docket No. 2005N–0373]

RIN 0910–AF54

Use of Materials Derived from Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to prohibit the use of certain cattle material in, or in the manufacture (including processing) of, drugs, biologics, and medical devices intended for use in humans and human cells, tissues, and cellular and tissue-based products (HCT/Ps) (collectively, medical products for humans), and in drugs intended for use in ruminant animals (drugs for ruminants). FDA is also proposing new recordkeeping requirements for medical products for humans and drugs for ruminants that are manufactured from or otherwise contain material from cattle. FDA is proposing these actions as part of its continuing efforts to strengthen defenses against the potential risk of exposure to, and spread of, bovine spongiform encephalopathy (BSE) and related human disease in the United States.

DATES: Submit written or electronic comments on the proposed rule by March 13, 2007. Submit written comments on the information collection requirements by February 12, 2007. Requests for an informal hearing on the proposed ban related to medical devices must be submitted by February 12, 2007.

ADDRESSES: You may submit comments, identified by Docket No. 2005N–0373 and RIN number 0910–AF54, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see section VII ''Effective Date and Opportunity for Public Comment'' in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Information Collection Provisions: To ensure that comments on the information collection are received, Office of Management and Budget (OMB) recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT:

For information concerning products regulated by the Center for Drug Evaluation and Research: Vikki Kinsey, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5515 Security Lane, rm. 5110, Rockville, MD 20852, 301–443–5578, e-mail: *vikki.kinsey@fda.hhs.gov*.

For information concerning products regulated by the Center for Biologics Evaluation and Research: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, rm 594N, Rockville, MD 20852–1448, 301–827–6210, e-mail: *stephen.ripley@fda.hhs.gov*.

For information concerning products regulated by the Center for Devices and Radiological Health: Scott G. McNamee, Center for Devices and Radiological Health, Food and Drug Administration, 2094 Gaither Rd., rm. 230, Rockville, MD 20850, 240–276–0105, e-mail: *scott.mcnamee@fda.hhs.gov*.

For information concerning products regulated by the Center for Veterinary Medicine: Michael J. Popek, Center for Veterinary Medicine (HFV–144), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6462, e-mail: *michael.popek@fda.hhs.gov*.

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I. Introduction

On January 26, 2004, the U.S. Department of Health and Human Services announced its plan to establish new safeguards to strengthen existing firewalls against transmission of BSE in the United States. Consumption of products contaminated with the agent that causes BSE has been linked to the human disease variant Creutzfeldt-Jakob disease (vCJD). Current protections against the spread of BSE in the United States include:

- FDA's ruminant feed regulation (the 1997 ruminant feed rule) (62 FR 30936, June 5, 1997) (see section V.A.8 of this document for definition of ruminant),
- U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) interim final rule banning specified risk materials (SRMs) and certain other cattle material in human food (the USDA/FSIS IFR) (69 FR 1862, January 12, 2004; as amended, 70 FR 53043, September 7, 2005),
- FDA's interim final rule banning the use of SRMs and certain other cattle material in human food, including dietary supplements, and cosmetics (the Foods IFR) (69 FR 42256, July 14, 2004; as amended, 70 FR 53063, September 7, 2005), and
- Import controls.

FDA also has requirements for establishment and maintenance of records concerning use of materials derived from cattle in human food and cosmetics (the Foods Recordkeeping/Access final rule) (71 FR 59653, October 11, 2006). In addition, FDA, in conjunction with USDA, issued an advance notice of proposed rulemaking (ANPRM) to solicit comment on additional measures under consideration, including measures related to animal feeds (the joint ANPRM) (69 FR 42288, July 14, 2004). On October 6, 2005 (70 FR 58570), we issued a proposed rule that would prohibit certain cattle materials from all animal feed (FDA 2005 Animal Feed proposed rule).

In this medical products proposed rule, FDA is proposing to prohibit use of SRMs and certain other cattle material in, or in the manufacture (including processing) of, medical products for humans and drugs for ruminants because of the risk of transmission of BSE. FDA is also proposing recordkeeping requirements for medical products for humans and drugs for ruminants that are manufactured from or otherwise contain material from cattle to ensure compliance with the prohibitions in this proposed rule. The proposed requirements are consistent with the requirements in the USDA/FSIS IFR and the Foods IFR, as well as those in the Foods Recordkeeping/Access final rule. The proposed requirements in this medical products proposed rule only apply to medical products for humans and drugs for ruminants. They do not apply to any other product regulated by FDA.

II. Background

A. Transmissible Spongiform Encephalopathies

Transmissible spongiform encephalopathies (TSEs) are fatal neurodegenerative disorders that have been identified in humans and a number of animal species (e.g., cattle, sheep, goats, elk, deer, cats, and mink), but primarily in ruminants (i.e., animals that have a stomach with four compartments, such as cattle and buffalo). A TSE is characterized by a long incubation period, followed by a shorter course of neurological symptoms, followed by death (Ref. 1). Postmortem histopathology of the brain tissue from humans and animals with TSEs is characterized by a sponge-like appearance of the brain and deposits of abnormal forms of certain cell-associated proteins (normal prion proteins) in the brain.

TSEs in humans include CJD, vCJD, Gerstmann-Sträussler-Scheinker syndrome, kuru, fatal familial insomnia, and sporadic fatal insomnia (Ref. 8). Nonhuman TSEs include BSE in cattle, scrapie in sheep and goats, transmissible mink encephalopathy (TME) in mink, feline spongiform encephalopathy (FSE) in cats, and chronic wasting disease (CWD) in deer and elk (Ref. 8). Scrapie and CWD occur, and TME has occurred, in the United States. On December 23, 2003, USDA diagnosed BSE in an adult cow in the United States that had been imported from Canada. Since then, USDA has confirmed two other cases of BSE in adult cows in the United States. One cow, which was diagnosed on June 24, 2005, was born and raised in Texas. The other cow, which was diagnosed on March 15, 2006, had been on a farm in Alabama for less than a year. The Texas cow was 12 years old and the Alabama cow was determined to be more than 10 years old. Therefore, both cows were born before the 1997 ruminant feed rule was in place. USDA determined that no part of the animals entered the human food or animal feed chains.

The pathogenesis of TSEs is poorly understood. TSE agents resist complete inactivation by treatments that destroy conventional microorganisms, like bacteria and viruses. Thus, conventional microorganisms are not likely causes of TSEs (Ref. 9). The most widely accepted explanation for TSEs, the prion theory, suggests that the infectious agents of TSEs are abnormally folded forms of normal prion proteins (Refs. 10 and 11). Normal prion protein genes are found widely in nature. In mammals, normal prion proteins are primarily expressed in neurons, but also can be found in other tissues in lower concentrations, depending on the mammalian species (Ref. 12). It is not well understood how the abnormal folding of prion proteins occurs or why hosts cannot efficiently dispose of or develop immunity to these proteins.

The current lack of an antemortem diagnostic test for TSEs in either humans or animals limits surveillance

for these diseases, studies of disease pathogenesis, and other research efforts. Diagnosis is confirmed by special postmortem examination of brain tissue by identification of abnormal prion proteins in advanced stages of the disease. At earlier stages of disease development, abnormal prion proteins are undetectable in brain tissue. Presently, there are no effective treatments for TSEs, and all TSEs are invariably fatal (Ref. 1).

B. Bovine Spongiform Encephalopathy

BSE is a TSE of cattle with a long incubation period (up to 8 years or longer), most likely acquired following consumption of an animal product containing the BSE infectious agent (Refs. 13 and 14). The British Ministry of Agriculture, Fisheries and Food (now known as the Department for Environment, Food, and Rural Affairs) first recognized BSE as a distinct disease in November 1986. The clinical signs of BSE include behavioral, gait, and postural abnormalities. The disease usually presents in cattle as increased apprehension, increased reaction to sound and touch, and a swaying gait. These signs are accompanied by subtle changes in the normal behavior of the cow, such as separation from the herd while at pasture, disorientation, staring, and excessive licking of the nose or flanks. The disease progresses to stumbling and falling, and ends with seizures, coma, and death (Ref. 15).

Experiments indicate that the infectious dose for cattle is very low. One gram of homogenized brain from affected cattle caused BSE in 7 out of 10 calves fed the brain sample. Six years after oral consumption of lower doses of brain material, 3 of 15 calves fed 0.1 gram, and 1 of 15 calves fed 0.01 gram, and 1 of 15 calves fed 0.001 gram (1 mg) of brain sample had developed the disease. This experiment is ongoing (Ref. 16).

Epidemiological studies have characterized the outbreak of BSE in the United Kingdom as a prolonged epidemic in which early cases were seen simultaneously at various locations, but with all occurrences presumably due to a common point source of infection (Ref. 17). Consistent with this observation, the subsequent spread of BSE was associated with the feeding of meat-and-bone-meal from rendered BSE-infected cattle to non-infected cattle (Ref. 17). It appears likely that the BSE agent was transmitted among cattle at an increasing rate by ruminant-to-ruminant feeding until the United Kingdom ban on such practices went into effect in 1988 (Ref. 13). The United Kingdom instituted a ruminant-to-ruminant feed ban to stop the cycle of infection, restrict the geographic spread of the disease, and eliminate potential sources of new infections. Since BSE was first identified in the United Kingdom, approximately 185,000 cattle have been diagnosed with the disease there (Ref. 18). The precautionary slaughter of millions of British cows and increasingly stringent prohibitions on certain animal feeding practices appear to have slowed, but not eradicated, the BSE epidemic in the United Kingdom. In 1992 (the peak year of the epidemic), there were over 37,000 cases of BSE in the United Kingdom; in 2005, there were 225 cases (Ref. 18).

The introduction of BSE into other countries presumably originated from their import of cattle, or animal feed made with cattle material, from the United Kingdom during the BSE epidemic (Ref. 13). In addition to the United Kingdom, BSE has been detected in indigenous cattle in Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Israel, Italy, Japan, Liechtenstein, Luxembourg, the Netherlands, Poland, Portugal, the Republic of Ireland, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United States (Ref. 19).

C. Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease

Creutzfeldt-Jakob Disease (CJD) is a sporadic disease of humans that exists throughout the world with an annual incidence of approximately one case per million population (Ref. 10). The highest death rates in the United States and the United Kingdom occur in individuals between the ages of 60 and 70 (Ref. 20). Death generally occurs after less than a year of progressive neurological deterioration (Ref. 10). Early symptoms typically include changes in sleeping and eating patterns, followed by inappropriate behavior and eventual dementia, lack of coordination, and myoclonic spasms. CJD is always fatal (Ref. 20). The cause of sporadic CJD is not fully understood, but genetic susceptibility may play a role (Ref. 10). CJD has been inadvertently transmitted between humans during medical treatment or diagnostic procedures via contaminated neurosurgical instruments, transplants of dura mater and corneas, and injection of pituitary extract (Ref. 10).

In April 1996, British scientists reported a previously undetected new vCJD in young patients, with symptoms somewhat different from sporadic CJD (Refs. 21 and 22). All cases of vCJD had histopathologic evidence of spongiform changes in the brain, but also showed formation of ''florid'' plaques (a core of amyloid protein with surrounding halos of vacuoles) not typically seen in other forms of CJD (Ref. 10). Clinically, vCJD usually begins with a psychiatric presentation, such as depression, anxiety, nightmares, or hallucinations. These symptoms are followed by memory impairment, then dementia in the late stages. The clinical course generally ranges from 9 months to 3 years before death occurs (Ref. 23). The probable incubation period for vCJD in humans may range from 5 to more than 20 years (Ref. 39).

Scientists have concluded that exposure to the BSE agent is the most plausible explanation for the occurrence of vCJD (Refs. 24 through 27). Monkeys (genetically the closest animal model to humans) inoculated with samples of brain from BSE-infected cattle have been found to develop a TSE that is histopathologically similar to vCJD (Ref. 28), as have mice inoculated or fed with BSE-infected tissue (Ref. 29). Studies have shown that abnormal prion proteins from vCJD patients are molecularly similar to abnormal prion proteins from BSE-infected cattle, but different from abnormal prion proteins from patients with CJD (Ref. 23). Although the exact route of exposure is not known, most scientists believe that vCJD in humans has been caused by consumption of cattle products contaminated with the agent that causes BSE (Refs. 20, 30, and 31). There is thought to be a 10- to 10,000–fold increase in the amount of infectious material needed to cause illness in humans as compared with cattle because of the species barrier, although the European Commission's Scientific Steering Committee cautioned that this range is uncertain and in an unlikely, but worst case scenario, the species barrier may not exist (Ref. 40).

As of August 2006, 162 probable and confirmed cases of vCJD have been reported in the United Kingdom (Ref. 32). In addition, there have been 15 vCJD cases in France, 3 in Ireland, 2 in the United States ,and 1 each in Canada, Italy, the Netherlands, Portugal, Japan, Spain, and Saudi Arabia (Refs. 33 through 38 and 70). The two cases in the United States, one of the three from Ireland, and the single cases from Canada and Japan are likely due to the individual's exposure to BSE in the United Kingdom (Refs. 34, 36, and 70).

The infectious dose for humans is not known. Despite widespread exposure in the United Kingdom to BSE-contaminated meat products, only a very small percentage of the exposed population has been diagnosed with vCJD to date. This may reflect a partial

species barrier to disease transmission from cattle to humans via the oral route of exposure (Ref. 40).

D. BSE Risk Assessments

1. Harvard-Tuskegee Study

In 1998, USDA asked the Harvard Center for Risk Analysis (HCRA) and the Center for Computational Epidemiology at Tuskegee University to evaluate United States measures to prevent the spread of BSE to animals and humans if it were to occur in this country. The Harvard-Tuskegee risk assessment (the Harvard-Tuskegee study determined that the United States was highly resistant to any proliferation of BSE or a similar disease (Ref. 41). The risk assessment model also demonstrated that certain new control measures could reduce the small risk even further.

The Harvard-Tuskegee study involved a probabilistic simulation model to determine the consequences of introducing BSE into the U.S. cattle population. This simulation indicated that, in a hypothetical situation in which 10 infected cattle were imported into the United States, on average only 4 new cases of BSE would arise, and the disease would be eliminated in 20 years. The Harvard-Tuskegee study determined that these new cases of BSE would most likely arise in the United States from incomplete compliance with the FDA 1997 ruminant feed rule (see section III.A.1 of this document), and also concluded that an epidemic of BSE in this country resulting from scrapie, CWD, or another TSE is unlikely.

The Harvard-Tuskegee study estimated the number of cattle infectious doses that might be available for human exposure, but it did not estimate the likelihood of human disease from this exposure because the relationship between the two is not known. According to the study, the estimated total infectivity available for human exposure from the importation of 10 infected cattle is 39 cattle infectious doses over 20 years. The Harvard-Tuskegee study determined that the greatest sources of infectivity to consumers from food are direct consumption of cattle brain and spinal cord and also meat that contains central nervous system tissue from advanced meat recovery systems. The Harvard-Tuskegee study did not address potential human exposure to the BSE agent through food, medical products for humans, or drugs for ruminants that contain ingredients of bovine origin, such as gelatin (from bovine bones and hides), heparin and surfactants (from bovine lung), insulin (from bovine pancreas), hormones (from bovine urine and serum), enzymes (from bovine intestine), or glycosphingolipids (from bovine brains).

The Harvard-Tuskegee study identified three pathways that could lead to cattle or human exposure to the BSE agent through food or feed: (1) Noncompliance with the FDA 1997 ruminant feed rule prohibiting the use of certain proteins in feed for cattle and other ruminants; (2) rendering of animals that die on the farm and use (through illegal diversion or cross-contamination) of the rendered product in ruminant feed; and (3) the inclusion of high-risk tissues from cattle, such as brain and spinal cord, in products for human oral consumption. Evaluation of potential risk mitigation measures in the study found that a prohibition against rendering of animals that die on the farm would reduce the potential cases of BSE following hypothetical exposure by 82 percent. In addition, a ban on including SRMs (defined in the study as brain, spinal cord, gut, eyes, and advanced meat recovery products without reference to age of the animals at slaughter) in human and animal food would reduce potential BSE cases in cattle by 88 percent and potential human exposure to BSE by 95 percent. The Harvard-Tuskegee study also noted the value of ensuring that low-risk cattle tissues are not cross-contaminated with high-risk tissue.

USDA recently released an updated version of the BSE risk assessment model and report, completed by HCRA (Ref. 42). USDA requested that HCRA utilize an updated risk assessment model to evaluate the impact of measures implemented after the discovery of a BSE-positive cow in Washington State in December 2003, and recommendations made by an international BSE panel. The updated risk assessment estimates that the measures adopted by USDA in January 2004 will result in a 99.6 percent (at the mean) relative reduction in potential human exposure to the BSE agent through consumption of beef and beef products.

2. USDA Surveillance Program

The USDA has led targeted BSE surveillance efforts since 1990. On June 1, 2004, in response to a recommendation from the international scientific review panel that assessed USDA's investigation into the discovery of a BSE positive cow in Washington State on December 23, 2003, USDA began an enhanced BSE surveillance effort. This effort continued to focus on the targeted subpopulation of cattle, with a goal to obtain as many samples as possible from the targeted population, to help determine whether BSE is present in the United States. Targeted cattle are defined as nonambulatory cattle; cattle exhibiting signs of a central nervous system disorder; cattle exhibiting other signs that may be associated with BSE, such as emaciation or injury; or dead cattle. To date, USDA has sampled more than 700,000 targeted cattle, only two of which were positive for BSE (Ref. 43). A detailed analysis of surveillance data obtained through March 2006 concluded that the prevalence of BSE in the United States is less than one infected animal per million adult animals (Ref. 7).

3. BSE Testing for Product Safety Purposes

No validated antemortem tests for BSE exist. The currently available postmortem tests, although useful for disease surveillance (i.e., determining the rate of disease in the population of cattle), are not appropriate as safety indicators for food, medical products for humans, or drugs for ruminants. This is due, in part, to limitations on the existing testing methods, which rely on the use of postmortem brain tissue. Experimental evidence demonstrates that, in cattle infected orally, certain potentially infective tissues (such as the distal ileum and tonsil) are the first tissues to accumulate infectivity in the incubation period and this infectivity occurs prior to any demonstrated infectivity in brain tissue (Refs. 3, 45, and 46). Therefore, tests conducted on brain tissue may not reflect accurately the potential infectivity in other tissues that develop infectivity earlier, such as the distal ileum. Development of effective safety indicators for food, medical products for humans, and drugs for ruminants will require improved understanding of the pathogenesis of the disease and improved laboratory methods.

4. BSE Infectivity via Medical Products for Humans and Drugs for Ruminants

While BSE is usually a concern identified with food safety or animal health, medical products for humans or drugs for ruminants, because of the ways they are used or come into contact with the body, provide another route for human or ruminant exposure to the BSE infectious agent. Medical products for humans and drugs for ruminants may contain or be made using a variety of cattle-derived materials. Examples of materials that are sometimes derived from cattle and that are used in, or in the manufacture of, these products include gelatin, heparin, surfactants, hormones, enzymes,

glycosphingolipids, amino acids, glycerol, detergents, blood, collagen, fetal calf serum, bovine meat, and tallow and tallow derivatives.

The route by which TSE-contaminated material is introduced into a host is an important determinant of TSE transmissibility. Animal studies have indicated that injection of a TSE agent directly into the brain or spinal cord is the most efficient route of transmission, followed by intravenous, intraperitoneal, and subcutaneous routes, and then by the oral route (Refs. 2 and 47 through 56). Topical administration on intact skin is unlikely to lead to disease transmission, but topical products presumably can cause disease if administered to skin with cuts, abrasions, or open wounds, or if administered to the eyes or other mucosal tissue (Refs. 57 through 59).

Currently, no validated method for testing products for humans and ruminants for the agent that causes BSE is available; therefore, we do not have a means of distinguishing products that contain infectious material from products that do not. End users (e.g., consumers, physicians, farmers, veterinarians) also often are not able to determine which products contain prohibited cattle materials and which products do not because such information is generally not included in product labels or labeling. For example, rendered material including brain and spinal cord may become an ingredient in a medical product for humans or a drug for ruminants, although its presence may not be indicated on the label. Furthermore, end users have no way to determine whether cattle material in these products was sourced from nonambulatory disabled cattle or from cattle that were not inspected and passed for human consumption.

Based on what is known about transmission of BSE, there is risk of occurrence of vCJD in humans and of TSE in ruminants from the use of high-risk cattle-derived materials in medical products for humans and drugs for animals. While the results from USDA's ongoing testing are reassuring and so far have identified only two additional BSE-infected cows in the United States, one cannot rule out the possibility of future discovery of additional positive animals in the United States or in a country allowed to export cattle material to the United States, or of a future introduction of BSE. To provide consistent protection across the range of FDA-regulated products, it is necessary to put in place measures to reduce further the risk of spread of BSE in cattle and the risk of vCJD in humans. These risks may be reduced by restricting the use of high-risk cattle materials in the manufacture of drugs for ruminants and medical products for humans, similar to existing restrictions for food and cosmetics.

E. Cattle Materials

This proposed rule would apply to medical products for humans and drugs for ruminants that are manufactured from or otherwise contain certain cattle material. This section discusses the reasons for FDA's decision to propose to restrict the use of such material in medical products for humans and drugs for ruminants.

1. Specified Risk Materials

This proposed rule would designate SRMs as prohibited cattle materials in medical products for humans and drugs for ruminants. Specified risk materials would be defined, consistent with the Foods IFR (69 FR 42256 at 42259 and 70 FR 53063 at 53064 through 53065; discussed in section IV.A.3 of this document) and the USDA/FSIS IFR (69 FR 1862 and 70 FR 53043; discussed in section III of this document) as the brain, skull, eyes, trigeminal ganglia (clusters of nerve cells connected to the brain that lie close to the exterior of the skull), spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia (clusters of nerve cells attached to the spinal cord that are contained within the bones of the vertebral column) of cattle 30 months and older, and the tonsils and distal ileum of the small intestine of all cattle.

In a pathogenesis study in which cattle were orally inoculated with BSE and then one to three animals were killed and tested at sequential 4- to 6-month intervals, Wells et al. found infectivity using a mouse bioassay at 32 months postinoculation in brain, spinal cord, dorsal root ganglia, and trigeminal ganglia (Ref. 3). Unequivocal clinical disease was first observed at 38 months postinoculation. It is not known how representative these results are, given the extremely small number of cattle tested and the limitations inherent in the mouse bioassay. It also should be noted that only one animal was tested at 26 months postinoculation and no testing was performed again until 32 months postinoculation. Thus, no conclusion can be drawn as to when, in the period between 26 and 32 months postinoculation, infectivity appeared in the tested tissues. The studies will continue for several more years, using a more sensitive cattle assay, to determine if any of the tissues that initially did not appear to be infective actually contain low levels of infection (Refs. 2 through 6 and 60). Infectivity has also been found at 6 months postinoculation in distal ileum and at 10 months postinoculation in tonsils (Refs. 4 and 60).

In cattle infected with BSE under field conditions (i.e., not intentionally exposed to BSE as part of an experiment), infectivity has been found in the brain, spinal cord, and retina of the eye in animals with clinical disease (Ref. 60). The Scientific Steering Committee of the European Union (Ref. 31) has reported on the proportion of total infectivity in various tissues. They estimate that in an animal with clinical disease, approximately 64 percent of the infectivity is in the brain, 26 percent is in the spinal cord, 4 percent is in the dorsal root ganglia, 2.5 percent is in the trigeminal ganglia, and 3 percent is in the distal ileum. The eyes are estimated to contain less than 1 percent of the infectivity. In 2003, P. J. Comer and P. J. Huntly reported generally similar estimates of infectivity (i.e., 60.2 percent in brain, 24.1 percent in the spinal cord, 3.6 percent in the dorsal root ganglia, 2.4 percent in the trigeminal ganglia and 9.6 percent in the distal ileum) (Ref. 44).

Clinical cases of BSE in cattle under 30 months old are rare. For example, according to the United Kingdom's Department of Environment, Food and Rural Affairs, among the birth cohort of cattle in the United Kingdom that had the highest incidence of BSE (those born in 1987–88), cattle under 3 years old represented less than 0.16 percent of cattle with BSE (61 out of 39,140 cattle with BSE) (Ref. 61). Another report, looking at selected herds whose ages were known, found that in the first 6 months of 1989 and 1990, the BSE incidence in 2–year-old cattle (0.04 percent in 1989 and 0.05 percent in 1990) was approximately 15–fold lower than that in 3–year-old cattle (0.56 percent in 1989 and 0.86 percent in 1990), and was 45- to 75–fold lower than the incidence in 4–year-old cattle (2.83 percent in 1989 and 2.76 percent in 1990) (Ref. 62). Two-year-old cattle represented only about one-half of 1 percent of the total BSE cases in the selected herds in those 6-month periods. The incidence in 2–year-old cattle (0.01 percent) decreased considerably in 1991, presumably reflecting the fact that they were born after July 1988, when the United Kingdom instituted measures prohibiting the use of meat and bone meal in cattle feed.

We recognize that certain tissue from infected animals will be infectious a number of months before the animals exhibit clinical symptoms. However, in

BSE, as in other TSEs, the total amount of infectivity in an animal increases throughout the incubation period reaching the highest load when an animal begins to demonstrate clinical signs (Ref. 44). Because of this evidence combined with the very low incidence of clinical BSE in cattle younger than 30 months, we are proposing, consistent with the Foods IFR (69 FR 42256 at 42259) and the USDA/FSIS IFR (69 FR 1862), that brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia should be considered SRMs only in cattle 30 months and older. We include the skull and the vertebral column in the list of SRMs because, even though they have not been shown to harbor BSE infectivity, they contain tissues (i.e., brain and spinal cord) that have been shown to be infectious. We did not include, consistent with the Foods IFR (69 FR 42256 at 42259) and the USDA/FSIS IFR (69 FR 1862 at 1868), the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum as SRMs with the rest of the vertebral column because they do not contain spinal cord or dorsal root ganglia. As the science and epidemiology on this issue develop, FDA may find it necessary through future rulemaking to modify the tissues classified as SRMs and the age at which these tissues are classified as SRMs.

Based on the previously mentioned experimental evidence indicating that tonsils become infective by 10 months postinoculation and distal ileum by 6 months postinoculation (Refs. 3 and 4), we are proposing, consistent with the Foods IFR (69 FR 42256 at 42259 and 70 FR 53063 at 53064 through 53065) and USDA/FSIS IFR (69 FR 1862 and 70 FR 53043), that the tonsil and distal ileum of the small intestine of all cattle be considered SRMs.

2. Small Intestine

The small intestine is not considered prohibited cattle material if the distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine as measured from the caeco-colic junction and progressing proximally towards the jejunum or by a procedure that the establishment can demonstrate is equally effective in ensuring complete removal of the distal ileum. In this medical products proposed rule, we are proposing to prohibit the use of small intestine of all cattle in medical products for humans and drugs for ruminants if procedures that completely remove the distal ileum are not used. This provision is consistent with USDA (70 FR 53043) and FDA (70 FR 53063) requirements. .

3. Mechanically Separated Beef

Mechanically Separated (Species) is a standardized food defined by USDA in 9 CFR 319.5 (see section V.A of this document for the proposed definition of mechanically separated beef). The standard does not limit the amount of spinal cord and dorsal root ganglia allowed in vertebral column used to produce the product. Consequently, mechanically separated beef may contain concentrated amounts of such tissues. Because we are proposing that spinal cord, dorsal root ganglia and vertebral column be considered SRMs, we are also proposing, consistent with the USDA/FSIS and Foods IFRs (69 FR 1862 at 1866 through 1867 and 69 FR 42256 at 42259), to include mechanically separated beef as a prohibited cattle material.

4. Nonambulatory Disabled Cattle

Experience has shown that nonambulatory disabled cattle (see section V.A of this document for the proposed definition) are the population at greatest risk for harboring BSE. Surveillance data in the European Union in 2002 showed that there were 29 positive/10,000 tests for BSE among healthy-appearing cattle of all ages and 148 positive/10,000 tests for BSE among nonambulatory animals of all ages (Ref. 63). In Switzerland, sampling of particular populations of cattle revealed that BSE-positive animals were 49 to 58 times more likely to be found in the nonambulatory population than in the population selected for passive surveillance (Ref. 64). The Harvard-Tuskegee study estimated that, following importation of 10 infected cattle, a prohibition against rendering animals that die on the farm (these animals could be nonambulatory disabled) would decrease the number of new cases of BSE by 82 percent.

Because typical clinical signs of BSE cannot always be observed in nonambulatory disabled cattle, and because evidence has indicated these cattle are more likely to have BSE than apparently healthy cattle, FDA is proposing, consistent with the Foods IFR (69 FR 42256 at 42259), to include material from nonambulatory disabled cattle as prohibited cattle materials. This proposal is also consistent with USDA's requirement that all nonambulatory disabled cattle presented for slaughter be condemned (69 FR 1862 at 1870 and 1871).

5. Cattle Not Inspected and Passed for Human Consumption

Cattle that have not been inspected (see section V.A of this document for the proposed definition) are at higher risk of having BSE, as well as other diseases, because they will not have been examined by USDA for their disease status in general and potential for harboring BSE in particular. In addition, such cattle are likely to have died on the farm or en route to slaughter, and these animals are not eligible for inspection by USDA. For cattle that are inspected but not passed, a regulatory authority (USDA or other) has made a determination that they are not appropriate for use in human food (69 FR 42256 at 42259). Such a determination may be based, among other things, on evidence of a neurological disorder associated with a higher risk of BSE. Moreover, material from cattle not inspected or inspected and not passed for human consumption is prohibited from human food (69 FR 42256 at 42259). In this rulemaking, FDA is proposing to extend this prohibition to medical products for humans and drugs for ruminants. By requiring that material from cattle for use in medical products for humans and drugs for ruminants be inspected and passed for human consumption, we would minimize the risk to humans and ruminants of exposure to the agent that causes BSE.

6. Tallow and Tallow Derivatives

Tallow is an animal-derived hard fat that has been heat processed; most tallow is derived from cattle. In this proposed rule, we use the term tallow to refer only to tallow derived from cattle. Any risk of BSE transmission from tallow is a result of protein that is present as an impurity in the tallow. Taylor et al. (Refs. 65 and 66) found in rendering studies with abnormal prion protein that the prion protein did not preferentially migrate into the fat fraction, but remained with the protein fraction. Therefore, there is no reason to believe that tallow is likely to contain unusually high amounts of prion protein as a constituent of the insoluble impurities fraction that remains in tallow after rendering. Taylor et al. (Refs. 65 and 66) also reported that the various rendering processes used for tallow production in the United Kingdom were sufficient to produce tallow that did not result in infection when injected into the brains of mice, even though the starting material was highly spiked with the scrapie agent. Wilesmith et al. (Ref. 67) noted that the geographical variation in the incidence

of BSE in the United Kingdom was not consistent with the use of tallow in cattle feed and concluded that the most likely source of infection in cattle was BSE-contaminated meat and bone meal.

The World Organisation for Animal Health (OIE) (formerly the Office International des Epizooties), the international animal health standard setting body, categorizes tallow with insoluble impurities of no more than 0.15 percent as protein-free tallow and indicates that tallow that meets this standard can be safely consumed by animals, regardless of the starting materials (Ref. 68). FDA's Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC) considered the safety of tallow in 1998 (Ref. 69). Although members of the TSEAC indicated that tallow is a food with extremely low risk of transmitting BSE to humans or animals, they did not see a need to change FDA's recommendation that tallow not be sourced from cattle born, raised, or slaughtered in countries where BSE is known to exist.

Based on the research and the opinions noted previously that show that tallow is inherently a low risk material because of the procedures by which it is manufactured, we are proposing to permit tallow from any country to be used in medical products for humans and drugs for ruminants, as we have for human food and cosmetics (69 FR 42256 at 42260 and 42261), if it contains no more than 0.15 percent insoluble impurities regardless of the starting materials or if it otherwise complies with these regulations (e.g., made without the use of any prohibited cattle materials). We recognize that the TSEAC did not see a need to change FDA's tallow import policy, which recommended against use of tallow from cattle born, raised, or slaughtered in countries where BSE is known to exist. However, the TSEAC was not asked to provide recommendations regarding import of tallow that met our proposed requirements. We believe we are proposing a tallow standard for medical products for humans and drugs for ruminants that is consistent with statutory safety standards and the recommendations by OIE with respect to bovine-derived tallow to prevent BSE in cattle and vCJD in humans.

Distinct from tallow are tallow derivatives. These derivatives are produced by subjecting tallow to chemical processes (hydrolysis, trans-esterification, or saponification) that involve high temperature and pressure. The TSEAC considered tallow derivatives in 1998 (Ref. 69) and determined that the rigorous conditions of manufacture are sufficient to further reduce the BSE risk in tallow derivatives. In addition, the OIE also recommends that derivatives of protein-free tallow be freely traded among countries because they pose an insignificant BSE risk to animals (Ref. 68). Because we believe that tallow has negligible risk of transmitting BSE, and tallow derivatives undergo additional processing, we do not believe that tallow derivatives pose a risk of transmitting the agent that causes BSE to humans. Therefore, we are proposing, consistent with the Foods IFR (69 FR 42256 at 42261), that tallow derivatives not be considered a prohibited cattle material. FDA proposes to clarify, as in the amendments to the Foods IFR (70 FR 53063), that the ''no more than 0.15 percent insoluble impurities'' restriction for tallow does not apply to tallow derivatives.

7. Fetal Calf Serum

Current evidence suggests that cow-to-calf transmission of BSE is unlikely to occur (Refs. 14 and 46). Therefore, the serum of fetal calves is unlikely to contain any BSE infectious material, irrespective of the age of the mother. However, because fetal calf serum (FCS) is generally collected from fetuses of dairy cows culled for low milk production or for health reasons, these cows are often considerably older than 30 months. FDA believes that manufacturers commonly take appropriate steps to prevent contamination of the FCS with specified risk materials from the mother. These steps include the normal dressing procedures used in slaughter houses, consisting of removing the uterus completely from the carcass and other viscera of cows that were inspected and passed, taking it to a separate space free of prohibited cattle materials for cardiac puncture, and collecting the fetal blood in a closed collection system using aseptic technique. Other procedures could also be used to provide adequate assurance that contamination has been prevented.

8. Additional Requirements

If the agency finds that additional protections are needed for specific products or classes of products covered by applications (e.g., products with direct routes of exposure into the bloodstream or neural tissue such as injectable, ophthalmic, intranasal, or implanted FDA-regulated products), it intends to provide those protections through the application review process or through other means, such as special controls for Class II devices. The agency believes it is possible that injectable, ophthalmic, intranasal, or implanted FDA-regulated products that contain cattle material other than prohibited cattle materials and that do not have an FDA approval covering use of that material may appear to be adulterated or misbranded under certain circumstances. If the agency finds that classes of such products or specific products do not meet the applicable statutory standards, it may take action even if the products comply with the requirements in this proposed regulation.

F. Medical Products for Humans and Drugs for Ruminants That May Contain Cattle Material

1. Drugs for Humans

Under this proposed rule, drugs for humans cannot be manufactured from or otherwise contain prohibited cattle materials without written permission from FDA. For drugs subject to applications, the agency may provide additional protections through the application review process on a case-by-case basis to ensure that the products are safe and effective for their intended uses under section 505 of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 355) and safe, pure, and potent under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262). For drugs not subject to applications, if the agency finds that specific products or product classes do not meet the applicable statutory standards regarding adulteration and misbranding, it may take action even if the products comply with the requirements in this proposed rule.

Many approved human drugs, as well as investigational human drugs, contain ingredients that are derived from cattle. Over the last 10 years, FDA has maintained a database that identifies these drugs and their cattle-derived ingredients. Based on the information in this database, we are aware of no approved drugs and no investigational drugs that are manufactured with cattle material that would be prohibited under this proposed rule based on the type of cattle tissue used.[1]

In addition to human drugs with approved applications, a number of human drugs are marketed without an approved application and, therefore, have not been subject to the new drug application (NDA) review process (e.g., products marketed under FDA's over-the-counter (OTC) monograph system, Active Pharmaceutical Ingredients,

[1]All manufacturers would have to ensure that any cattle material they use comes from cattle that are inspected and passed and otherwise complies with the other requirements proposed in this rule.

homeopathic preparations, or products that purport to be ''grandfathered''). Although FDA's database of these products is incomplete, some of them may contain cattle materials that would be prohibited under this proposed rule. The requirements proposed in this rulemaking apply to all drugs for humans, including those marketed without an approved application.

2. Biologics for Humans

Many biological products are manufactured with, or otherwise use, cattle-derived material because this material can provide necessary nutrients for cell growth. For example, microorganisms used for vaccine manufacture are typically grown under controlled conditions in media that may contain cattle materials. Animal-derived products used in vaccine manufacture include amino acids, glycerol, detergents, gelatin, enzymes, and blood. Cattle skeletal muscle is used to prepare broths used in certain complex media.

Many microorganisms that are difficult to grow and cells that are used to propagate viruses require serum in the growth media, which is typically derived from cattle blood. Cattle-derived materials (e.g., fetal calf serum, insulin, aprotinin, enzymes) are often used in cell culture techniques to manufacture hematological, cell, and gene-therapy products.

Manufacturers of licensed products and sponsors of investigational new drug products are currently requested to provide, in their biologics license application (BLA) or investigational new drug application (IND), information regarding the source of all bovine-derived materials used in the manufacture of their product. This information is reviewed by FDA along with other information provided in the application. SRMs are not ordinarily used in the manufacture of biological products. Biological products that are not intended for use in or on the body (e.g., in vitro diagnostics) would not be subject to the provisions of this proposed rule.

3. HCT/Ps

This proposed rule would affect all HCT/Ps. HCT/Ps are defined in part 1271 (21 CFR part 1271) as ''articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of HCT/Ps include, but are not limited to, bone, ligament, skin, dura mater, heart valve, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue'' (§ 1271.3(d)). Certain exceptions apply (§ 1271.3(d)(1) through (d)(7)).

HCT/Ps are regulated according to a tiered, risk-based framework. HCT/Ps meeting the criteria listed in § 1271.10 (e.g., minimally manipulated, intended for homologous use only (i.e., perform the same basic function(s) in the recipient as in the donor), not combined with a drug or device, and not having a systemic effect) are regulated solely under the authority of section 361 of the PHS Act (42 U.S.C. 264). These ''361'' HCT/Ps are required to comply only with the applicable requirements in part 1271. Premarket review is not required for such products; therefore, FDA does not review any information regarding cattle-derived material that might be used in such products. This proposed rule would ban the use of prohibited cattle material in these products, which we believe would help reduce any possible BSE transmission through the use of ''361'' HCT/Ps manufactured using cattle-derived material.

HCT/Ps that do not meet the criteria in § 1271.10 are regulated as drugs and devices under the act, and/or biological products under section 351 of the PHS Act and the act. Establishments that manufacture such HCT/Ps must comply with the requirements in subparts C and D of part 1271 in addition to all other applicable regulations, including submission of the appropriate premarketing applications, and are included in this proposed rule. Information regarding the use of cattle-derived material in the manufacture of such HCT/Ps would be submitted as part of the premarket review, giving us the opportunity to evaluate any potential for risk of BSE transmission.

4. Medical Devices for Humans

The Center for Devices and Radiological Health (CDRH) has an administrative database that FDA reviewers use to record PMA and 510(k) submissions. In 2002, FDA added an ''animal tissue flag'' to the CDRH administrative database. This ''flag'' indicates that the device contains or is manufactured with animal tissue of some kind; the species of animal tissue is not identified. The animal tissue flag has been recorded for 68 PMAs and 2,164 510(k)s. These numbers represent only devices for which PMAs or 510(k)s were filed since the animal tissue flag was added in 2002. They do not account for devices cleared or approved for marketing before that time that may contain or that may be manufactured with animal tissue.

Examples of cattle material used in devices range from high risk tissues (such as bovine pituitary extract used as a component of growth media) used in a low risk clinical setting (such as a topical application), to low risk cattle tissues (such as collagen from cattle hide or muscle) used in a high risk clinical setting (such as direct application to the central nervous system).

Premarket submissions for devices do not always include complete information about the source of animal components. In addition, not all devices are subject to premarket review, either because they are exempt from such review or because they have already been cleared or approved. FDA believes that it is important to help ensure that all devices that are intended for use in or on the body do not contain prohibited cattle materials. Examples of devices intended for use in or on the body include, but are not limited to, vascular grafts, bone fillers, lacrimal plugs, sutures, wound dressings, and heart valves (other than human heart valve allografts regulated solely under section 361 of the PHS Act). FDA has determined that the banning and recordkeeping provisions of this proposed rule are necessary to help ensure the safety of devices intended for use in or on the body. Medical devices that are not intended for use in or on the body (e.g., in vitro diagnostics, x-ray machines) would not be subject to the provisions of this proposed rule. FDA is not aware of any currently marketed device that is manufactured with cattle material that would be prohibited under this proposed rule.

5. Drugs for Ruminants

The requirements proposed in this rulemaking would cover new animal drugs for ruminants. Ruminants present the highest risk of any animals for contracting BSE from prohibited cattle materials. Because FDA has other mechanisms to restrict the extralabel use of approved human and animal drugs that contain prohibited cattle materials in ruminants (see section V.D of this document), this proposed rule would only prohibit the use of certain cattle material in drugs intended for use in ruminants.

Some drugs for ruminants may contain or be manufactured with cattle-derived materials. We are not aware of any drugs for ruminants that contain, as a component of the drug, cattle material that would be prohibited by the proposed rule. However, although the FDA animal drug database lists materials contained in drugs for animals, it does not identify materials

that are used in the manufacture of drugs for animals but that are not intended to be components of the drug (e.g., materials used in fermentation or cell culture production of drugs for animals). Because the FDA database does not contain information on materials used in the manufacture of drugs for animals, we cannot definitively conclude that no drugs for ruminants are manufactured with the use of cattle material that would be prohibited by this proposed rule. However, based on our knowledge of the processes and materials used in manufacture of drugs for ruminants, as well as the fact that very little cattle material is prohibited if sourced from cattle that were inspected and passed and were younger than 30 months old when slaughtered, we do not believe that prohibited cattle material is needed in the manufacture (through fermentation, cell culture or otherwise) of drugs for ruminants.

III. USDA/FSIS IFR

On January 12, 2004, in response to the diagnosis of BSE in a cow in the United States, USDA published a series of interim final rules, including ''Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle'' (69 FR 1862). The USDA/FSIS IFR declared that SRMs were inedible and unfit for food and prohibited their use as human food. It also prohibited the use of the entire small intestine of all cattle in human food. In 2005, the USDA/FSIS IFR was amended, in part, to permit use of the small intestine of all cattle in human food if appropriate procedures are used to completely remove the distal ileum (70 FR 53043). In the Foods IFR, FDA extended similar protections to FDA-regulated human food and cosmetics. (See section IV.A.3 of this document for a discussion of the Foods IFR.)

The USDA/FSIS and Foods IFRs will reduce but will not, by themselves, eliminate the use of prohibited cattle materials in domestic and imported FDA-regulated medical products for humans and drugs for ruminants. Even when excluded from human food produced in USDA-inspected establishments, prohibited cattle materials that have been denatured may leave the establishments for rendering or destruction. These materials, which previously have not been explicitly prohibited in medical products for humans and drugs for ruminants by FDA, might then be used in FDA-regulated medical products for humans and drugs for ruminants.

Under the USDA/FSIS IFR, SRMs and carcasses of nonambulatory disabled cattle are designated as inedible. However, certain products, such as gelatin and collagen (which are both covered by the provisions of this medical products proposed rule) used in FDA-regulated medical products for humans and drugs for ruminants, have traditionally been produced from cattle material deemed inedible by the USDA. Therefore, such a designation by the USDA may not be enough to preclude use of prohibited cattle materials in FDA-regulated products without additional regulation by FDA. Furthermore, some cattle are not slaughtered under continuous USDA inspection (e.g., some are sent directly to rendering without first passing inspection). Cattle material from these animals, such as brains or bones, which include SRMs, could end up as starting material for medical products for humans and drugs for ruminants. If prohibited cattle materials were unlawfully used in FDA-regulated medical products for humans and drugs for ruminants, this proposed rule if finalized would facilitate FDA's ability to use the enforcement mechanisms of the act that apply to adulterated products (e.g., seizure) to prevent human or ruminant exposure to the prohibited cattle materials.

Imported products also may contain the types of materials prohibited by the USDA, but would not fall within the scope of the USDA's import regulations either because of the nature of the products or their country of origin. Specifically, although both FSIS and USDA's Animal and Plant Health Inspection Service (APHIS) impose BSE-related prohibitions, these prohibitions collectively do not cover all FDA-regulated medical products for humans and drugs for ruminants. For example, APHIS' BSE-related restrictions on imports do not cover gelatin for human use (beyond requiring a permit) and apply only to a limited number of countries (9 CFR 94.18).

IV. FDA Actions on BSE

A. Regulations

1. FDA 1997 Ruminant Feed Rule

In the **Federal Register** of June 5, 1997 (62 FR 30936), FDA published a regulation that prohibits, with some exceptions, the use of protein derived from mammalian tissue in feed for cattle and other ruminant animals (21 CFR 589.2000). The agency published the FDA 1997 ruminant feed rule to prevent the establishment and amplification of BSE in the United States and thereby minimize any risk to animals and humans. FDA recently proposed changes to these requirements to further strengthen the rule (see section IV.A.2 of this document).

2. FDA/USDA Animal Feed ANPRM and FDA 2005 Animal Feed Proposed Rule

Following detection of BSE in an imported dairy cow in Washington State in December 2003, the Secretaries of the U.S. Departments of Agriculture and Health and Human Services announced a series of regulatory actions and policy changes to strengthen protections against the spread of BSE in U.S. cattle and against human exposure to the BSE agent. The Secretary of Agriculture also convened an international panel of experts on BSE to review the U.S. response to the Washington case and make recommendations that could provide meaningful additional public or animal health benefits.

In the **Federal Register** of July 14, 2004 (69 FR 42287), FDA and USDA's FSIS and APHIS jointly published an ANPRM to solicit comment on additional measures under consideration based on those recommendations and other factors. FDA has since received comments on the joint ANPRM, and in the **Federal Register** of October 6, 2005 (70 FR 58570), published the FDA 2005 Animal Feed proposed rule to prohibit certain material from all animal food or feed.

3. Foods IFR

In the **Federal Register** of July 14, 2004 (69 FR 42256), FDA published an IFR prohibiting the use of certain cattle material to address the potential risk of BSE in human food, including dietary supplements, and cosmetics. This rule took effect immediately upon publication. On September 7, 2005, FDA amended the Foods IFR to revise or clarify provisions with regard to: (1) Use of small intestine (see section II.E.2 of this document) (2) use of hide and hide-derived products (see section V.A of this document), (3) use of milk and milk products (see section V.A of this document), (4) source tallow for tallow derivatives (see section II.E.6 of this document), and (5) testing method cited for determining the level of insoluble impurities in tallow (see section V.C of this document). As a result, cattle materials prohibited in human food and cosmetics include SRMs, small intestine of all cattle if procedures that completely remove the distal ileum are not used, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated beef. SRMs include the brain,

skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives, hides and hide-derived products, and milk and milk products. This action was taken to minimize human exposure to materials that are highly likely to contain the BSE agent in cattle infected with the disease.

4. Foods Recordkeeping/Access Final Rule

In the **Federal Register** of October 11, 2006 (71 FR 59653), FDA also published a final rule to require that manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain, material from cattle establish and maintain records sufficient to demonstrate that the food and cosmetics are in compliance with the Foods IFR. FDA believes that records documenting the absence of prohibited cattle materials in human food and cosmetics are critical for manufacturers, processors, and FDA to ensure compliance with the ban on the use of prohibited cattle materials in the Foods IFR. FDA solicited comment on the types of records that may already be available to document the absence of prohibited cattle materials in human food and cosmetics and the types of records that could be established to document the absence of prohibited cattle materials in these FDA-regulated products. The effective date of the Foods Recordkeeping/Access final rule is January 9, 2007. Until the Foods Recordkeeping/Access final rule is effective, FDA is ensuring that it can enforce the new prohibitions in the Foods IFR through the provisions in that rule requiring that FDA be given access to any existing records relevant to compliance with the ban on prohibited cattle materials.

This proposed rule for medical products for humans and drugs for ruminants is a companion to the Foods IFR and responds to the same public health concerns. This proposed rule serves as an additional safeguard to reduce human exposure to the agent that causes BSE that may be present in cattle-derived medical products for humans and drugs for ruminants that are from domestic and imported sources.

B. FDA Guidance

During the past decade, we have communicated with the public and manufacturers, applicants, importers, and processors of FDA-regulated human and animal products regarding appropriate steps to increase product safety and minimize the risk of products being contaminated with the BSE agent. Most of our communications have been in the form of letters and guidance to industry and import alerts.

- November 1992—We wrote to manufacturers of dietary supplements to alert them to the developing concern about TSEs in animals and CJD in humans and recommended that they investigate the geographic sources of any bovine and ovine material used in their products.
- December 1993—We wrote to manufacturers of drugs, biologics, and medical devices and recommended against the use of bovine-derived materials from cattle that have resided in, or originated from, BSE countries.
- August 1994—We published a notice in the **Federal Register** (59 FR 44592, August 29, 1994) entitled ''Bovine-Derived Materials; Agency Letters to Manufacturers of FDA-Regulated Products.'' In the notice, we published the text of the November 1992 and December 1993 letters previously described and, in addition, the text of letters to manufacturers of FDA-regulated products for animals (August 17, 1994), and manufacturers and importers of dietary supplements and cosmetics (August 17, 1994).
- October 1994—We issued Import Alert 17–04, which allowed for the detention, without physical examination, of bulk shipments of high-risk bovine tissues and tissue-derived ingredients from BSE countries. We have updated this alert whenever APHIS has revised the list of countries in 9 CFR 94.18.
- October 1997—We published a notice of availability (62 FR 52345, October 7, 1997) of a guidance for industry entitled ''The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) in FDA-Regulated Products for Human Use.''

The rule, if finalized, will supersede prior communications that address the same issues, including the communications identified previously.

V. Description of Proposed Rule

A. Definitions

For the purposes of this regulation, we are proposing to define the terms ''prohibited cattle materials,'' ''inspected and passed,'' ''mechanically separated beef,'' ''nonambulatory disabled cattle,'' ''specified risk materials,'' ''tallow,'' ''tallow derivative,'' and ''ruminant'' (proposed §§ 300.200(a), 500.200(a), 600.16(a), 895.102(a) and 1271.470(a)). The proposed terms and definitions are the same as those used in the Foods IFR (69 FR 42256 and 70 FR 53063), except that we are now including in proposed § 500.200(a) a definition for ruminant and we have revised the definition of prohibited cattle materials as it relates to fetal calf material. We have also made minor editorial revisions to the definition of inspected and passed. The proposed definitions are consistent with definitions used by the USDA (69 FR 1862 and 70 FR 53043).

1. *Prohibited cattle materials* means specified risk materials, small intestine of all cattle if procedures that completely remove the distal ileum are not used, material from nonambulatory disabled cattle, material from cattle not inspected and passed, or mechanically separated beef. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives, hides and hide-derived products, and milk and milk products. Prohibited cattle materials also do not include materials obtained from fetal calves of cows that were inspected and passed as long as the materials were obtained by procedures adequate to prevent contamination with specified risk materials.

With regard to hides and hide-derived products, we are proposing that these products not be included in the definition of ''prohibited cattle materials.'' We are proposing this exemption because cattle hide has been determined to be a tissue with negligible risk of transmitting the agent that causes BSE; the OIE recommends that it be freely traded regardless of the BSE risk status of the exporting countries. Even though we are proposing to exempt hides and hide-derived products from the provisions of this proposed rule, applicants and manufacturers would be required to take precautions to avoid cross contamination of hides and other nonprohibited cattle material with prohibited cattle material during slaughter and processing.

With regard to milk and milk products, we are proposing that these products also not be included in the definition of ''prohibited cattle materials.'' We recognize that milk and milk products present a negligible risk of transmitting the agent that causes BSE. The OIE recommends that milk and milk products be freely traded

among countries, regardless of the BSE risk status of the exporting country. In addition, the prohibitions for medical products for humans and drugs for ruminants applies to materials from cattle slaughtered on or after the effective date of the rule and is not meant to apply to milk and milk products, which come from live cattle.

2. *Inspected and passed* means that the material is from an animal that has been inspected and passed for human consumption by the appropriate regulatory authority, and at the time the animal was inspected and passed, it was found to be not adulterated.

3. *Mechanically separated beef* means a meat food product that is finely comminuted, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses, that meets the specifications contained in 9 CFR 319.5, USDA's regulation that prescribes the standard of identity for Mechanically Separated (Species).

4. *Nonambulatory disabled cattle* means cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

5. *Specified risk material* means the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older, and the tonsils and distal ileum of the small intestine of all cattle.

6. *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues. Tallow must be produced from tissues that are not prohibited cattle materials or must contain not more than 0.15 percent insoluble impurities as determined by the method entitled ''Insoluble Impurities'' (AOCS Official Method Ca 3a–46), American Oil Chemists' Society (AOCS), 5th Edition, 1997, incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision, and sensitivity to AOCS Official Method Ca 3a–46. You may obtain copies of the method from AOCS (*http://www.aocs.org*) 2211 W. Bradley Ave., Champaign, IL 61821. Copies may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

7. *Tallow derivative* means any chemical obtained through initial hydrolysis, saponification, or trans-esterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or trans-esterification may be applied to obtain the desired product.

8. *Ruminant* means any member of the suborder of animals that has a stomach with four compartments (rumen, reticulum, omasum, and abomasum) through which feed passes in digestion. The suborder includes, but is not limited to, cattle, buffalo, sheep, goats, deer, elk, and antelopes.

B. Proposed Requirements for Prohibited Cattle Materials and Permission for an Exception or Alternative to These Requirements

USDA and FDA prohibit the use of SRMs, and mechanically separated beef in human food (69 FR 1862; 69 FR 42256). USDA also requires that all nonambulatory disabled cattle presented for slaughter be condemned (69 FR 1862), while FDA prohibits use of such cattle in human food (69 FR 42256). USDA and FDA permit use of the small intestine of all cattle in human food if appropriate procedures are used to completely remove the distal ileum (70 FR 53043; 70 FR 53063).

FDA imposes these prohibitions for cosmetics as well, and also prohibits material from cattle not inspected and passed in both human food and cosmetics (69 FR 42256; 70 FR 53063). To ensure that the same materials are not incorporated into other FDA-regulated products, we are now proposing to prohibit the use of these materials in, or in the manufacture of, medical products for humans and drugs for ruminants. As with human food and cosmetics, we are proposing the following five categories of material as prohibited cattle materials: (1) The small intestine from all cattle if procedures that would completely remove the distal ileum are not used, (2) SRMs, (3) mechanically separated beef, (4) material from nonambulatory disabled animals, and (5) material from cattle not inspected and passed.

Scientists believe that the human disease vCJD is likely caused by the consumption of products contaminated with the agent that causes BSE. The relationship between the agent that causes BSE and human cases of vCJD has been described previously in section II.C of this document. Consumption of contaminated material is thought to cause illness in humans, although scientific research has not determined the infectious dose (see section II.C of this document), and there is not a test that would allow screening of cattle materials or derivative products for infectious material (see section II.D of this document). Therefore, we are proposing in § 300.200(b)(1) that, except as provided in proposed § 300.200(b)(2), no human drug be manufactured from or otherwise contain prohibited cattle materials obtained from cattle slaughtered on or after the effective date of the final rule based on this proposal. We are proposing similar limitations for other products: drugs for ruminants, human biological products (including blood products) and medical devices that are intended for use in or on the body, and HCT/Ps (defined at 21 CFR 1271.3(d)) (proposed §§ 500.200(b), 600.16(b), 895.102(b), and 1271.470(b)). With regard to HCT/Ps, this proposed prohibition (proposed § 1271.470(b)) applies to use of prohibited cattle materials in the manufacture of the HCT/P rather than the manufacture of the HCT/P from prohibited cattle materials because HCT/Ps exclude animal tissues (§ 1271.3(d)(2)(vi)).

FDA is proposing to apply the requirements of this proposed rule to all products or components of products manufactured for use in the United States or imported into the United States. This proposed rule contains the basic requirements needed to provide further protection of humans and ruminants from the potential risks of BSE posed by the use of cattle material in the manufacture of these products. Additional measures that FDA determines are needed for individual products would be addressed on a case-by-case basis through the application review process. For non-application products, if the agency finds that specific products or product classes do not meet the applicable statutory standards regarding adulteration and misbranding, it may take action even if the products comply with the requirements in this proposed rule.

The provisions in this proposed rule would apply to medical products for humans and drugs for ruminants that are manufactured from or that otherwise contain material from cattle slaughtered on or after the effective date of any final rule. The restrictions would not apply to such products (including cell lines used in the manufacture of products) that use or contain materials from cattle

slaughtered before the effective date of any final rule.

The proposed rule would provide applicants and manufacturers a mechanism for requesting FDA to grant written permission for an exception or alternative to the limitations on the use of prohibited cattle materials in medical products for humans or drugs for ruminants (proposed §§ 300.200(b)(2), 500.200(b)(2), 600.16(b)(2), 895.102(b)(2), and 1271.470(b)(2)). Applicants and manufacturers that choose to request such permission would be required to submit the request in writing to the applicable FDA Center with the requisite information as detailed below. For products subject to an application or premarket notification, this written request would be required to reference the product's application number. The Center Director may permit an exception or alternative to this proposed rule's limitation on the use of prohibited cattle materials upon the submitter's request or on his or her own initiative. Including the application number of the product in a written request for products subject to applications or premarket notifications would ensure that existing applications and clearances reflect when an exception or alternative to these proposed requirements has been submitted and when an exception or alternative has been approved.

FDA expects that applicants or manufacturers may submit a request for an exception or alternative when filing a new application or premarket notification for a product containing cattle material that would be prohibited under this proposed rule. Applicants or manufacturers may also submit a request for an exception or alternative if an existing product contains prohibited cattle materials under this proposal. Although FDA believes it is unlikely that applicants or manufacturers who currently are not using prohibited cattle materials in their products will reformulate their products to include prohibited cattle materials, proposing to do so would require not only a request for an exception or alternative but also a supplement to the approved application or a new premarket notification, consistent with existing regulations.

A request for an exception or alternative to the requirements would include: (1) The reasons why an exception or alternative to the requirements is needed, (2) a description of the product, including the type of prohibited cattle materials used in its manufacturing, its manufacturing and purification processes, and its route of administration, (3) a description of the source of the prohibited cattle materials, including information on the location where the cattle were born, raised, and slaughtered and any other information relevant to the likelihood of the cattle having ingested material prohibited under § 589.2000, and (4) any other relevant information (paragraphs (b)(2)(ii)(A) through ((b)(2)(ii)(C) and (b)(2)(ii)(E) of proposed §§ 300.200, 500.200, 600.16, 895.102, and 1271.470). For medical products for humans, the request would be required to include a description of how the requirement is not necessary based on the risks of the prohibited cattle materials in the product and the benefits of the product or how such restrictions are not necessary to ensure the safety of the product (paragraph (b)(2)(ii)(D) of proposed §§ 300.200, 600.16, 895.102, and 1271.470). For drugs for ruminants, the request would be required to include either: (1) A description of how the requirements are not necessary: (i) Based on the risks of the prohibited cattle materials in the product to the target animal and the benefits of the product to the target animal and (ii) to ensure a reasonable certainty of no harm to humans from any food derived from the target animal to which the product was administered, or (2) a description of how the requirements are not necessary to ensure the safety of the product with respect to both the target animal and any food derived from the target animal to which the product is administered (proposed § 500.200(b)(2)(ii)(D)). FDA would respond to all requests in writing and could impose conditions in granting a request. FDA could also grant permission for an exception or alternative to the requirements on its own initiative based on an evaluation of the criteria described previously. A record of any exception or alternative to the requirements in paragraph (b)(1) of proposed §§ 300.200, 500.200, 600.16, 895.102, and 1271.470 that is granted by FDA would be required to be maintained by the applicant or manufacturer under the proposed recordkeeping requirements discussed in section V.E of this document.

Although FDA believes that exceptions or alternatives to the requirements of this proposed rule would be rare, the proposal would allow medical products for humans and drugs for ruminants to be manufactured from or otherwise contain prohibited cattle materials if the agency determines that the risk posed by the use of prohibited cattle materials in the product would be outweighed by the benefits of the particular product or if the agency determines that prohibiting the use of these materials would be otherwise unnecessary to ensure the safety of the product. In the case of drugs intended for use in food-producing ruminant species, the benefits of the product relate primarily to the target animal species (ruminants), whereas the risks relate to both the health of the target animal as well as the safety of the food derived from the target animal. However, the agency does not weigh the benefits of a drug to an animal against the risks of the drug to human health, but rather considers whether there is a reasonable certainty of no harm to humans from the use of the drug in animals. Therefore, the reasonable certainty of no harm standard would be applied when considering requests for exceptions or alternatives to the proposed requirements for drugs intended for use in food-producing ruminant species. In all cases, FDA intends to apply existing statutory safety standards in determining whether to grant a written request for an exception or alternative to the proposed limitations on the use of prohibited cattle materials. (See section V.E of this document for discussion.)

In the joint ANPRM, USDA's FSIS sought comment on the issue of equivalence and BSE requirements (whether the agency should consider a country's BSE risk when determining whether a country has implemented equivalent sanitary measures to those required by the United States to prevent human exposure to the BSE agent) (69 FR 42287 at 42299 and 42300). In the Foods IFR, FDA sought comment on the standards that should be applied when determining another country's BSE status, providing an exemption for ''BSE-free'' countries, and how to determine that countries meet any standards that might be developed (69 FR 42256 at 42263). FDA here again requests comment on whether and, if so, on what basis to exempt products and components of products from ''BSE-free'' countries from our respective requirements related to BSE, including those issued by this proposed rule.

Proposed §§ 211.116 and 226.60, which would be part of FDA's current good manufacturing practice (CGMP) requirements for finished pharmaceuticals for humans and ruminants and for type A medicated articles for ruminants would prohibit use of certain cattle materials, as described in proposed §§ 300.200, 500.200 and 600.16. The CGMP requirements contain the minimum methods that must be used for the manufacture, processing, packing, or holding of a drug to ensure that the drug

meets the quality and purity characteristics that it purports or is represented to possess. The CGMP requirements contained in part 211 (21 CFR part 211) apply to finished pharmaceuticals and components of finished pharmaceuticals for both humans and animals.

The CGMP requirements contained in part 226 (21 CFR part 226) apply to Type A medicated articles. Type A medicated products are intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. A Type A medicated article consists of a new animal drug(s), with or without carrier, with or without inactive ingredients. Type A medicated articles are new animal drugs, and the manufacture of a Type A medicated article requires an approved new animal drug application (21 CFR part 514).

C. Tallow and Tallow Derivatives

Tallow would be defined as ''the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues'' (proposed §§ 300.200(a)(6), 500.200(a)(6), 600.16(a)(6), 895.102(a)(6) and 1271.470(a)(6)). Tallow derivatives would be defined as any chemical obtained through initial hydrolysis, saponification, or trans-esterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or trans-esterification may be applied to obtain the desired product (proposed §§ 300.200(a)(7), 500.200(a)(7), 600.16(a)(7), 895.102(a)(7) and 1271.470(a)(7)). For the reason described in section II.K of this document, we are proposing that tallow with no more than 0.15 percent insoluble impurities and tallow derivatives would not be defined as prohibited cattle materials under this rule even when manufactured with prohibited materials (proposed §§ 300.200(a)(1), 500.200(a)(1), 600.16(a)(1), 895.102(a)(1) and 1271.470(a)(1)). (Tallow made without using prohibited cattle materials would not be subject to this purity requirement.) We are proposing that the insoluble impurities in tallow be measured by the method entitled ''Insoluble Impurities'' (AOCS Official Method Ca 3a–46), American Oil Chemists' Society (AOCS), 5th Edition, 1997, incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision, and sensitivity to the AOCS Official Method Ca 3a–46 (proposed §§ 300.200(a)(6), 500.200(a)(6), 600.16(a)(6), 895.102(a)(6) and 1271.470(a)(6)). The AOCS Official Method Ca 3a–46 is currently used by the domestic tallow industry. Reference to the AOCS Official Method Ca 3a–46 in this proposed definition does not exclude use of another method. Any testing method may be used that is equivalent to the AOCS Official Method Ca 3a–46 in accuracy, precision, and sensitivity. Those wishing to use an alternate test would be responsible for determining that it is equivalent to the AOCS Official Method Ca 3a–46; it would not be necessary for FDA to approve the use of an alternate test.

Tallow that contains more than 0.15 percent insoluble impurities could be used if it complies with the proposed requirements for cattle materials in proposed § 300.200 for drugs for humans, proposed § 500.200 for drugs for ruminants, proposed § 600.16 for biological products, proposed § 895.102 for medical devices for humans that are intended for use in or on the body, and proposed § 1271.470 for HCT/Ps (e.g., made without the use of any prohibited cattle materials).

We note that, regardless of its purity level, tallow to be used in medical products for humans and drugs for ruminants would be subject to the other provisions of the act and would be adulterated if, for example, it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth (section 501(a)(2)(A) of the act)(21 U.S.C. 351(a)(2)(A)).

D. Proposed Requirements Regarding Extralabel Drug Use in Animals

In 1994, Congress enacted the Animal Medicinal Drug Use Clarification Act (AMDUCA)(Public Law 103–396). This act authorizes the extralabel use of approved animal and human drugs in animals. The act, as well as FDA regulations in part 530 (21 CFR part 530), sets out certain conditions for extralabel use and authorizes FDA to prohibit the extralabel use of approved animal or human drugs in animals. Because FDA, elsewhere in this proposed rule, would prohibit the use of certain cattle materials in drugs for ruminants only, the agency is concerned that ruminants could still be exposed to prohibited cattle materials through the extralabel use in ruminants of a drug that was approved for a nonruminant species. Also, the agency is concerned about the extralabel use in ruminants of a drug that was approved for humans to the extent an exception or alternative to these proposed requirements has been granted. Therefore, in order to prevent the intentional or unintentional use of a drug containing prohibited cattle materials in ruminants, FDA is proposing to revise § 530.41 to prohibit in ruminants the extralabel use of drugs containing prohibited cattle material and approved for use in other animals (nonruminants) or for humans (proposed § 530.41(c)).

FDA is also proposing to add new § 530.42 that would require labels for drugs prohibited from extralabel use in ruminants and described under proposed § 530.41(c) to bear or be accompanied by labeling information to communicate to the user that extralabel use in ruminants is prohibited. The proposed regulation would require label information to include the statement ''Federal law prohibits the extralabel use of this product in ruminants.'' AMDUCA and the implementing regulation at § 530.11, however, prohibit the extralabel use of an approved new animal drug or human drug in or on animal feed. Since the extralabel use of all drugs in or on animal feed is excluded from the extralabel use provisions of AMDUCA, FDA believes it is unnecessary and potentially confusing to include the previous statement only on those feed products that contain drugs described in proposed § 530.41(c). Therefore, the labeling requirement under proposed § 530.42 would apply to all products that contain drugs described in proposed § 530.41(c) except those products used in or on an animal feed. FDA intends for sponsors of approved products that would be subject to proposed § 530.42 to revise their labeling by the effective date of the final rule based on this proposal. If necessary, FDA also would have the ability under proposed § 300.200(b)(2)(iii) to impose a labeling condition on a human drug regarding the extralabel use in ruminants of that human drug if an exception or alternative is granted.

E. Proposed Recordkeeping Requirements

We are proposing that applicants and manufacturers of medical products for humans and drugs for ruminants that are manufactured from or otherwise contain material from cattle be required to establish and maintain records that demonstrate that the material from cattle meets the requirements of this proposed rule (proposed §§ 300.200(c)(1), 500.200(c)(1), 600.16(c)(1), 895.102(c)(1) and 1271.470(c)(1)). Because at this time there is no way to screen reliably for the presence of the BSE agent or for the presence of prohibited cattle materials, applicants and manufacturers of medical products for humans and drugs

for ruminants must depend on records from the suppliers of cattle material to demonstrate that their source material is free from prohibited cattle materials. Similarly, without adequate records, FDA may not know whether applicants and manufacturers of medical products for humans and drugs for ruminants have complied with the prohibitions against use of prohibited cattle materials. Therefore, under proposed §§ 300.200(c)(1), 500.200(c)(1), 600.16(c)(1), 895.102(c)(1) and 1271.470(c)(1), applicants and manufacturers of medical products for humans and drugs for ruminants that are manufactured from or otherwise contain material from cattle would be required to establish and maintain records sufficient to demonstrate that the medical products for humans and drugs for ruminants do not contain prohibited cattle materials.

1. Types of Records

For example, to satisfy the requirement in proposed §§ 300.200(c)(1), 500.200(c)(1), 600.16(c)(1), 895.102(c)(1), and 1271.470(c)(1) that records show the absence of prohibited cattle materials, applicants and manufacturers of medical products for humans and drugs for ruminants that are manufactured from or otherwise contain brain from cattle would have to establish and maintain records to demonstrate, among other things, that the cattle brain used is not from cattle over 30 months of age.

In general, we would expect that having the following types of records on FDA-regulated medical products for humans or drugs for ruminants containing cattle material would be sufficient to demonstrate that the product is not manufactured from and does not otherwise contain prohibited cattle materials:

- A signed and dated affirmation (with contact information) by a slaughter establishment that cattle material supplied by that establishment in a particular shipment does not contain prohibited cattle materials. If two or more lots of cattle material from different slaughter establishments are pooled into a final product, then having records from each slaughter establishment should be sufficient.
- For products containing tallow, records from a slaughter establishment affirming that the tallow was produced from material containing no prohibited cattle materials or records (i.e., signed, dated, with contact information) from the tallow supplier affirming that the tallow contains no more than 0.15 percent insoluble impurities (e.g., a certificate of analyses).
- For products containing fetal calf materials, records from a slaughter establishment affirming that the fetal calf material was obtained: (1) From cows that were inspected and passed and (2) using procedures that ensure that the fetal material was not contaminated with prohibited cattle materials during slaughter or processing.

Consistent with CGMP recordkeeping requirements, applicants and manufacturers who maintain documentation of compliance should maintain that information on a lot-by-lot basis. The lot-by-lot records would ensure that each time a shipment of cattle material is sent or received, there is documentation that a management official confirmed that the shipment was free of any prohibited cattle material.

We request comments on alternative recordkeeping requirements that would ensure the requirements of the proposed rule would be met. We also request comments on whether existing recordkeeping practices include the required information and, if not, what changes the proposal would necessitate. In addition, we request comment on whether the rule should specifically require certain types of records.

2. Proposed Periods for Records Retention

The following record retention time periods would be required by this proposal:

- For drugs for humans, we are proposing, consistent with our CGMP regulations for these products (§ 211.180), to require that records be retained for at least 1 year after the expiration date of the drug (proposed § 300.200(c)(2)).
- For drugs for humans lacking an expiration date, we are proposing, consistent with our CGMP regulations for these products (§ 211.180), to require that records be retained for at least 3 years after distribution of the last lot of the drug (proposed § 300.200(c)(2)).
- For drugs for ruminants other than Type A medicated articles, we are proposing, consistent with our CGMP regulations for these products (§ 211.180), to require that records be retained for at least 1 year after the expiration date of the product (proposed § 500.200(c)(2)(ii)). Because all new animal drugs are required to have an expiration date, only the proposed 1-year records retention period would apply to all drugs for ruminants.
- For Type A medicated articles intended for use in ruminants, records would be retained, consistent with our CGMP regulations for these products (§ 226.110), for at least 2 years after distribution by the manufacturer (proposed § 500.200(c)(2)(i)).
- For human biological products, we reference 21 CFR 600.12(b) for consistency with established recordkeeping periods. Records would be retained for no less than 5 years after the records of manufacture have been completed or 6 months after the latest expiration date for the individual product, whichever represents a later date (proposed § 600.16(c)(2)).
- For medical devices that are intended for use in or on the body, we reference 21 CFR 820.180(b) for consistency with established recordkeeping periods. Records would be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer (proposed § 895.102(c)(2)).
- For HCT/Ps, we reference § 1271.270(d) for consistency with established recordkeeping periods. Records would be retained for 10 years after their creation unless otherwise stated in part 1271 (proposed § 1271.470(c)(2)).

As discussed previously, records documenting the absence of prohibited cattle materials in medical products for humans and drugs for ruminants are needed to help applicants and manufacturers ensure that they meet the proposed requirements of this rulemaking and to help FDA monitor compliance. It is important for recall purposes that records be retained for the likely period of time during which the product might be used, so that FDA can assess compliance with the requirements for cause or otherwise. The proposed timeframes for retaining records reflect the likely period of time during which medical products for humans and drugs for ruminants covered by this proposed rule might be used. The proposed timeframes for retaining records are consistent with the relevant CGMP requirements in current rules. Because of the lengthy incubation period of BSE (see section II.C of this document), we are requesting comment on whether records should be required for a longer period of time than proposed in this rulemaking. This may assist with traceback and may assist applicants and manufacturers in proving that their products are not the source of BSE infection.

In the Foods Recordkeeping/Access final rule, we require that records for FDA-regulated human food and cosmetics be retained for 2 years after the date the records were created (21 CFR 189.5(c)(2) and 21 CFR 700.27(c)(2)). FDA is requiring this

timeframe for these products so that the records will be available during the entire shelf life of the products covered by that rule.

3. Location of Records

We are proposing that records be maintained at the applicant's or manufacturer's establishment or at a reasonably accessible location. Records would be considered to be reasonably accessible if they are accessible from an onsite location (proposed §§ 300.200(c)(3), 500.200(c)(3), 600.16(c)(3), 895.102(c)(3) and 1271.470(c)(3)). Electronic recordkeeping requirements for all types of FDA required recordkeeping are addressed under part 11 (21 CFR part 11). These requirements would pertain to any records that would be required by this proposed rule.

Proposed §§ 300.200(c)(4), 500.200(c)(4), 600.16(c)(4), 895.102(c)(4) and 1271.470(c)(4) provide that records required by this subpart must be readily available to FDA for inspection and copying. All the records would be required to be in English.

Because of inherent difficulties in accessing records maintained at foreign establishments, we are proposing requirements for importers of record of medical products for humans and drugs for ruminants (proposed §§ 300.200(c)(5), 500.200(c)(5), 600.16(c)(5), 895.102(c)(5) and 1271.470(c)(5)). When filing entry with the U.S. Customs and Border Protection, importers of record of a product manufactured from or otherwise containing cattle material would be required to affirm that the product for import was manufactured from or otherwise contains cattle material and affirm that the product was manufactured in accordance with proposed §§ 300.200(b), 500.200(b), 600.16(b), 895.102(b) and 1271.470(b), as applicable. If the product was manufactured from or otherwise contains cattle material, then the importer of record would be required, if requested, to provide to FDA within 5 days records that would be sufficient to demonstrate that the product was not manufactured from and does not contain prohibited cattle material. FDA expects that the content of these records would be the same as that described as being sufficient for domestic products.

FDA believes 5 days is a reasonable amount of time for the importer of record to respond while still allowing FDA sufficient time to review the documents to make an initial admissibility decision before the conditional release period for the product expires. If the importer of record fails to provide FDA with the records within 5 days, the product would be subject to detention because it would appear to be adulterated, and the owner or consignee would be afforded notice and an opportunity for hearing in accordance with section 801(a) of the act (21 U.S.C. 381).

VI. Legal Authority

FDA has the authority to take the actions proposed in this rule under various statutory provisions. These provisions include sections 201, 301, 501, 502, 505, 512, 516, 519, 701, 704, and 801(a) of the act (21 U.S.C. 321, 331, 351, 352, 355, 360b, 360f, 360i, 371, 374, and 381(a)) and sections 351, 361, and 368 of the PHS Act (42 U.S.C. 262, 264, and 271).

With respect to drugs for humans, including drugs that are biological products, FDA is proposing these regulations under the adulteration provision in section 501(a)(2)(B) of the act, and under sections 201, 505, 701(a) and (b), 704, and 801(a) of the act.

Under section 501(a)(2)(B) of the act, FDA has the authority to impose requirements necessary to ensure that drugs meet the requirements of the act with respect to identity, strength, quality, and purity. Under section 501(a)(2)(B) of the act, a drug is adulterated if: ''the methods used in, or the facilities and controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.''

FDA is proposing to amend its CGMP regulations (proposed § 211.116) to prohibit the use of certain cattle materials in human drug products and components, including biological products, as provided by proposed §§ 300.200 and 600.16. Proposed §§ 300.200 and 600.16 would require that no drug or biological product ''be manufactured from or otherwise contain prohibited cattle materials'' unless FDA has granted a request for an exception or alternative to the requirements. Proposed § 211.116 would apply to drugs, including biological products, that are directly subject to the CGMP regulations. For drugs not directly subject to the CGMP regulations, such as active pharmaceutical ingredients and source materials, section 501(a)(2)(B) of the act supports the proposed requirements in §§ 300.200 and 600.16.

As provided in proposed §§ 300.200(d) and 600.16(d), a drug or biological product that fails to comply with the requirements of §§ 300.200(b) and 600.16(b), respectively, would be adulterated under section 501(a)(2)(B) of the act. Because of the possibility of disease transmission to humans from exposure to prohibited cattle materials, prohibiting such cattle materials in drugs and biological products will help ensure that they meet the requirements of the act with respect to safety and have the identity, and meet the quality and purity characteristics they are purported or represented to possess.

Section 201(p) of the act defines a new drug to include ''[a]ny drug *** the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof ***.'' Based on the scientific data and information available to FDA regarding the possibility of disease transmission to humans from exposure to prohibited cattle materials, under this proposed rule any human drug manufactured from, or otherwise containing, prohibited cattle materials is not generally recognized as safe and effective (GRAS/GRAE), and therefore is a new drug under section 201(p) of the act.

Section 505(a) of the act requires that ''[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) [of section 505] is effective with respect to such drug.'' Under section 505 of the act, new drug applications must demonstrate that a drug is safe and effective for its intended use(s). Because of the possibility of disease transmission to humans from exposure to prohibited cattle materials, prohibiting such cattle materials in drugs will help ensure that drugs are safe for their intended use(s). Based on the scientific data and information available to FDA regarding the possibility of disease transmission to humans from exposure to prohibited cattle materials, under this proposed rule FDA would not approve an application or supplement for a drug containing prohibited cattle materials unless an exception or alternative has been granted based upon the Center Director's determination that the safety standard in section 505 of the act would still be met. In addition, under the proposed rule, a drug containing prohibited cattle materials that is

already subject to an approval would no longer be shown to be safe based on the presence of prohibited cattle materials, and would be in violation of section 505 of the act unless an exception or alternative for use of the prohibited cattle materials has been granted. Section 505 of the act also allows FDA to impose additional conditions on an application product on a case-by-case basis, should such conditions be necessary to ensure that the product meets the standard for approval set forth in section 505 of the act.

Under section 701(a) of the act, FDA is authorized to issue regulations for the act's efficient enforcement. The proposed regulations would require measures to ensure that drugs for humans, including biologics, are being manufactured, processed, packed, or held in conformity with CGMP, and to ensure that new drugs comply with section 505 of the act, which would allow for efficient enforcement of the act. Under the proposed regulations, applicants and manufacturers of drugs for humans that are manufactured from or otherwise contain material from cattle also would be required to establish and maintain records that document the absence of prohibited cattle materials in such products and have such records readily available to FDA for inspection and copying. These proposed recordkeeping requirements are also authorized under sections 501(a)(2)(B) and 505(k) of the act.

Once material is removed from cattle, we may not be able to obtain the information necessary to determine whether it is prohibited cattle material. For example, we would not know from examination of a spinal cord whether the source animal was 30 months of age or over at the time of slaughter, or whether it was inspected and passed. Because at this time there is no way to test reliably for the presence of the BSE agent or the presence of the cattle materials prohibited in proposed § 300.200, applicants and manufacturers of drugs for humans would have to depend on records from their suppliers of cattle materials to ensure that their source material does not contain any cattle materials prohibited under proposed § 300.200. Without adequate records, FDA cannot know whether applicants and manufacturers of drugs for humans have complied with the prohibitions against certain cattle materials under proposed § 300.200. Therefore, the proposed recordkeeping requirements are necessary for the efficient enforcement of these rules and authorized under section 701(a) of the act. Under proposed § 300.200(e) and 600.16(e), the failure of an applicant or manufacturer to comply with the requirements of §§ 300.200(c) and 600.16(c), respectively, would render a drug or biological product adulterated.

We are also proposing provisions relating to records regarding imported drugs for humans under sections 801(a) and 701(b) of the act. Importers of record of such a drug product manufactured from or otherwise containing cattle material would be required to affirm that such a drug product for import was manufactured from or contains cattle material, and affirm that it was manufactured in compliance with the proposed rule. If such a drug was manufactured from or otherwise contains cattle material, then importers of record would also be required, if requested, to provide records to FDA within 5 days sufficient to demonstrate compliance. Under proposed §§ 300.200(f) and 600.16(f), failure of an importer of record to comply with those requirements causes a drug for humans to appear to be adulterated.

Section 801(a) of the act provides requirements with regard to imported drugs and provides for refusal of admission into the United States of drugs for humans that appear to be adulterated. Section 701(b) of the act authorizes the Secretaries of Treasury[2] and Health and Human Services to jointly prescribe regulations for the efficient enforcement of section 801 of the act.

Because most biological products, including blood, are also drugs, the sections of the act discussed previously provide legal authority for issuing a regulation limiting the use of prohibited cattle materials in such biological products. There is, however, additional legal authority for the proposed rule's requirements with respect to biological products generally. Section 351(a)(2)(A) of the PHS Act (42 U.S.C. 262(a)(2)(A)) requires that FDA ''establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.'' Approval of a biologics license application (BLA) must be based on a demonstration that the biological product is ''safe, pure, and potent'' (section 351(a)(2)(C)(i)(I) of the PHS Act). Limiting the use of prohibited cattle materials in biological products is designed to ensure the safety, purity, and potency of such licensed biological products. Based on the scientific data and information available to FDA regarding the possibility of disease transmission to humans from exposure to prohibited cattle materials, under the proposed rule FDA would not approve a BLA or supplement for a biological product containing prohibited cattle materials unless an exception or alternative has been granted based upon the Center Director's determination that the safety standard in section 351(a)(2)(C) of the PHS Act would still be met. In addition, under the proposed rule, a biological product containing prohibited cattle materials that is already licensed would no longer be demonstrated to be safe based on the presence of prohibited cattle materials, and would be in violation of section 351(a)(1) of the PHS Act and section 505 of the act, unless an exception or alternative for use of the prohibited cattle materials has been granted. Accordingly, FDA is proposing to amend its biological product regulations to prohibit the use of certain cattle materials in biological products as provided by proposed § 600.16.

With respect to devices, FDA is proposing to issue these regulations under the adulteration provision in section 501(g) of the act, under the misbranding provision in section 502(t) of the act, and under sections 516, 519(a), 701(a) and (b), and 801 of the act.

Under section 516 of the act, FDA may issue a regulation making a device a banned device if the agency determines, on the basis of all available data and information, that a device presents an unreasonable and substantial risk of illness or injury that can not be corrected or eliminated by labeling. A banned device is deemed adulterated under section 501(g) of the act. There are several routes through which devices intended for use in or on the body have the potential to introduce the BSE agent into humans if the devices contain prohibited cattle materials. It is well documented that central nervous system tissue, including the optic nerve, carries infectivity in animals with TSEs and humans with vCJD. Infectivity has also been transmitted to animals via mucosal tissue. Finally, although transmission through intact skin is not likely, the BSE agent has the potential to be introduced into the body through cut or abraded skin. FDA has concluded, therefore, that devices intended for use in or on the body that contain prohibited cattle materials have the potential to expose recipients of those devices if the originating cattle had BSE. Although the

[2]Under the Homeland Security Act of 2002 (Public Law 107–296), the Secretary of the Treasury has delegated all relevant Customs revenue authorities to the Secretary of Homeland Security, who has, in turn, delegated them to the Commissioner of Customs and Border Protection (CBP or Customs). If finalized, we will issue this rule jointly with the Department of Homeland Security.

over all risk of exposure is low given the low rate of BSE in U.S. cattle, this risk is deemed unacceptable given the fatal nature of vCJD. The agency is not aware of any device that can be manufactured only with prohibited cattle materials; thus, there should be no benefit to the public health from the continued marketing of devices containing these materials. FDA has determined, therefore, that devices intended for use in or on the body that contain prohibited cattle materials present an unreasonable risk to health in relation to the benefit to the public health from their continued marketing. Moreover, because there is no safe way to use these devices, the risk of disease cannot be corrected or eliminated by labeling.

It is clear, based on all available data and information, that the risk of BSE exposure may be significantly reduced by banning devices intended for use in or on the body that contain prohibited cattle materials. The agency is proposing to ban such devices, therefore, in accordance with section 516 of the act. Devices already in commercial distribution or already sold to the ultimate user are not subject to this ban because FDA is not aware of any currently marketed device that contains prohibited cattle materials. Manufacturers currently are not required to maintain records that contain information about bovine materials that would be needed to identify devices that might contain such materials. In accordance with section 516 of the act and 21 CFR part 895, interested persons may request an informal hearing on the provisions of the proposed regulation with respect to medical devices within 30 days. If a request for an informal hearing is granted, the hearing will be conducted as a regulatory hearing under 21 CFR part 16.

The proposed recordkeeping requirements for devices in this proposed rule are authorized under section 519(a) of the act. Under section 519(a), the agency may, by regulation, require that manufacturers and importers establish and maintain records, make reports, and provide information that the agency determines is necessary to ensure that devices are not adulterated or misbranded and to otherwise ensure their safety and effectiveness. FDA has determined that the recordkeeping requirements in this proposed rule are necessary to ensure that devices intended for use in or on the body do not contain prohibited cattle materials and, thus, are not adulterated under section 501(g) of the act. A device for which there is a failure or refusal to furnish any material or information required under this proposed regulation would be deemed misbranded under section 502(t) of the act.

The proposed recordkeeping requirements are also authorized under sections 701(a) and (b) and 801(a) of the act. Because at this time there is no way to screen reliably for the presence of the BSE agent or the presence of the cattle materials prohibited under this proposed rule, applicants and manufacturers of medical devices would have to depend on records from their suppliers of cattle materials to ensure that their source material does not contain any prohibited cattle materials. The proposed requirements also would allow the agency to monitor compliance with the proposed ban and, therefore, are necessary for the efficient enforcement of the act, in accordance with section 701(a) of the act. Section 801(a) of the act contains requirements with regard to imported devices and provides for refusal of admission into the United States of devices that appear to be adulterated or misbranded. Section 701(b) of the act authorizes the Secretaries of the Treasury and Health and Human Services to jointly prescribe regulations for the efficient enforcement of section 801 of the act.

With respect to new animal drugs, FDA is proposing to issue these regulations under the adulteration provision in section 501(a)(2)(B) of the act and sections 512, 701(a) and (b) and 801(a) of the act. The adulteration provision in section 501(a)(2)(B) of the act provides FDA the same authority for new animal drugs as described for drugs for humans previously in this document.

FDA is proposing to amend its CGMP regulations to prohibit the use of certain cattle materials in drug products and components intended for use in ruminant animals (proposed § 211.116). Proposed § 500.200 would require that no drug product or component intended for use in ruminants ''be manufactured from or otherwise contain prohibited cattle materials.'' Proposed § 211.116 would apply to drugs that are directly subject to the CGMP regulations. For drugs for ruminants that are not directly subject to the CGMP regulations, section 501(a)(2)(B) of the act supports the proposed requirements in proposed § 500.200.

As provided in proposed § 500.200(d), a drug that fails to comply with the requirements of § 500.200(b) would be adulterated under section 501(a)(2)(B) of the act. Because of the possibility of disease transmission to ruminants from exposure to prohibited cattle materials and to humans from consuming food from animals exposed to prohibited cattle material, prohibiting such cattle materials in drugs for ruminants would help ensure that new animal drugs for ruminants meet the requirements of the act with respect to safety, and have the identity, and meet the quality and purity characteristics they are purported or represented to possess.

Section 201(v) of the act defines a new animal drug to include ''[a]ny drug intended for use for animals other than man *** the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof ***.'' Based on the scientific data and information available to FDA regarding the possibility of disease transmission to ruminants from exposure to prohibited cattle materials, under this proposed rule any drug for ruminants manufactured from or otherwise containing prohibited cattle materials is not GRAS/GRAE, and therefore is a new animal drug under section 201(v) of the act.

Section 512 of the act provides that a new animal drug is unsafe for purposes of the adulteration provisions in section 501(a)(5) and section 402(a)(2)(C)(ii) of the act (21 U.S.C. 342(a)(2)(c)(ii)) unless there is an approval of that new animal drug application in effect. For a new animal drug application to be approved, the drug must be safe and effective for its intended use(s). Based on the scientific data and information available to FDA regarding the possibility of disease transmission to humans from exposure to prohibited cattle materials, under the proposed rule FDA would not approve an application or supplement for a drug for ruminants containing prohibited cattle materials unless an exception or alternative has been granted based upon the Center Director's determination that the safety standard in section 512 of the act would still be met. In addition, under the proposed rule, a drug for ruminants containing prohibited cattle materials that is already subject to an approval would no longer be shown to be safe based on the presence of prohibited cattle materials, and would be in violation of section 512 of the act unless an exception or alternative for use of the prohibited cattle materials has been granted.

Under section 512(a)(4) and section (a)(5) of the act, extralabel use of an approved animal drug or human drug in animals is authorized if done under certain conditions set out in FDA

regulations. However, section 512(a)(4)(A) of the act also allows FDA to prohibit particular extralabel uses of an approved new animal drug. Thus, for example, a drug approved for use in treating an animal of a nonruminant species could legally be used extralabelly to treat a ruminant animal, if it meets required conditions, unless specifically prohibited. Such drugs for nonruminant animals are allowed to contain cattle materials prohibited from use in drugs for ruminants. Absent a special prohibition, these drugs also could be used in ruminants, through extralabel use, thereby providing an avenue through which ruminants could be exposed to prohibited cattle material. Any human drug for which an exception or alternative is granted could also be used extralabelly in ruminants, which could also provide another avenue through which ruminants could be exposed to prohibited cattle materials. Therefore, under section 512(a)(4)(A) of the act (for drugs for animals) and section 512(a)(5) of the act (for drugs for humans), FDA is proposing to prohibit such extralabel use in ruminants of drugs for nonruminants or for humans containing the prohibited material.

FDA is issuing the proposed labeling requirement under sections 502(a) and 201(n) of the act (21 U.S.C. 352(a) and 321(n)). Section 502(a) provides that a drug is deemed misbranded if its labeling is false or misleading in any particular. Section 201(n) provides that ''*** in determining whether the labeling *** is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling *** fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling *** relates under the conditions of use *** as are customary or usual.'' The proposed rule would require drugs for non-ruminants that contain prohibited materials that are prohibited from extralabel use in ruminants to be labeled ''Federal law prohibits the extralabel use of this product in ruminants.'' We believe this statement is material with respect to the consequences that may result from the extralabel use of nonruminant drugs with prohibited materials in ruminants. As discussed in other sections of this preamble, the use of materials prohibited in drugs for ruminants presents a risk of BSE. Therefore, under this proposed rule, the failure to include the labeling statement on drugs for nonruminants which contain prohibited materials would render the drugs misbranded under section 502(a) of the act. Under section 701(a) of the act, FDA is authorized to issue regulations for the act's efficient enforcement. Regulations that propose measures to ensure that drugs for animals are being manufactured, processed, packed, or held in conformity with CGMP, and to ensure that they comply with section 512 of the act, allow for efficient enforcement of the act. These proposed regulations would require applicants and manufacturers of drugs for ruminants that are manufactured from or otherwise contain material from cattle to establish and maintain records that document the absence of prohibited cattle materials in such products and make such records readily available to FDA for inspection and copying. These proposed recordkeeping requirements are also authorized under sections 501(a)(2)(B) and 512(l) of the act.

Once material is removed from cattle, we may not be able to obtain the information necessary to determine whether it is prohibited cattle material. As noted previously, we would not know from examination of a spinal cord whether the source animal was over 30 months of age at the time of slaughter or whether it was inspected and passed. Because at this time there is no way to test reliably for the presence of the BSE agent or the presence of the cattle materials prohibited in proposed § 500.200, applicants and manufacturers of drugs for ruminants must depend on records from their suppliers of cattle materials to ensure that their source material does not contain any cattle materials prohibited under proposed § 500.200. Therefore, the proposed recordkeeping requirements are necessary for the efficient enforcement of the proposed rule. Under proposed § 500.200(e), the failure of an applicant or manufacturer to comply with the requirements of § 500.200(c) would render a drug for ruminants adulterated.

We are also proposing provisions relating to records regarding imported drugs for ruminants under sections 801(a) and 701(b) of the act. Importers of record of a drug for ruminants that was manufactured from or otherwise contains cattle material would be required to affirm that the drug product for import was manufactured from or contains cattle material, and affirm that it was manufactured in compliance with the proposed rule. If a drug was manufactured from or otherwise contains cattle material, then importers of record would also be required, if requested, to provide records to FDA within 5 days sufficient to demonstrate compliance. Under proposed § 500.200(f), failure of an importer of record to comply with these requirements causes a drug to appear to be adulterated. Section 801(a) of the act provides requirements with regard to imported drugs and provides for refusal of admission into the United States of drugs for ruminants that appear to be adulterated. Section 701(b) of the act authorizes the Secretaries of Treasury[3] and Health and Human Services to jointly prescribe regulations for the efficient enforcement of section 801 of the act.

FDA has invoked section 361 of the PHS Act (42 U.S.C. 264) to prevent the transmission of numerous communicable diseases, including diseases spread through certain shellfish, turtles, birds, and human tissue intended for transplantation (see 21 CFR 1240.60 (molluscan shellfish), 1240.62 (turtles), 1240.65 (parrots and other psittacine birds), and parts 1270 and 1271 (human tissue)). Recently, FDA also issued under section 361 of the PHS Act regulations designed to prevent the spread of monkeypox from African rodents to humans (21 CFR 1240.63).

Section 361 of the PHS Act provides legal authority for FDA to limit the use of prohibited cattle materials in drugs, biological products, devices, new animal drugs for ruminants, and HCT/Ps and to inspect and copy pertinent manufacturing records to ensure compliance. Section 361(a) of the PHS Act authorizes issuance and enforcement of regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries or between states. Section 361(a) of the PHS Act also provides for such inspection and destruction of articles found to be so infected or contaminated as to be ''sources of dangerous infection to human beings,'' as well as other measures that may be necessary to prevent the introduction, transmission, or spread of communicable diseases from a foreign country into a State, or from one State to another State.

Because the use of prohibited cattle materials in medical products for humans and drugs for ruminants increases the risk that the agent that

[3]Under the Homeland Security Act of 2002 (Public Law 107–296), the Secretary of the Treasury has delegated all relevant Customs revenue authorities to the Secretary of Homeland Security, who has, in turn, delegated them to the Commissioner of Customs and Border Protection (CBP or Customs). If finalized, we will issue this rule jointly with the Department of Homeland Security.

causes BSE could be transmitted to humans, limiting the use of prohibited cattle materials in medical products for humans and drugs for ruminants is a needed component of our efforts to prevent the transmission and spread of TSEs including vCJD, in humans. Scientists have concluded that exposure to the BSE agent is the most plausible explanation for the occurrence of vCJD (Refs. 24 through 27). For medical products for humans, by prohibiting use of certain cattle materials, the proposed rule would reduce the risk that the BSE agent would be transmitted directly into any person through exposure to an infectious medical product. For drugs for ruminants, by prohibiting use of certain cattle materials, the proposed rule would reduce the risk that the BSE agent would be transmitted directly into any ruminant. By protecting ruminants from exposure to the BSE agent through animal drugs, the proposed rule would also prevent transmission of the BSE agent to humans who may be exposed to products containing any ruminant materials. Consistent with the authority granted by section 361 of the PHS Act to issue and enforce such regulations as are necessary to prevent communicable disease transmission from foreign countries into the United States and from one State or possession into another, this proposed rule would provide for FDA to be able to inspect and copy pertinent manufacturing records. Because at this time there is no way to screen reliably for the presence of the BSE agent or the presence of the cattle materials prohibited under this proposed rule, the requirements with respect to the maintenance, inspection, and copying of manufacturing records are directly necessary to permit FDA to enforce the other measures designed to prevent transmission of BSE.

The proposed rule contains a procedure under which FDA could permit a manufacturer an exception or alternative to the restrictions on the use of prohibited cattle materials under limited circumstances. Specifically, a manufacturer would submit a written request for an exception or alternative to the requirements by describing: (1) Why an exception or alternative is needed; (2) the implicated product, including the type of prohibited cattle material, its manufacturing and purification processes, and its route of administration; (3) the source of the prohibited cattle material including information on the location where the cattle was born, raised, and slaughtered; and (4) any other information relevant to the likelihood of the cattle having ingested material prohibited under § 589.2000. For medical products for humans, the written request also would include: (1) How the limitations are not necessary based on the risks of the prohibited cattle materials in the product and the benefits of the product or (2) how such restrictions are not necessary to ensure the safety of the product. For drugs for ruminants, the written request would also include: (1) How the requirement is not necessary: (i) Based on the risks of the prohibited cattle materials in the product to the target animal and the benefits of the product to the target animal and (ii) to ensure a reasonable certainty of no harm to humans from any food derived from the target animal to which the product is administered, or (2) how the requirement is not necessary to ensure the safety of the product with respect to both the target animal and any food derived from the target animal to which the product is administered. The relevant Center Director could also grant written permission for an exception or alternative to the proposed requirements on his own initiative, based on these same criteria.

As discussed previously, under this proposal, FDA expects that applicants or manufacturers may submit a request for an exception or alternative when filing a new application or premarket notification for a product containing prohibited cattle materials, or if an existing product contains prohibited cattle materials. Although FDA believes it is unlikely that applicants or manufacturers who currently are not using prohibited cattle materials in their products will reformulate their products to include prohibited cattle materials, proposing to do so would require not only a request for an exception or alternative but also a supplement to the approved application or a new premarket notification, consistent with existing regulations.

In considering whether an exception or alternative to requirements of this proposed rule would meet the criteria described previously and therefore be appropriate, FDA would be required to ensure that the statutory safety standards would still be met if the exception or alternative were permitted. For drugs for humans, FDA intends to apply the safety standards set forth in sections 501(a)(2)(B) and 505 of the act. Specifically, FDA would only approve a request for an exception or alternative to the proposed limitations on prohibited cattle material if, notwithstanding the exception or alternative: (1) The drug and the methods used in, or the facilities or controls used for, its manufacturing, processing, packing, or holding conform to or are operated or administered in conformity with CGMP to ensure that such drug meets the requirements of the act as to safety and (2) the drug is safe for its intended use(s).

For biological products, FDA intends to apply the safety standard provided in section 351 of the PHS Act. Specifically, FDA would only approve a request for an exception or alternative to the proposed limitations on prohibited cattle material if, notwithstanding the exception or alternative: (1) The biological product that is the subject of the application is safe and (2) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to ensure that the biological product continues to be safe.

For human cells, tissues, and cellular and tissue-based products and other products regulated under the authority of section 361 of the PHS Act, FDA would only approve a request for an exception or alternative to the proposed limitations on prohibited cattle material if such limitations are not necessary to prevent the introduction, transmission, or spread of TSE.

For devices, FDA intends to apply the standard in section 516 of the act. Specifically, FDA would approve a request for an exception or alternative to the proposed ban on prohibited cattle materials only if, notwithstanding the exception or alternative, the device does not present an unreasonable and substantial risk of illness or injury.

For new animal drugs, FDA intends to apply the safety standards set forth in section 512 and 501(a)(2)(B) of the act. Specifically, FDA would approve a request for an exception or alternative to the proposed limitations on prohibited cattle material only if, notwithstanding the exception or alternative: (1) The drug and the methods used in, or the facilities or controls used for, its manufacturing, processing, packing, or holding conform to or are operated or administered in conformity with CGMP to ensure that such drug meets the requirements of the act as to safety and (2) the drug is safe for its intended use(s).

VII. Effective Date and Opportunity for Public Comment

We are proposing that any final rule based on this proposal be effective 30 days after its issuance in the **Federal Register**.

Requests for an informal hearing on the proposed ban related to medical devices must be submitted by (see **DATES**).

FDA invites public comment on this proposed rule, including the proposed

effective date for any final rule issued as a result of this proposal. The comment period on this proposed rule will be 60 days. The agency will consider modifications to this proposed rule based on comments made during the comment period. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this proposed rule. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is not an economically significant regulatory action as defined by the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because FDA has taken regulatory action to reduce the risk of exposure to BSE in the United States and kept affected entities informed on best practices, FDA believes the proposed rule would codify current practices of most affected entities and ensure regulatory consistency across FDA-regulated products. Few entities will need to reformulate with alternative ingredients, submit a request for exception or alternative to the limitation on the use of prohibited cattle material, or cease marketing. The FDA believes most market adjustments have taken place and this rule will not have a significant economic impact on a substantial number of small entities. A few manufacturers of certain drugs prohibited from extralabel use in ruminants would incur one-time costs to add a warning statement to the product labeling. In addition, all manufacturers that use cattle material would incur minor annual incremental recordkeeping costs. Over 10 years, the annualized costs of the proposed rule range from about $235,000 to $922,000 (at a 3 percent discount rate) and from about $235,000 to $923,000 (at a 7 percent discount rate).

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this rule to result in any 1-year expenditure that would meet or exceed this amount.

A. Need for the Proposed Rule

The need for this rule stems from inadequate information. Consumers, physicians, farmers, and veterinarians lack the information necessary to determine whether medical products for humans or drugs for ruminants have the potential to contain materials contaminated with the agent that causes BSE.

Currently, no validated method exists for testing medical products for humans and drugs for ruminants for the agent that causes BSE; therefore, we do not have a means of distinguishing products that contain infectious material from products that do not. For example, rendered material including brain and spinal cord may become an ingredient in medical products for humans or drugs for ruminants even though its presence may not be indicated as such on the label. Furthermore, end users have no way to determine whether cattle material in these products was sourced from nonambulatory disabled cattle or from cattle that were not inspected and passed for human consumption.

Based on what is known about the transmission of BSE, there is some risk of occurrence of vCJD in humans or of BSE in ruminants from the use of certain cattle-derived materials in medical products for humans and drugs for ruminants, respectively. While the results from USDA's ongoing testing[4] are reassuring, one cannot rule out the possible future discovery of other positive animals in the United States or in a country allowed to export cattle material to the United States, or of a future introduction of BSE. To provide consistent protection across the range of FDA-regulated products, it is necessary to put in place measures to reduce further the risk of spread of BSE in cattle and the risk of vCJD in humans. This risk may be reduced by restricting the use of high-risk cattle materials in the manufacture of drugs for ruminants and medical products for humans, similar to existing restrictions for food and cosmetics.

As discussed in section IV of this document, for over a decade the FDA has taken various actions to reduce the risk of exposure to BSE in agency-regulated medical products for humans and drugs for ruminants, including: (1) Providing information (through letters to manufacturers), import alerts, and guidances to industry related to bovine materials, (2) convening TSE advisory committee meetings to provide guidance on the sourcing of certain bovine products, including gelatin, (3) encouraging companies to be aware of and to document sourcing of bovine material through letters to manufacturers of drugs, biologics, and medical devices, and through the product approval processes, and (4) recommending that manufacturers develop plans to ensure, with a high degree of certainty, that bovine and ovine materials used in their products were not from countries where BSE exists (''BSE countries'' specified by USDA's APHIS in 9 CFR 94.18) or from sheep flocks (foreign or domestic) infected with scrapie. Moreover, manufacturers who also operate in Europe have taken steps to comply with European Union TSE regulations and guidances. The agency has also taken regulatory action to decrease the likelihood of human and ruminant exposure to BSE (e.g., FDA 1997 ruminant feed rule, FDA/USDA Animal Feed ANPRM, FDA 2005 Animal Feed proposed rule, Foods IFR, and Foods Recordkeeping/Access final rule).

The agency is proposing additional regulatory action with this rule for medical products for humans and drugs for ruminants that contain certain cattle material. Existing regulations do not explicitly bar the use of prohibited cattle material for these products. By requiring that no medical product for humans or drug for ruminants be manufactured from or otherwise contain prohibited cattle materials, this proposed rule adds another safeguard to minimize human and ruminant

[4] USDA began a BSE testing program for cattle on June 1, 2004, after discovery of a case of BSE in a cow in Washington State on December 23, 2003.

exposure to cattle material that scientific studies have demonstrated could contain the BSE agent. This proposed rule is consistent with interim final rules issued by the USDA (USDA/FSIS IFR) and FDA (Foods IFR) that exclude certain cattle material from human food, including dietary supplements, and cosmetics.

B. Scope of the Proposed Rule

Both the USDA/FSIS and Foods IFRs define SRMs as: (1) Brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older, and (2) the tonsils and distal ileum of the small intestine of all cattle. The USDA/FSIS IFR: (1) Declares SRMs, mechanically separated beef, and the carcasses and parts of nonambulatory disabled cattle to be inedible and unfit for human food, and prohibits their use in human food and (2) requires that the entire small intestine of all cattle be removed and disposed of as inedible if procedures that completely remove the distal ileum are not used. The Foods IFR limits the use of prohibited cattle materials in FDA-regulated human food, including dietary supplements, and cosmetics. Prohibited cattle material includes: (1) All materials declared inedible by the USDA/FSIS IFR and (2) material from cattle not inspected and passed for human consumption. However, prohibited cattle materials do not include tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives, hides and hide-derived products, and milk and milk products.

This proposed rule would define SRMs consistent with both the USDA/FSIS and Foods IFRs and would define prohibited cattle materials consistent with the Foods IFR. The proposed rule would also clarify for medical products for humans and drugs for ruminants that prohibited cattle materials do not include materials obtained from fetal calves of cows that were inspected and passed, as long as the materials were obtained from suppliers who follow procedures adequate to prevent contamination with SRMs.

Current industry practices and full compliance with the USDA/FSIS and Foods IFRs serve as the baseline for this proposed rule. As discussed in section IV of this document, the agency has taken various actions over 10 years to reduce the risk of exposure to the agent that causes BSE in FDA-regulated products. We believe that most affected manufacturers have taken steps to address FDA's existing recommendations regarding the use of cattle material in FDA-regulated products. Because medical products for humans and drugs for ruminants normally use edible cattle material, we assume that the prohibited materials are not widely used in the manufacture and processing of these FDA-regulated products. By determining that medical products for humans and drugs for ruminants manufactured from, or otherwise containing, prohibited cattle materials violate the act and the PHS act, this proposed rule would clarify FDA's ability to bar the use of prohibited cattle materials in medical products for humans and drugs for ruminants that would be outside the scope of other BSE regulations.

C. Costs of the Proposed Rule

We assume that the recent USDA/FSIS and Foods IFRs have already led to most market adjustments regarding prohibited cattle materials. The manufacturers of products currently using materials from the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle would presumably be able to continue to use these ingredients, but exclusively from cattle younger than 30 months of age. However, if manufacturers use cattle tonsils, the distal ileum of small intestine of cattle, or mechanically separated beef in the manufacture of medical products for humans or drugs for ruminants, they would need to reformulate with alternative ingredients, submit a request for exception or alternative to the requirements of the proposed rule, or cease marketing the products.

1. Potential Market Adjustments

To the best of our knowledge, there are only a small number of manufacturers with drugs that do not have FDA approval (such as homeopathic drugs) that may be using prohibited cattle material. We believe the recent USDA/FSIS and Foods IFRs may have led any existing manufacturers to find substitutes for prohibited materials. The agency requests information about the impact of the proposed rule on manufacturers or importers of record of drugs that are marketed without an approved application for any reason.

2. Cost of Requests for Exceptions or Alternatives to the Limitation on the Use of Prohibited Cattle Material

We estimate that very few firms would submit requests for exceptions or alternatives to the proposed rule's requirements. We estimate that those that do would spend between 60 hours and 120 hours to prepare and submit requests for exceptions or alternatives to the limitation on the use of prohibited cattle material. With an average loaded wage of $41.50, including 33 percent for benefits ($31.16 x 1.33), each request would cost from $2,500 to $5,000 (source: Bureau of Labor Statistics (BLS) National Compensation Survey: Occupational Wages in the United States, July 2002, for executive, administrative, and managerial employees). Under this proposed rule, we estimate industry would submit three requests in the first year. Depending on the time needed to prepare and submit the request, first-year costs could range from $7,500 to $15,000. Moreover, as markets adjust further, we expect manufacturers would seek and obtain alternatives to prohibited cattle material, eliminating the need for future requests for exceptions or alternatives to the requirements of the proposed rule.

3. Cost of Substitutes

Since the USDA/FSIS and Foods IFRs bar prohibited cattle material from edible rendering (i.e., processing of edible cattle waste material into marketable products such as gelatin or tallow), manufacturers of FDA-regulated human medical products for humans and drugs for ruminants using rendered material could continue to use edible rendered products.

Some companies may need to find substitutes for other prohibited cattle material used in the manufacture of medical products for humans or drugs for ruminants. Agency records suggest that, because adequate substitutes exist, it is unlikely that the proposed rule would adversely affect markets. Nevertheless, we request comment from affected manufacturers about the costs and extent of substitution.

4. Recordkeeping Requirements of the Proposed Rule

The USDA/FSIS IFR and the Foods IFR may affect the availability of prohibited cattle materials, but would not ensure that FDA-regulated medical products for humans or drugs for ruminants are free of prohibited cattle materials. Because at this time there is no way to screen reliably for the presence of the BSE agent or for the

presence of cattle materials prohibited under this proposed rule, applicants and manufacturers would have to depend on records from their suppliers of cattle materials to ensure that their source material does not contain any cattle materials prohibited under this proposal. In addition, the agency must be able to determine whether prohibited cattle materials are used in the products it regulates. Without records, FDA may not be able to determine the inspectional status or age of the source animal once cattle material is separated from its source. The proposed rule would require that applicants and manufacturers using cattle material establish and maintain records. Records must be kept at the manufacturing or processing establishment or another reasonably accessible location, and the agency's inspectors must have access to these records.

The agency also proposes that importers of record of a medical product for humans or drug for ruminants that was manufactured from or otherwise contains cattle material affirm that the product was manufactured from or otherwise contained cattle material and affirm that the product was manufactured in accordance with the requirements in this proposed rule. Upon agency request, importers of record of affected products would provide to FDA within 5 days records that are sufficient to demonstrate compliance.

a. *Number of affected establishments.* The proposed rule is expected to affect all establishments with medical products for humans or drugs for ruminants that are manufactured from, or otherwise contain cattle materials. According to 2002 Economic Census data, up to 6,195 establishments manufactured affected products. In addition, for the current good tissue practice (CGTP) final rule, the agency estimated there are about 1,300 HCT/P establishments, most of which would be considered small (69 FR 68612 at 68654 and 68674).

FDA has developed an automated system, the Operational and Administrative System for Import Support (OASIS), to process shipments of foreign products. According to a preliminary examination of OASIS data from fiscal year 2005, approximately 3,800 unique filers requested entry of FDA-regulated products into the United States. We believe, however, that the actual number of affected filers would be less than this number because some companies may specialize in imports of products such as food, dietary supplements or cosmetics that are outside the scope of this proposed rule. Nevertheless, for this analysis we assume that all filers identified by OASIS could be affected by the proposed requirements for importers of record.

As shown in table 1 of this document, about 1,280 manufacturing establishments and 3,800 importers of record could be affected by the recordkeeping requirements. The agency seeks comment on these estimates from affected entities. In addition, although we believe the Foods Recordkeeping/Access final rule accounts for the recordkeeping burden to domestic and foreign suppliers, the agency requests comment from firms supplying cattle material to manufacturers of medical products for humans or drugs for ruminants about any additional burden that may be imposed by the recordkeeping requirements of this proposed rule.

TABLE 1.—ESTIMATED NUMBER OF AFFECTED ESTABLISHMENTS

North American Industry Classification Scheme (NAICS) Code	Total Number of Establishments[1]	Estimated Percentage of Establishments Using Cattle Material[2]	Estimated Number of Affected Establishments	Percent of Establishments Considered Small[3]
325411—medicinal & botanical manufacturing	367	75	275	98
325412—pharmaceutical preparation manufacturing[4]	901	75	674	91
325414—biological product manufacturing[5]	296	85	253	96
339112, 339113, 339114, 339115—medical devices	4,631	0.25	12	98
621991—HCT/P[6]	1,302	5	65	66
Subtotal	7,497	—	1,278	92
Importers of record[7]	3,787	unknown	3,787	unknown
Total	11,284		5,065	

[1] Source: NAICS 325411, 325412, 325414, 339112, 339113, 339114, and 339115, table 4 of the 2002 Economic Census, Manufacturing, Industry Series; NAICS 621991, table 3 in 69 FR 68612 at 68654. Number of importers of record estimated from FDA's OASIS data for FY 2005.

[2] Percentages are based on FDA's knowledge of products containing cattle material. We assume equal distribution of affected products across all establishments.

[3] The SBA considers entities small if they have less than: (1) 750 employees for NAICS 325411 and 325412, (2) 500 employees for NAICS 32514, 339112, 339113, 339114, and 339115, or (3) $9.0 million in revenues or receipts for NAICS 621991. Because the Economic Census uses different size categories than SBA, this analysis treats establishments in NAICS 325411 and 325412 with less than 999 employees as small. The agency previously estimated that about 66 percent of establishments in NAICS 621991 are small (table 14 in 69 FR 68612 at 68674).

[4] We assume that cattle materials are used by 70 percent of establishments primarily manufacturing products for veterinary use and 75 percent of establishments primarily manufacturing products for human use. Source for the total number of establishments and the number of establishments manufacturing each primary product class: Tables 4 and 5 of the 2002 Economic Census, Manufacturing, Industry Series, EC02–311–325412.

[5] We assume that cattle materials are used by 70 percent of establishments primarily manufacturing products for veterinary use and 90 percent of establishments primarily manufacturing products for human use. Source for the total number of establishments and the number of establishments manufacturing each primary product class: Tables 4 and 5 of the 2002 Economic Census, Manufacturing, Industry Series, EC02–311–325412.

[6] We assume that from 1 to 5 percent of establishments use cattle materials.

[7] Based on FY 2005 data in OASIS; equals the total number of unique filers for all FDA-regulated products.

b. *Recordkeeping costs.* Manufacturers of medical products for humans and drugs for ruminants would need to establish and maintain appropriate records that document the absence of prohibited cattle materials in their products. This would require that manufacturers verify and maintain records from suppliers of any material derived from cattle. In addition, when filing an entry with the U.S. Customs and Border Protection, importers of record of affected products would be required to affirm that the product was manufactured from or otherwise contains cattle material and affirm that the product was manufactured in accordance with the proposed provisions. If a product was manufactured from, or otherwise contains, cattle material, then importers of record would also be required, if requested, to provide within 5 days records sufficient to demonstrate that the product was not manufactured from and does not contain prohibited cattle material.

As noted previously, we believe that most entities have taken steps to address the sources of cattle materials. Moreover, the CGMP and CGTP regulations covering medical products for humans and drugs for ruminants require that procedures be in place for purchasing controls. We believe, however, that some affected manufacturers currently may not keep adequate records and might incur minor incremental recordkeeping costs. For this analysis, therefore, we assume that, on average, all affected small manufacturers may spend slightly more than 1 hour annually to maintain records. Similarly, we assume that, on average, all affected large manufacturers may spend slightly less than 3 hours annually to maintain records. With a loaded wage rate of $33.00 (source: Bureau of Labor Statistics (BLS) National Compensation Survey: Occupational Wages in the United States, July 2002, adding 33 percent overhead for a computer programmer), small and large manufacturers might incur about $45 and $90, respectively, to ensure full compliance with the requirements to establish and maintain records.

This rule would require importers of record of affected products to affirm that the product was manufactured from or otherwise contains cattle material and affirm that the product was manufactured in accordance with the proposed provisions. Although the marginal burden of each affirmation would be negligible, we believe the cumulative burden might cause smaller importers to spend about the same level of effort as small manufacturers (i.e., $45 annually). In contrast, we assume that larger importers might spend about 5 times the level of effort as small importers (i.e., $225 annually). Because the agency lacks information about importer size, we include a range of possible recordkeeping costs for this analysis. Table 2 shows the estimated recurring recordkeeping costs for this proposed rule. However, because there is some uncertainty about the new burden that might be imposed and the number of firms that might be affected by this proposed rule, the agency requests comment from affected manufacturers and importers of record on this estimated recordkeeping burden.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN BY INDUSTRY AND ESTABLISHMENT SIZE[1]

NAICS or Type of Industry	Small		Large		Total Cost ($)
	Number Affected	Cost ($)	Number Affected	Cost ($)	
325411	269	12,100	7	600	12,700
325412	615	27,700	58	5,200	32,900
325414	243	11,000	9	800	11,800
339112, 339113, 339114, 339115	11	500	0	0	500
621991 (HCT/P)	43	1,900	22	2,000	3,900
Subtotal	1,182	53,200	96	8,600	61,800
	Lower Bound (i.e., 3,787 small importers)		Upper Bound (i.e., 3,787 large importers)		
Importers of record[2]		170,400		852,100	170,400 to 852,100
Total					232,200 to 913,900

[1] Totals may not multiply or sum due to rounding.

[2] Because we lack data on the size of affected importers of record, we calculate the lower and upper bounds for these costs, assuming that either all firms are small or all firms are large.

5. Labeling Costs for New Animal Drugs Prohibited from Extralabel Use

Manufacturers of new animal drugs prohibited from extralabel use in ruminants would need to add a warning statement to the product labeling. We estimate manufacturers of about eight animal products would spend from $1,600 to $6,400 to change the product labeling and file a labeling supplement for each affected product. Costs are based on discussions with experts in the Center for Veterinary Medicine and are presented in table 3 of this document.

TABLE 3.—ESTIMATED ONE-TIME COSTS OF LABELING CHANGES AND FILING A SUPPLEMENT

Cost Component	Hours/ Establishment	Total Cost [1] ($)
Regulatory review and approval	3 to 12	1,000 to 3,980
Artwork [2]	-	4,000
Manufacturing	4 to 12	570 to 1,710
Inventory Loss [3]	-	6,640 to 40,000
Supplement preparation and Submission	2 to 5	660 to 1,660
Total Cost[4]		12,870 to 51,350

[1] We calculated using a loaded wage rate for regulatory review and filing a supplement of $41.50, for manufacturing changes $17.80. Source: BLS National Compensation Survey: Occupational Wages in the United States, July 2002, adding 33 percent for benefits.

[2] We assume the unit costs for artwork are $500 per product.

[3] We assume the unit costs for inventory loss range from $830 to $5,000 per product.

[4] Totals may not add or multiply due to rounding.

6. Summary of the Costs for the Proposed Rule

Few firms will incur one-time costs for requests for exceptions or alternatives to the limitation on the use of prohibited cattle material. In addition, manufacturers of about eight animal products prohibited from extralabel use in ruminants would incur one-time costs to add a warning statement to the product labeling. All firms that use cattle material or import products that do would incur annual incremental costs for additional recordkeeping. The total one-time costs range from $20,400 to $66,300; annual costs range from $232,200 to $913,900. The total annualized costs of this option range from $234,600 to $921,700 (at a 3 percent discount rate) and from $235,100 to $923,300 (at a 7 percent discount rate) over 10 years. These costs are summarized in table 4 of this document.

TABLE 4.—SUMMARY OF TOTAL COMPLIANCE COSTS [1]

One-Time Cost	Lower Bound ($)	Upper Bound ($)
Requests for exception or alternative	7,500	15,000
Change labeling and file a supplement	12,900	51,300
Total one-time cost	20,400	66,300
Annual recordkeeping cost	232,200	913,900
Total annualized cost at 3 percent	234,600	921,700
Total annualized cost at 7 percent	235,100	923,300

[1] Numbers may not add due to rounding.

D. Benefits of the Proposed Rule

1. Reduced Risk of Exposure to BSE Infectivity

USDA analyses to date have found the United States is highly resistant to the introduction or establishment of BSE and predict that even if BSE were introduced into the United States, only a small amount of potentially BSE-contaminated tissues would reach the human food supply and be available for consumption (Ref. 41). Moreover, their models predict that implementation of a ban on specified risk materials (e.g., spinal cords, brains, vertebral columns) from both human food and animal feed would reduce substantially the very low risk of additional BSE cases in cattle and the potential human exposure to infectivity from meat and meat products.

None of these risk assessments considered the potential exposure to BSE infectivity from certain FDA-regulated products containing bovine material. The risks of exposure to BSE infectivity from medical products for humans and drugs for ruminants are unknown, but the risk of transmission could be higher than for foods and cosmetics assuming the presence of BSE infectivity. For example, the routes of administration for some of these products (such as from injectable and implantable products) are associated with higher risk than oral or topical exposure associated with foods and cosmetics. This proposed rule covers products not included in the recent USDA or Foods IFRs and would ensure that medical products for humans and drugs for ruminants containing cattle material meet specific requirements designed to reduce the risk of human exposure to BSE-infective materials.

The proposed rule would decrease the likelihood of human and ruminant exposure to BSE in several ways. First, this rule would provide additional regulatory protection, beyond existing rules, by making clear that prohibited cattle material cannot be used in FDA-regulated medical products for humans or drugs for ruminants. Second, because affected products manufactured from or otherwise containing prohibited cattle materials would be adulterated and the failure of an importer of record to comply with applicable reporting requirements creates the appearance of adulteration under section 801, the proposed rule would clarify FDA's ability to bar importation of medical products for humans or drugs for ruminants that contain prohibited cattle materials. For example, imported products may contain the types of materials prohibited by FDA, but may not fall under the scope of USDA's import restrictions.

2. Value of the Potential Reduction of Human Illness

The public health benefit of this proposed rule is the value of the reduction in the risk of the human illness associated with exposure to the agent that causes BSE. If we define the baseline risk as the expected annual number of cases of vCJD per year, then the annual benefits of barring prohibited cattle materials from use in affected products would be: (baseline annual cases of vCJD—annual cases of vCJD under FDA PR) x (value of preventing a case of vCJD).

We do not know the baseline expected annual number of cases, but based on the epidemiology of vCJD in the United Kingdom, we anticipate much less than one case of vCJD per year in the United States. Because the proposed rule would reduce rather than eliminate risk of exposure to BSE infectious materials, the reduction in the number of cases would be some fraction of the expected number. FDA uses the concept of the Value of a Statistical Life (VSL) in order to describe the value of preventing a case

of vCJD. This term refers to the sum of risk reductions expected in a population exposed to small changes in risk. It has no application to identifiable individuals or large reductions in risk. Most recent studies suggest values ranging from about $1 million to $10 million. In recent rulemakings, we have used $5 million and $6.5 million as the value of a statistical life, and we believe it is reasonable to use a similar VSL to value the cases of vCJD avoided.

E. Summary of the Potential Costs and Benefits of the Proposed Rule

The total annualized costs of this proposed rule range from $234,600 to $921,700 (at a 3 percent discount rate) and from $235,100 to $923,300 (at a 7 percent discount rate) over 10 years. By reducing exposure to potentially infectious materials, the requirements of the proposed rule would provide an additional safeguard against a case of vCJD occurring in humans if cattle infected with BSE were used in the manufacture or processing of medical products for humans and drugs for ruminants. We are unable to estimate the value of this potential reduction in the risk of cases of vCJD, even though we estimate the value of avoiding one death at $5.8 million. Nonetheless, we believe the potential benefits of the proposed rule justify the small costs of the rule.

F. Regulatory Options Considered

For this proposed rule, FDA considered three regulatory options:

(1) *No new regulation*. By definition, no costs and benefits are associated with the baseline. As noted previously, USDA and FDA actions to date would reduce, but not eliminate, the availability and use of prohibited cattle materials in domestic and imported FDA-regulated medical products for humans and drugs for ruminants. Without regulation, FDA would not be explicitly barring the use of prohibited cattle materials that could potentially contain the BSE infectious agent.

(2) *Propose a rule that (i) bars the use of prohibited cattle materials in medical products for humans and drugs for ruminants, unless a request for exception or alternative to the limitation of the use of prohibited cattle material has been granted, and (ii) requires establishment, maintenance, and access to records demonstrating that no medical products for humans or drugs for ruminants are manufactured from or otherwise contain prohibited cattle material*. These would be the minimum basic requirements, and would not preclude the imposition of additional measures through the application review process or other means if FDA determined that they were necessary for ensuring the safety of individual products on a case-by-case basis.

This is the regulatory option selected. The agency believes that this is the best option to meet its goal of minimizing human and ruminant exposure to materials that scientific studies have demonstrated are likely to contain the BSE agent in cattle infected with the disease. The ban on use of prohibited materials would eliminate exposure to the highest risk animals and the majority of the infectivity in an animal infected with the BSE agent. This option would provide reasonable balance by explicitly barring from medical products for humans and drugs for ruminants the use of potentially infectious materials already deemed unfit for foods by USDA and FDA and by imposing minimal regulatory burden. The agency must be able to determine that the products it regulates contain no prohibited cattle materials. Applicants and manufacturers must depend on records to ensure that affected products do not contain any cattle materials prohibited under the proposal. Without recordkeeping requirements, FDA may not be able to determine the source or age of cattle material once it is separated from the animal. In addition, records would allow the agency to determine the inspectional status of the source animals.

(3) *Propose a rule that, in addition to the requirements listed in option (2), bars the use in medical products for humans and drugs for ruminants of all neural material from cattle from countries with a high or medium risk of BSE if the cattle were slaughtered when over 6 months old, unless a request for exception or alternative to the requirements has been granted*. This approach would be more consistent with recommendations of OIE and would add an additional layer of protection to that provided by option (2). This alternative would put an additional burden on those parts of the affected industries that source cattle materials from such countries and do not already have procedures in place ensuring and documenting compliance with the requirement.

Compared to the preferred option (2), we believe this alternative would impose higher costs on, at most, a small segment of the affected industries. In fact, we know of no manufacturers of U.S. licensed or approved medical products for humans and drugs for ruminants for which this alternative would impose any additional burdens beyond those imposed under option (2), because they do not source such materials from such countries. However, we also believe it would not provide significant additional risk reduction because so few animals diagnosed with BSE are younger than 3 years old. For example, cattle born in 1987/1988 in the United Kingdom had the highest incidence of BSE, with over 39,000 cattle diagnosed with BSE. Among those animals, cattle under 3 years old represented only 0.16 percent of cattle with BSE (61 cattle). Once controls were put in place, that number decreased, so that of animals born after 1996, all cattle diagnosed with BSE have been 3 years old or older.

G. Regulatory Flexibility Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. The FDA believes this proposed rule will not have a significant economic impact on a substantial number of small entities and requests comment.

The proposed rule may affect entities classified in several industries including Medicinal & Botanical Manufacturing (NAICS 325411), Pharmaceutical Preparation Manufacturing (NAICS 325412), Biological Product (Except Diagnostic) Manufacturing (NAICS 325414), Surgical and Medical Instrument Manufacturing (NAICS 339112), Surgical Appliance and Supplies Manufacturing (NAICS 339113), Dental Equipment and Supplies Manufacturing (NAICS 339114), Ophthalmic Goods Manufacturing (NAICS 339115), and Blood and Organ Banks (NAICS 621991). The Small Business Administration (SBA) regards an entity as small based on the number of employees or the average annual receipts. The size standards are: (1) 750 employees for NAICS categories 325411 and 325412, (2) 500 employees for NAICS categories 325414, 339112, 339113, 339114 and 339115, and (3) $9.0 million average annual receipts for NAICS 621991. The U.S. Census gathers employment data for establishments by NAICS and uses size categories that differ from those of the SBA for NAICS 325411 and 325412. For this regulatory flexibility analysis, therefore, we consider entities in these NAICS categories with less than 999 employees to be small. Using these size standards, 2002 Census data, and the CGTP final rule (69 FR 68612 at 68654 and 68674),

over 90 percent of these establishments would be considered small (see tables 1 and 2 of this document). However, the agency lacks information on the types of importers of record that might be affected by the proposed rule. Agency data on filers that import FDA-regulated products into the United States does not include the size of the importer of record. Therefore, for the initial regulatory flexibility analysis, we assume that all affected importers of record would be classified as small. The agency requests comment on this assumption.

We believe requirements in this proposed rule must apply to all entities, regardless of size. No new skills are needed. To meet the proposed requirements, those applicants and manufacturers of medical products for humans or drugs for ruminants manufactured from or otherwise containing cattle tonsils, the distal ileum of the small intestine of cattle, or mechanically separated beef might need to switch to an alternative source material, submit a request for exception or alternative to the limitation on prohibited cattle material in this proposed rule, or cease marketing the products. We expect that other affected manufacturers would continue to use age-specific cattle material from animals under 30 months of age. A few small entities could incur from $2,500 to $5,000 for each request submitted unless a request for exception or alternative to requirements of the proposed rule has already been granted. In addition, manufacturers of about eight animal products prohibited from extralabel use in ruminants would incur costs of between $1,600 and $6,400 per product to add a warning statement to the product labeling and file a labeling supplement. Although it is uncertain if any small entities will incur these costs, Table 5 shows that for very small establishments with less than 10 employees these one-time costs would equal less than 1.6 percent of the average annual value of shipments. Moreover, for all small establishments in each of the affected industries, the one-time costs to revise labeling or prepare a request for exception or alternative to requirements of the proposed rule would equal no more than 0.15 percent of the average annual value of shipments.

TABLE 5. POTENTIAL DIRECT COMPLIANCE COSTS OF THE PROPOSED RULE AS A PERCENTAGE OF AVERAGE ANNUAL SHIPMENTS FOR AFFECTED ESTABLISHMENTS WITH LESS THAN 10 EMPLOYEES.[1]

NAICS Category	Average Annual Shipments Per Establishment ($)	Compliance Costs as a Percentage of Average Annual Shipments[2]		
		Recordkeeping ($45 Per Establishment)	Labeling Revision ($6,500 Per Product)	Request for Exception or Alternative ($5,000 Per Request)
325411, Medicinal and botanical manufacturing	1,059,245	0.004%	0.6%	0.5%
325412, Pharmaceutical preparation manufacturing	1,656,743	0.003%	0.4%	0.3%
325414, Biological product (except diagnostic) manufacturing	1,057,862	0.004%	0.6%	0.5%
339112, Surgical and medical instrument manufacturing	610,138	0.007%	1.0%	0.8%
339113, Surgical appliance and supplies manufacturing	618,207	0.007%	1.0%	0.8%
339114, Dental equipment and supplies manufacturing	396,666	0.011%	1.6%	1.3%
339115, Ophthalmic goods manufacturing[3]	1,121,083	0.004%	0.6%	0.4%
621991 Blood and organ banks	4,281,172	0.001%	0.1%	0.1%

[1] Source: Table 4 of 2002 Economic Census for NAICS 325411, 325412, 325414, 339112, 339113, 339114, 339115, and 621991.
[2] Averages based on the sum of data for establishments with 1 to 4 employees and 5 to 9 employees. For establishments with 1 to 4 employees, recordkeeping costs equal less than 0.02 percent of average annual shipments for all NAICS categories. It is unlikely that entities with 1 to 4 employees would incur compliance costs for a labeling revision or a request for exception or alternative to requirements of the proposed rule. Nevertheless, for these smallest entities, as a percentage of average annual shipments, a labeling revision equals less than 2.6 percent and a request for exemption or alternative equals less than 2.0 percent for all NAICS categories.
[3] No information for establishments with 1 to 4 employees.

Besides the one-time compliance burden that a few small entities might incur, most affected small manufacturers would incur minor new compliance costs for recordkeeping. For small manufacturers and small importers of record, these annual costs would equal about $45, a negligible amount for even the smallest entities. Table 5 shows that these incremental recordkeeping costs for establishments with less than 10 employees would equal less than 0.02 percent of their average annual value of shipments.

FDA lacks the data required to estimate the number of requests, the distribution of one-time labeling costs, and the new annual recordkeeping burden on small entities. We anticipate, however, that the potential costs might represent a very small percentage of their annual revenues and would not be a significant economic impact on affected small entities. Nevertheless, the agency requests detailed data on small business impacts from affected firms.

As discussed in section VIII. F. of this document, FDA considered other regulatory options. The proposed rule is the least burdensome option that meets FDA's goal of minimizing human and ruminant exposure to materials that scientific studies have demonstrated are

likely to contain the BSE agent in cattle infected with the disease.

IX. Paperwork Reduction Act Analysis

This proposed rule contains information collection requirements that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501 3520). A description of these provisions is given below with an estimate of the annual reporting and recordkeeping 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 each collection of information.

FDA invites comments on the following topics: (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.

Title: Use of Materials Derived from Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants

Description: As discussed previously in this document, we are proposing to prohibit the use of certain cattle material in medical products for humans and drugs for ruminants because of the risk of BSE and related human disease. The rulemaking contains reporting and recordkeeping requirements that are subject to review by OMB.

Reporting. Under proposed §§ 300.200(b)(2)(i) and (b)(2)(ii) for drugs for humans, 500.200(b)(2)(i) and (b)(2)(ii) for drugs for ruminants, 600.16(b)(2)(i) and (b)(2)(ii) for biological products, 895.102(b)(2)(i) and (b)(2)(ii) for human medical devices that are intended for use in or on the body, and 1271.470(b)(2)(i) and (b)(2)(ii) for HCT/Ps, applicants and manufacturers could request permission for an exception or alternative to the requirements in proposed §§ 300.200(b)(1), 500.200(b)(1), 600.16(b)(1), 895.102(b)(1), and 1271.470(b)(1) that no medical product for humans or drug for ruminants be manufactured from or otherwise contain prohibited cattle materials obtained from cattle slaughtered on or after the effective date of the regulation. To obtain written permission from FDA for an exception or alternative to the requirements, applicants and manufacturers would send a written request to the director of the Center having jurisdiction over the relevant product. Any request would contain the following:

- A statement of the reasons why an exception or alternative is needed;
- A description of the product, including the type of prohibited cattle materials used in its manufacturing, its manufacturing and purification processes, and its route of administration;
- A description of the source of the prohibited cattle materials, including information on the location where the cattle were born, raised, and slaughtered, and any other information relevant to the likelihood of the cattle having ingested material prohibited under ? 589.2000;
- A description, if applicable, of how the requirements that pertain to their product in proposed §§ 300.200(b)(1), 600.16(b)(1), 895.102(b)(1), or 1271.470(b)(1) are not necessary based on the risks of the prohibited cattle materials in the product and the benefits of the product, or how such restrictions are not necessary to ensure the safety of the product;
- A description, if applicable, of: (1) How the requirements that pertain to their product in proposed § 500.200(b)(1) are not necessary: (i) Based on the risks of the prohibited cattle materials in the product to the target animal and the benefits of the product to the target animal and (ii) to ensure a reasonable certainty of no harm to humans from any food derived from the target animal to which the product was administered, or (2) how such restrictions are not necessary to ensure the safety of the product with respect to both the target animal and any food derived from the target animal to which the product is administered; and
- Any other relevant information.

As discussed in the Analysis of Impacts (see section VIII of this document), we estimate that a request for an exception or alternative to the requirements would take between 60 and 120 hours to complete and submit to FDA. For purposes of this information collection analysis, we estimate, as indicated in table 6 of this document, that each request would take approximately 120 hours. We estimate that only three requests would be submitted to FDA in the first year by applicants and manufacturers of medical products for humans and drugs for ruminants because only a small number of such products are currently manufactured with cattle materials that would be prohibited under this rule. We expect that applicants and manufacturers would seek, and obtain, alternatives to prohibited cattle materials, eliminating the need for future requests for an exception or alternative to the requirements of the proposed rule. We request comments on our estimates of the number of exception/alternative requests, the time for preparation and submission of the request, and the likelihood of requests beyond the first year after the rule would be in effect.

Under proposed §§ 300.200(c)(5), 500.200(c)(5), 600.16(c)(5), 895.102(c)(5), and 1271.470(c)(5), when filing entry with the U.S. Customs and Border Protection, importers of record of a medical product for humans or a drug for ruminants that was manufactured from, or otherwise contains, cattle material would be required to affirm that the product was manufactured from or otherwise contained cattle material and affirm that the product was manufactured in accordance with the requirements in this proposed rule. If a product was manufactured from, or otherwise contains, cattle material, then importers of record would also, if requested, have to provide to FDA within 5 days records that would be sufficient to demonstrate that the product was not manufactured from, and does not contain, prohibited cattle material. As discussed in the Analysis of Impacts (see section VIII of this document), we estimate that 3,787 importers of record would be subject to this affirmation and potential record submission and that it would take each of them between 1 and 5 hours annually to process. For purposes of this information collection analysis, we estimate, as indicated in table 6 of this document, that this proposed provision would take each importer of record approximately 2.5 hours annually to process.

Under proposed § 530.42, FDA would require that labels for drugs prohibited from extralabel use in ruminants by proposed § 530.41(c) bear or be accompanied by the statement ''Federal law prohibits the extralabel use of this product in ruminants.'' This labeling statement is not subject to review by OMB because it is ''originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and, therefore, does not constitute a ''collection of information'' under the PRA.

Recordkeeping. Under proposed §§ 300.200(c), 500.200(c), 600.16(c), 895.102(c), and 1271.470(c), applicants and manufacturers of medical products for humans and drugs for ruminants that are manufactured from, or otherwise contain, material from cattle would be required to establish and maintain records demonstrating that their products have not been manufactured from and do not otherwise contain, prohibited cattle materials and make such records available to FDA for inspection and copying. These proposed requirements are necessary because, once materials are separated from an animal, it may not be possible without records to know the following: (1) Whether the cattle material contains SRMs, (2) whether the material was sourced from an animal that was inspected and passed for human consumption, (3) whether the material was sourced from a nonambulatory disabled animal, and (4) whether the product contains mechanically separated beef. Under the proposed rule, applicants and manufacturers must retain records the varying periods of time consistent with the applicable CGMP or CGTP requirements (e.g., for drugs for humans, it would be at least 1 year after the expiration date of the drug; for drugs for humans lacking an expiration date, it would be at least 3 years after distribution of the last lot of the drug). These records would be required to be maintained at the applicant's or manufacturer's establishment or another reasonably accessible location.

Recordkeeping requirements currently exist for applicants and manufacturers of medical products for humans and drugs for ruminants under FDA's CGMP and CGTP regulations. For drugs and biological products for humans and drugs for ruminants, these requirements are at part 210 (21 CFR part 210) and part 211 (CGMP), and the information collection requirements for these regulations are already approved by OMB under OMB Control Number 0910–0139 until September 30, 2008. For blood and blood components, these requirements are at 21 CFR part 606 (CGMP), and the information collection requirements for these regulations are already approved by OMB under OMB Control Number 0910–0116 until December 31, 2008. For Type A medicated articles, these requirements are at part 226 (CGMP), and the information collection requirements for these regulations are already approved by OMB under OMB Control Number 0910–0154 until December 31, 2007. For medical devices for humans, these requirements are at 21 CFR part 820 (CGMP/quality system regulations), and the information collection requirements for these regulations are already approved by OMB under OMB Control Number 0910–0073 until September 30, 2007. For HCT/Ps, these requirements are at part 1271, subpart D (CGTP regulations), and the information collection requirements for these regulations are already approved by OMB under OMB Control Number 0910–0559 until November 30, 2007. In accordance with the previously mentioned CGMP and CGTP regulations, applicants and manufacturers of medical products for humans and drugs for ruminants would be responsible for maintaining records regarding use of cattle materials in, or in the manufacture of, their products. However, FDA estimates that, in accordance with this rulemaking, applicants and manufacturers would expend a small amount of additional effort to comply with the proposed recordkeeping requirements. FDA has determined, as indicated in table 7 of this document, that there are 1,278 applicants and manufacturers of a medical product for humans or drug for ruminants that would be responsible for recordkeeping. This would include verifying records and storing records that contain information on sources of cattle materials that are to be used in medical products for humans and drugs for ruminants. As discussed in the Analysis of Impact (see section VIII of this document), we estimate that this recordkeeping burden will be about 1 to 3 hours per year. For purposes of this document, we estimate, as indicated in table 7, that this burden would take about 2 hours/year. Therefore, the total annual burden will be 2 hrs x 1,278 = 2,556 hours, as shown in table 7 of this document.

Description of Respondents: Applicants and manufacturers of medical products for humans and drugs for ruminants that are manufactured from, or otherwise contain, material from cattle slaughtered on or after the effective date of the regulation.

TABLE 6.—ESTIMATED REPORTING BURDEN [1]

21 CFR Section	Number of Respondents	Frequency per Response	Total Responses	Hours per Response	Total Hours
300.200(b)(2)(i) and (b)(2)(ii), 500.200(b)(2)(i) and (b)(2)(ii), 600.16(b)(2)(i) and (b)(2)(ii), 895.102(b)(2)(i) and (b)(2)(ii), and 1271.470(b)(2)(i) and (b)(2)(ii)	3	1	3	120	360
300.200(c)(5), 500.200(c)(5), 600.16(c)(5), 895.102(c)(5), and 1271.470(c)(5)	3,787	1	3,787	2.5	9,467.5
Total					9,827.5

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 7.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
300.200(c), 500.200(c), 600.16(c), 895.102(c), and 1271.470(c)	1,278	1	1,278	2	2,556

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection to OMB (see **DATES** and **ADDRESSES**).

X. Environmental Impact Analysis

FDA has carefully considered the potential environmental effects of this proposed rule (i.e., ban use of prohibited cattle materials in medical products for humans and drugs for ruminants, unless a request for exception or alternative to the requirements has been granted) and of two possible alternative actions: (1) No action and (2) in addition to the requirements proposed in this rule, ban use in medical products for humans and drugs for ruminants of all neural material from cattle from countries with a high or medium risk of BSE if the cattle were slaughtered when over 6 months old, unless a request for exception or alternative to the requirements has been granted. In doing so, the agency focused on the environmental impacts of its action, specifically, disposal of unused cattle byproducts (e.g., dead animals and slaughter byproducts) that can no longer be used in medical products for humans or drugs for ruminants after the rule becomes effective.

The environmental assessment (EA) considered each of the alternatives in terms of the need to provide maximum reasonable protection of human health without resulting in a significant impact on the environment. The EA considered environmental impacts related to landfill, incineration, composting, and land burial. The additional waste that might result from the selected action would be an extremely small amount compared to the total amount of waste generated by the cattle industry.

The agency has concluded that the proposed rule will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact (FONSI) and the evidence supporting that finding, contained in an EA prepared under 21 CFR 25.40, may be seen in the Dockets Management Branch (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday. FDA invites comments and submission of data concerning the EA and FONSI.

XI. Federalism

We have analyzed this proposed rule in accordance with the principles in Executive Order 13132. We have determined that the proposed rule does not contain policies 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. Accordingly, we have concluded that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

XII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

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6. Brown, K. L, D. L. Ritchie, P. A. McBride, and M. E. Bruce, ''Detection of PrP in Extraneural Tissues,'' *Microscopy Research and Technique*, 50:40–45, 2000.
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List of Subjects

21 CFR Part 211

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

21 CFR Part 226

Animal drugs, Animal feeds, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 300

Drugs, Incorporation by reference, Prescription drugs.

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Incorporation by reference, Labeling, Packaging and containers, Polychlorinated biphenyls (PCBs).

21 CFR Part 530

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

21 CFR Part 600

Biologics, Incorporation by reference, Reporting and recordkeeping requirements.

21 CFR Part 895

Administrative practice and procedure, Incorporation by reference, Labeling, Medical devices.

21 CFR Part 1271

Biologics, Drugs, Human cells and tissue-based products, Incorporation by reference, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, FDA proposes to amend 21 CFR parts 211, 226, 300, 500, 530, 600, 895, and 1271 as follows:

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

1. The authority citation for 21 CFR part 211 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

2. Section 211.116 is added to subpart F to read as follows:

§ 211.116 Use of cattle material.

Use of certain cattle material in drug products and components is prohibited as provided by §§ 300.200, 500.200, and 600.16 of this chapter.

PART 226—CURRENT GOOD MANUFACTURING PRACTICE FOR TYPE A MEDICATED ARTICLES

3. The authority citation for 21 CFR part 226 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360b, 371, 374.

4. Section 226.60 is added to subpart C to read as follows:

§ 226.60 Use of cattle material.

Use of certain cattle material in Type A medicated articles for ruminants is prohibited as provided by § 500.200 of this chapter.

PART 300—GENERAL

5. The authority citation for 21 CFR part 300 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360b, 361, 371, 381; 42 U.S.C. 264, 271.

6. Section 300.200 is added to subpart C to read as follows:

§ 300.200 Prohibited cattle materials.

(a) *Definitions*. The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321) apply to such terms when used in this section. The following definitions also apply:

(1) *Prohibited cattle materials* means specified risk materials; small intestine of all cattle except as provided in paragraph (b)(3) of this section; material from nonambulatory disabled cattle; material from cattle not inspected and passed; or mechanically separated beef. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives, hides and hide-derived products, and milk and milk products. Prohibited cattle materials also do not include materials obtained from fetal calves of cows that were inspected and passed, as long as the materials were obtained by procedures adequate to prevent contamination with specified risk materials.

(2) *Inspected and passed* means that the material is from an animal that has been inspected and passed for human consumption by the appropriate regulatory authority, and at the time the animal was inspected and passed, it was found to be not adulterated.

(3) *Mechanically separated beef* means a meat food product that is finely comminuted, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses, that meets the specifications contained in 9 CFR 319.5, the U. S. Department of Agriculture's (USDA's) regulation that prescribes the standard of identity for Mechanically Separated (Species).

(4) *Nonambulatory disabled cattle* means cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

(5) *Specified risk materials* means the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older, and the tonsils and distal ileum of the small intestine of all cattle.

(6) *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues. Tallow must be produced from tissues that are not prohibited cattle materials or must contain not more than 0.15 percent insoluble impurities as determined by the method entitled ''Insoluble Impurities'' (AOCS Official Method Ca 3a–46), American Oil Chemists' Society (AOCS), 5th Edition, 1997, incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision, and sensitivity to AOCS Official Method Ca 3a–46. You may obtain copies of the method from the AOCS (*http://www.aocs.org*) 2211 W. Bradley Ave., Champaign, IL 61821. Copies may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(7) *Tallow derivative* means any chemical obtained through initial hydrolysis, saponification, or trans-esterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or trans-esterification may be applied to obtain the desired product.

(b) *Requirements*. (1) At a minimum, except as provided in paragraph (b)(2) of this section, no drug intended for use in humans shall be manufactured from, or otherwise contain, prohibited cattle materials obtained from cattle slaughtered on or after [effective date of final rule].

(2) The requirements in paragraph (b)(1) of this section with respect to prohibited cattle materials shall not apply if FDA grants written permission for an exception or alternative to such requirements.

(i) To obtain written permission from FDA, you must send a written request to the Director of the Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. For a drug subject to an application, your written request must reference its application number. The Center Director may also grant written permission for an exception or alternative to the requirements in paragraph (b)(1) of this section on his own initiative and shall base such a determination on an evaluation of the criteria described in paragraph (b)(2)(ii) of this section. You must maintain a record of any exception or alternative to the requirements in paragraph (b)(1) of this section that is granted by FDA, in accordance with paragraph (c) of this section.

(ii) A written request for an exception or alternative to the requirements in paragraph (b)(1) of this section must include, for each applicable product:

(A) A statement of the reasons why an exception or alternative is needed;

(B) A description of the product, including the type of prohibited cattle materials used in its manufacturing, its manufacturing and purification processes, and its route of administration;

(C) A description of the source of the prohibited cattle materials, including information on the location where the cattle were born, raised, and slaughtered, and any other information relevant to the likelihood of the cattle having ingested material prohibited under § 589.2000 of this chapter;

(D) A description of how the requirements in paragraph (b)(1) of this section are not necessary based on the risks of the prohibited cattle materials in the product and the benefits of the product or how such restrictions are not necessary to ensure the safety of the product; and

(E) Any other relevant information.

(iii) FDA shall respond in writing to all requests for an exception or alternative to the requirements and may impose conditions in granting any such request.

(3) The small intestine is not considered prohibited cattle material if the distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine, as measured from the caeco-colic junction and progressing proximally towards the jejunum, or by a procedure that the establishment can demonstrate is equally effective in ensuring complete removal of the distal ileum.

(c) *Records*. (1) Applicants and manufacturers of a drug that is manufactured from, or otherwise contains, cattle material must establish and maintain records sufficient to demonstrate that the material is not manufactured from, and does not contain, prohibited cattle materials.

(2) Records must be retained for at least 1 year after the expiration date of the drug or, for drugs lacking an expiration date, at least 3 years after distribution of the last lot of the drug.

(3) Records must be retained at the applicant's or manufacturer's establishment or at a reasonably accessible location. Records are considered to be reasonably accessible if they are accessible from an onsite location.

(4) Records required by this section must be readily available to FDA for inspection and copying. All the records must be in English.

(5) When filing entry with the U.S. Customs and Border Protection, the importer of record of a drug manufactured from, or otherwise containing, cattle material must affirm that the drug was manufactured from, or otherwise contains, cattle material and must affirm that the drug was manufactured in accordance with this section. If a drug was manufactured from, or otherwise contains, cattle material, then the importer of record must, if requested, provide to FDA within 5 days records that are sufficient to demonstrate that the drug is not manufactured from, and does not contain, prohibited cattle material.

(d) A human drug that is not in compliance with the requirements of paragraph (b) of this section is adulterated under section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B)).

(e) Failure of an applicant or manufacturer to comply with the requirements of paragraph (c) of this section renders a drug adulterated under section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B)).

(f) Failure of an importer of record to comply with the requirements of paragraph (c) of this section causes a drug to appear to be adulterated under section 801(a) of the act (21 U.S.C. 381(a)).

(g) A human drug that is a new drug and that is not in compliance with the requirements of paragraph (b) of this section is in violation of section 505 of the act (21 U.S.C. 355).

(h) Failure of an applicant or manufacturer to comply with the requirements of paragraph (c) of this section is a violation of section 301(e) of the act (21 U.S.C. 331(e)).

(i) Any person who violates the requirements of paragraph (b) or (c) of this section shall be subject to the penalties provided in section 368 of the Public Health Service Act (42 U.S.C. 271).

PART 500—GENERAL

7. The authority citation for 21 CFR part 500 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371, 381; 42 U.S.C. 264, 271.

8. New subpart F is added to part 500 to read as follows:

Subpart F—Substances Prohibited From Animal Drugs

§ 500.200 Prohibited cattle materials in drugs intended for use in ruminants.

(a) *Definitions*. The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321) apply to such terms when used in this section. The following definitions also apply:

(1) *Prohibited cattle materials* means specified risk materials; small intestine of all cattle except as provided in paragraph (b)(3) of this section; material from nonambulatory disabled cattle; material from cattle not inspected and passed; or mechanically separated beef. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives, hides and hide-derived products, and milk and milk products. Prohibited cattle materials also do not include materials obtained from fetal calves of cows that were inspected and passed, as long as the materials were obtained by procedures adequate to prevent contamination with specified risk materials.

(2) *Inspected and passed* means that the material is from an animal that has been inspected and passed for human consumption by the appropriate regulatory authority, and at the time the animal was inspected and passed, it was found to be not adulterated.

(3) *Mechanically separated beef* means a meat food product that is finely

comminuted, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses, that meets the specifications contained in 9 CFR 319.5, the U. S. Department of Agriculture's (USDA's) regulation that prescribes the standard of identity for Mechanically Separated (Species).

(4) *Nonambulatory disabled cattle* means cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column or metabolic conditions.

(5) *Specified risk materials* means the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older and the tonsils and distal ileum of the small intestine of all cattle.

(6) *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues. Tallow must be produced from tissues that are not prohibited cattle materials or must contain not more than 0.15 percent insoluble impurities as determined by the method entitled ''Insoluble Impurities'' (AOCS Official Method Ca 3a–46), American Oil Chemists' Society (AOCS), 5th Edition, 1997, incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision, and sensitivity to AOCS Official Method Ca 3a–46. You may obtain copies of the method from AOCS (*http://www.aocs.org*) 2211 W. Bradley Ave., Champaign, IL 61821. Copies may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(7) *Tallow derivative* means any chemical obtained through initial hydrolysis, saponification, or trans-esterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or trans-esterification may be applied to obtain the desired product.

(8) *Ruminant* means any member of the suborder of animals that has a stomach with four compartments (rumen, reticulum, omasum, and abomasum) through which feed passes in digestion. The suborder includes, but is not limited to, cattle, buffalo, sheep, goats, deer, elk, and antelopes.

(b) *Requirements*. (1) At a minimum, except as provided in paragraph (b)(2) of this section, no drug intended for use in ruminants shall be manufactured from, or otherwise contain, prohibited cattle materials obtained from cattle slaughtered on or after [effective date of final rule].

(2) The requirements in paragraph (b)(1) of this section with respect to prohibited cattle materials shall not apply if FDA grants written permission for an exception or alternative to such requirements.

(i) To obtain written permission from FDA, you must send a written request to the Director of the Center for Veterinary Medicine, 7519 Standish Place, Rockville, MD 20855. For a drug intended for use in ruminants that is subject to a new animal drug application, your written request must reference its application number. The Center Director may also grant written permission for an exception or alternative to the requirements in paragraph (b)(1) of this section on his own initiative and shall base such a determination on an evaluation of the criteria described in paragraph (b)(2)(ii) of this section. You must maintain a record of any exception or alternative to the requirements in paragraph (b)(1) of this section that is granted by FDA, in accordance with paragraph (c) of this section.

(ii) A written request for an exception or alternative to the requirements in paragraph (b)(1) of this section must include, for each applicable product:

(A) A statement of the reasons why the exception or alternative is needed;

(B) A description of the product, including the type of prohibited cattle materials used in its manufacturing, its manufacturing and purification processes, and its route of administration;

(C) A description of the source of the prohibited cattle materials, including information on the location where the cattle were born, raised, and slaughtered, and any other information relevant to the likelihood of the cattle having ingested material prohibited under § 589.2000 of this chapter;

(D)(*1*) A description of how the requirements in paragraph (b)(1) of this section are not necessary:

(*i*) Based on the risks of the prohibited cattle materials in the product to the target animal and the benefits of the product to the target animal; and

(*ii*) To ensure a reasonable certainty of no harm to humans from any food derived from the target animal to which the product was administered; or

(*2*) A description of how the requirements in paragraph (b)(1) of this section are not necessary to ensure the safety of the product with respect to both the target animal and any food derived from the target animal to which the product is administered; and

(E) Any other relevant information.

(iii) FDA shall respond in writing to all requests for an exception or alternative to the requirements and may impose conditions in granting any such request.

(3) The small intestine is not considered prohibited cattle material if the distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine, as measured from the caeco-colic junction and progressing proximally towards the jejunum, or by a procedure that the establishment can demonstrate is equally effective in ensuring complete removal of the distal ileum.

(c) *Records*. (1) Applicants and manufacturers of a drug intended for use in ruminants that is manufactured from, or otherwise contains, any cattle material must establish and maintain records sufficient to demonstrate that the material is not manufactured from, and does not contain, prohibited cattle materials.

(2) The following record retention periods apply:

(i) Records for a Type A medicated article intended for use in ruminants that is manufactured from, or otherwise contains, any cattle material must be retained for at least 2 years after distribution by the manufacturer.

(ii) Records for a drug intended for use in ruminants, other than a Type A medicated article, that is manufactured from, or otherwise contains, any cattle material must be retained for at least 1 year after the expiration date of the drug.

(3) Records must be retained at the applicant's or manufacturer's establishment or at a reasonably accessible location. Records are considered to be reasonably accessible if they are accessible from an onsite location.

(4) Records required by this section must be available to FDA for inspection and copying. All the records must be in English.

(5) When filing entry with the U.S. Customs and Border Protection, the importer of record of a drug intended for

use in ruminants that was manufactured from, or otherwise contains, cattle material must affirm that the drug was manufactured from, or otherwise contains, cattle material and must affirm that the drug was manufactured in accordance with this section. If a drug was manufactured from, or otherwise contains, cattle material, then the importer of record must, if requested, provide to FDA within 5 days records that are sufficient to demonstrate that the drug is not manufactured from, and does not contain, prohibited cattle material.

(d) A drug intended for use in ruminants that is not in compliance with the requirements of paragraph (b) of this section is adulterated under section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B)).

(e) Failure of an applicant or manufacturer to comply with the requirements of paragraph (c) of this section renders a drug intended for use(s) in ruminants adulterated under section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B)).

(f) Failure of an importer of record to comply with the requirements of paragraph (c) of this section causes a drug intended for use(s) in ruminants to appear to be adulterated under section 801(a) of the act (21 U.S.C. 381(a)).

(g) A drug intended for use in ruminants that is a new animal drug and that is not in compliance with the requirements of paragraph (b) of this section is in violation of section 512 of the act (21 U.S.C. 360b).

(h) Failure of an applicant or manufacturer to comply with the requirements of paragraph (c) of this section is in violation of section 301(e) of the act (21 U.S.C. 331(e)).

(i) Any person who violates the requirements of paragraph (b) or (c) of this section shall be subject to the penalties provided in section 368 of the Public Health Service Act (42 U.S.C. 271).

PART 530—EXTRALABEL DRUG USE IN ANIMALS

9. The authority citation for 21 CFR part 530 is revised to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 351, 352, 353, 355, 357, 360b, 371, 379e; 42 U.S.C. 264, 271.

10. Section 530.41 is amended by removing the word ''for'' from the section heading, paragraph (a) introductory text, and paragraph (b) and adding in its place the word ''from''; and by adding paragraph (c) to read as follows:

§ 530.41 Drugs prohibited from extralabel use in animals.

* * * * *

(c) Drugs that contain prohibited cattle material as defined in §§ 300.200(a)(1) and 500.200(a)(1) of this chapter are prohibited from extralabel use in ruminants.

* * * * *

11. Section 530.42 is added to subpart E to read as follows:

§ 530.42 Labeling requirements for new animal drugs prohibited from extralabel use in animals.

(a) The labeling of any approved new animal drug that is prohibited from extralabel use in ruminants by § 530.41(c) must bear the statement ''Federal law prohibits the extralabel use of this product in ruminants.''

(b) Failure to comply with the labeling requirements in paragraph (a) of this section renders a drug misbranded under section 502(a) of the act.

PART 600—BIOLOGICAL PRODUCTS: GENERAL

12. The authority for 21 CFR part 600 is revised to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264, 271, 300aa–25.

13. Section 600.16 is added to subpart B to read as follows:

§ 600.16 Prohibited cattle materials.

(a) *Definitions*. The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262), and § 600.3 apply to such terms when used in this section. The following definitions also apply:

(1) *Prohibited cattle materials* means specified risk materials; small intestine of all cattle except as provided in paragraph (b)(3) of this section; material from nonambulatory disabled cattle; material from cattle not inspected and passed; or mechanically separated beef. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives, hides and hide-derived products, and milk and milk products. Prohibited cattle materials also do not include materials obtained from fetal calves of cows that were inspected and passed, as long as the materials were obtained by procedures adequate to prevent contamination with specified risk materials.

(2) *Inspected and passed* means that the material is from an animal that has been inspected and passed for human consumption by the appropriate regulatory authority, and at the time the animal was inspected and passed, it was found to be not adulterated.

(3) *Mechanically separated beef* means a meat food product that is finely comminuted, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses, that meets the specifications contained in 9 CFR 319.5, the U. S. Department of Agriculture's (USDA's) regulation that prescribes the standard of identity for Mechanically Separated (Species).

(4) *Nonambulatory disabled cattle* means cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

(5) *Specified risk materials* means the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older, and the tonsils and distal ileum of the small intestine of all cattle.

(6) *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues. Tallow must be produced from tissues that are not prohibited cattle materials or must contain not more than 0.15 percent insoluble impurities as determined by the method entitled ''Insoluble Impurities'' (AOCS Official Method Ca 3a–46), American Oil Chemists' Society (AOCS), 5th Edition, 1997, incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision, and sensitivity to AOCS Official Method Ca 3a–46. You may obtain copies of the method from AOCS (*http://www.aocs.org*) 2211 W. Bradley Ave., Champaign, IL 61821. Copies may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(7) *Tallow derivative* means any chemical obtained through initial hydrolysis, saponification, or trans-esterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or trans-esterification may be applied to obtain the desired product.

(b) *Requirements*. (1) At a minimum, except as provided in paragraphs (b)(2) and (b)(4) of this section, no biological product intended for use in humans shall be manufactured from, or otherwise contain, prohibited cattle materials obtained from cattle slaughtered on or after [effective date of final rule].

(2) The requirements in paragraph (b)(1) of this section with respect to prohibited cattle materials shall not apply if FDA grants written permission for an exception or alternative to such requirements.

(i) To obtain written permission from FDA, you must send a written request to the Director of the Center for Biologics Evaluation and Research (see § 600.2 for mailing address) or the Director of the Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers lane, Rockville, MD 20857, depending on the Center with primary jurisdiction over the product. Your written request must reference its application number. The Center Director may also grant written permission for an exception or alternative to the requirements in paragraph (b)(1) of this section on his own initiative and shall base such a determination on an evaluation of the criteria described in paragraph (b)(2)(ii) of this section. You must maintain a record of any exception or alternative to the requirements in paragraph (b)(1) of this section that is granted by FDA, in accordance with paragraph (c) of this section.

(ii) A written request for an exception or alternative to the requirements in paragraph (b)(1) of this section must include, for each applicable product:

(A) A statement of the reasons why an exception or alternative is needed;

(B) A description of the product, including the type of prohibited cattle materials used in its manufacturing, its manufacturing and purification processes, and its route of administration;

(C) A description of the source of the prohibited cattle materials, including information on the location where the cattle were born, raised, and slaughtered, and any other information relevant to the likelihood of the cattle having ingested material prohibited under § 589.2000 of this chapter;

(D) A description of how the requirements in paragraph (b)(1) in this section are not necessary based on the risks of the prohibited cattle materials in the product and the benefits of the product or how such restrictions are not necessary to ensure the safety of the product; and

(E) Any other relevant information.

(iii) FDA shall respond in writing to all requests for an exception or alternative to the requirements and may impose conditions in granting any request.

(3) The small intestine is not considered prohibited cattle material if the distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine, as measured from the caeco-colic junction and progressing proximally towards the jejunum, or by a procedure that the establishment can demonstrate is equally effective in ensuring complete removal of the distal ileum.

(4) Biological products that are not intended for use in or on the body (e.g., in vitro diagnostics) are not subject to the requirements of paragraph (b)(1) of this section.

(c) *Records*. (1) Establishments that manufacture a biological product intended for use in or on the body that is manufactured from, or otherwise contains, cattle material must establish and maintain records sufficient to demonstrate that the material is not manufactured from, and does not contain, prohibited cattle materials.

(2) Records must be retained consistent with § 600.12(b).

(3) Records must be retained at the manufacturer's establishment or at a reasonably accessible location. Records are considered to be reasonably accessible if they are accessible from an onsite location.

(4) Records required by this section must be available to FDA for inspection and copying. All the records must be in English.

(5) When filing entry with the U.S. Customs and Border Protection, the importer of record of a biological product intended for use in or on the body that was manufactured from, or otherwise contains, cattle material must affirm that the product was manufactured from, or otherwise contains, cattle material and must affirm that the product was manufactured in accordance with this section. If a product was manufactured from, or otherwise contains, cattle material, then the importer of record must, if requested, provide to FDA within 5 days records that are sufficient to demonstrate that the product is not manufactured from, and does not contain, prohibited cattle material.

(d) A biological product that is a drug and that is not in compliance with the requirements of paragraph (b) of this section is adulterated under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B)) and not safe, pure, and potent under section 351 of the PHS Act (42 U.S.C. 262).

(e) Failure of an applicant or manufacturer of a biological product that is a drug to comply with the requirements of paragraph (c) of this section renders such product adulterated under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B)) and not safe, pure, and potent under section 351 of the PHS Act (42 U.S.C. 262).

(f) Failure of an importer of record to comply with the requirements of paragraph (c) of this section causes a biological product to appear to be adulterated under section 801(a) of the act (21 U.S.C. 381).

(g) A biological product that is a new drug and that is not in compliance with the requirements of paragraph (b) of this section is in violation of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and section 351 of the PHS Act (42 U.S.C. 262).

(h) A biological product that is a device and that is not in compliance with the requirements of paragraph (b) of this section is adulterated under section 501(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(g)) and in violation of section 351 of the PHS Act (42 U.S.C. 262).

(i) Failure of an applicant or manufacturer to comply with the requirements of paragraph (c) of this section is a violation of section 301(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)).

(j) Any person who violates the requirements of paragraph (b) or (c) of this section shall be subject to the penalties provided in section 368 of the PHS Act (42 U.S.C. 271).

PART 895—BANNED DEVICES

14. The authority citation for 21 CFR part 895 is revised to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360f, 360h, 360i, 371, 381; 42 U.S.C. 264, 271.

15. Section 895.102 is added to subpart B to read as follows:

§ 895.102 Prohibited cattle materials.

(a) *Definitions*. The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321) apply to such terms when used in

this section. The following definitions also apply:

(1) *Prohibited cattle materials* means specified risk materials; small intestine of all cattle except as provided in paragraph (b)(3) of this section; material from nonambulatory disabled cattle; material from cattle not inspected and passed; or mechanically separated beef. Prohibited cattle materials do not include tallow that contains no more that 0.15 percent insoluble impurities, tallow derivatives, hides and hide-derived products, and milk and milk products. Prohibited cattle materials also do not include materials obtained from fetal calves of cows that were inspected and passed, as long as the materials were obtained by procedures adequate to prevent contamination with specified risk materials.

(2) *Inspected and passed* means that the material is from an animal that has been inspected and passed for human consumption by the appropriate regulatory authority, and at the time the animal was inspected and passed, it was found to be not adulterated.

(3) *Mechanically separated beef* means a meat food product that is finely comminuted, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses, that meets the specifications contained in 9 CFR 319.5, the U. S. Department of Agriculture's (USDA's) regulation that prescribes the standard of identity for Mechanically Separated (Species).

(4) *Nonambulatory disabled cattle* means cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

(5) *Specified risk materials* means the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months or older and the tonsils and distal ileum of the small intestine of all cattle.

(6) *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues. Tallow must be produced from tissues that are not prohibited cattle materials or must contain not more than 0.15 percent insoluble impurities determined by the method entitled ''Insoluble Impurities'' (AOCS Official Method Ca 3a–46), American Oil Chemists' Society (AOCS), 5th Edition, 1997, incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision, and sensitivity to AOCS Official Method Ca 3a–46. You may obtain copies of the method from AOCS (*http://www.aocs.org*) 2211 W. Bradley Ave., Champaign, IL 61821. Copies may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(7) *Tallow derivative* means any chemical obtained through initial hydrolysis, saponification, or trans-esterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or trans-esterification may be applied to obtain the desired product.

(b) *Requirements*. (1) At a minimum, except as provided in paragraph (b)(2) of this section, no medical device for humans that is intended for use in or on the body shall be manufactured from, or otherwise contain, prohibited cattle materials obtained from cattle slaughtered on or after [effective date of final rule].

(2) The requirements in paragraph (b)(1) of this section with respect to prohibited cattle materials shall not apply if FDA grants written permission for an exception or alternative to such requirements.

(i) To obtain written permission from FDA, you must send a written request to the Director of the Center for Devices and Radiological Health, 9200 Corporate Blvd., Rockville, MD 20850. For a device subject to premarket approval or premarket clearance, your written request must reference its application number. The Center Director may also grant written permission for an exception or alternative to the requirements in paragraph (b)(1) of this section on his own initiative and shall base such a determination on an evaluation of the criteria described in paragraph (b)(2)(ii) of this section. You must maintain a record of any exception or alternative to the requirements in paragraph (b)(1) of this section that is granted by FDA, in accordance with paragraph (c) of this section.

(ii) A written request for an exception or alternative to the requirements in paragraph (b)(1) of this section must include, for each applicable product:

(A) A statement of the reasons why an exception or alternative is needed;

(B) A description of the product, including the type of prohibited cattle materials used in its manufacturing, its manufacturing and purification processes, and its route of administration;

(C) A description of the source of the prohibited cattle materials, including information on the location where the cattle were born, raised, and slaughtered, and any other information relevant to the likelihood of the cattle having ingested material prohibited under § 589.2000 of this chapter;

(D) A description of how the requirements in paragraph (b)(1) of this section are not necessary based on the risks of the prohibited cattle materials in the product and the benefits of the product or how such restrictions are not necessary to ensure the safety of the product; and

(E) Any other relevant information.

(iii) FDA shall respond in writing to all requests for an exception or alternative to the requirements and may impose conditions in granting any such request.

(3) The small intestine is not considered prohibited cattle material if the distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine, as measured from the caeco-colic junction and progressing proximally towards the jejunum, or by a procedure that the establishment can demonstrate is equally effective in ensuring complete removal of the distal ileum.

(c) *Records*. (1) Applicants and manufacturers of a medical device that is intended for use in or on the body that is manufactured from, or otherwise contains, cattle material must establish and maintain records sufficient to demonstrate that the material is not manufactured from, and does not contain, prohibited cattle materials.

(2) Records must be retained consistent with § 820.180(b) of this chapter.

(3) Records must be retained at the applicant's or manufacturer's establishment or at a reasonably accessible location. Records are considered to be reasonably accessible if they are accessible from an onsite location.

(4) Records required by this section must be available to FDA for inspection and copying. All the records must be in English.

(5) When filing entry with the U.S. Customs and Border Protection, the

importer of record of a medical device intended for use in or on the body that was manufactured from, or otherwise contains, cattle material must affirm that the device was manufactured from, or otherwise contains, cattle material and must affirm that the device was manufactured in accordance with this section. If a device was manufactured from, or otherwise contains, cattle material, then the importer of record must, if requested, provide to FDA within 5 days records that are sufficient to demonstrate that the device is not manufactured from, and does not contain, prohibited cattle material.

(d) A medical device that is intended for use in or on the body that is not in compliance with the requirements of paragraph (b) of this section is adulterated under section 501(g) of the act (21 U.S.C. 351(g)).

(e) Failure of an applicant or manufacturer of a medical device that is intended for use in or on the body to comply with the requirements of paragraph (c) of this section renders the device misbranded under section 502(t) of the act (21 U.S.C. 352(t)).

(f) Failure of an importer of record to comply with the requirements of paragraph (c) of this section causes a medical device that is intended for use in or on the body to appear to be adulterated under section 801 of the act (21 U.S.C. 381).

(g) Failure of an applicant or manufacturer to comply with the requirements of paragraph (c) of this section is a violation of section 301(e) of the act (21 U.S.C. 331(e)).

(h) Any person who violates the requirements of paragraph (b) or (c) of this section shall be subject to the penalties provided in section 368 of the Public Health Service Act (42 U.S.C. 271).

PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

16. The authority citation for 21 CFR part 1271 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 263a, 264, 271.

17. Part 1271 is amended by adding new subpart G to read as follows:

Subpart G—Prohibited Cattle Materials

§ 1271.465 Applicability.

The provisions set forth in this subpart are applicable only to HCT/Ps described in § 1271.10 and regulated solely under section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264) and the regulations in this part, and to the establishments that manufacture those HCT/Ps. HCT/Ps that are drugs or devices regulated under the Federal Food, Drug, and Cosmetic Act, or are biological products regulated under section 351 of the PHS Act (42 U.S.C. 262), are not subject to the regulations set forth in this subpart. Such products are subject to the applicable regulations for biological products and for drugs or devices.

§ 1271.470 Prohibited cattle materials.

(a) *Definitions*. The following definitions apply to this section:

(1) *Prohibited cattle materials* means specified risk materials; small intestine of all cattle except as provided in paragraph (b)(3) of this section; material from nonambulatory disabled cattle; material from cattle not inspected and passed; or mechanically separated beef. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives, hides and hide-derived products, and milk and milk products. Prohibited cattle materials also do not include materials obtained from fetal calves of cows that were inspected and passed, as long as the materials were obtained by procedures adequate to prevent contamination with specified risk materials.

(2) *Inspected and passed* means that the material is from an animal that has been inspected and passed for human consumption by the appropriate regulatory authority, and at the time the animal was inspected and passed, it was found to be not adulterated.

(3) *Mechanically separated beef* means a meat food product that is finely comminuted, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses, that meets the specifications contained in 9 CFR 319.5, the U. S. Department of Agriculture's (USDA's) regulation that prescribes the standard of identity for Mechanically Separated (Species).

(4) *Nonambulatory disabled cattle* means cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

(5) *Specified risk materials* means the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older, and the tonsils and distal ileum of the small intestine of all cattle.

(6) *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues. Tallow must be produced from tissues that are not prohibited cattle materials or must contain not more than 0.15 percent insoluble impurities as determined by the method entitled ''Insoluble Impurities'' (AOCS Official Method Ca 3a–46), American Oil Chemists' Society (AOCS), 5th Edition, 1997, incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision, and sensitivity to AOCS Official Method Ca 3a–46. You may obtain copies of the method from AOCS (*http://www.aocs.org*) 2211 W. Bradley Ave., Champaign, IL 61821. Copies may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(7) *Tallow derivative* means any chemical obtained through initial hydrolysis, saponification, or trans-esterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or trans-esterification may be applied to obtain the desired product.

(b) *Requirements*. (1) At a minimum, except as provided in paragraph (b)(2) of this section, no HCT/P intended for use in humans shall be manufactured using, or otherwise contain, prohibited cattle materials obtained from cattle slaughtered on or after [effective date of final rule].

(2) The requirements in paragraph (b)(1) of this section with respect to prohibited cattle materials shall not apply if FDA grants written permission for an exception or alternative to such requirements.

(i) To obtain written permission from FDA, you must send a written request to the Director of the Center for Biologics Evaluation and Research (see § 600.2 of this chapter for mailing address). The Center Director may also grant written permission for an exception or alternative to the requirements in paragraph (b)(1) of this section on his own initiative and shall base such a determination on an evaluation of the criteria described in

paragraph (b)(2)(ii) of this section. You must maintain a record of any exception or alternative from the requirements in paragraph (b)(1) of this section that is granted by FDA, in accordance with paragraph (c) of this section.

(ii) A written request for an exception or alternative to the requirements in paragraph (b)(1) of this section must include, for each applicable product:

(A) A statement of the reasons why an exception or alternative is needed;

(B) A description of the product, including the type of prohibited cattle materials used in its manufacturing, its manufacturing and purification processes, and its route of administration;

(C) A description of the source of the prohibited cattle materials, including information on the location where the cattle were born, raised, and slaughtered, and any other information relevant to the likelihood of the cattle having ingested material prohibited under § 589.2000 of this chapter;

(D) A description of how the requirements in paragraph (b)(1) of this section are not necessary based on the risks of the prohibited cattle materials in the product and the benefits of the product or how such restrictions are not necessary to ensure the safety of the product; and

(E) Any other relevant information.

(iii) FDA shall respond in writing to all requests for an exception or alternative to the requirements and may impose conditions in granting any request.

(3) The small intestine is not considered prohibited cattle material if the distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine, as measured from the caeco-colic junction and progressing proximally towards the jejunum, or by a procedure that the establishment can demonstrate is equally effective in ensuring complete removal of the distal ileum.

(c) *Records*. (1) Establishments that manufacture an HCT/P that is manufactured using, or otherwise contains, cattle material must establish and maintain records sufficient to demonstrate that the material is not manufactured using, and does not contain, prohibited cattle materials.

(2) Records must be retained for the period specified in § 1271.270(d).

(3) Records must be retained at the manufacturer's establishment or at a reasonably accessible location. Records are considered to be reasonably accessible if they are accessible from an onsite location.

(4) Records required by this section must be available to FDA for inspection and copying. All the records must be in English.

(5) When filing entry with the U.S. Customs and Border Protection, the importer of record of an HCT/P manufactured using, or otherwise containing, cattle material must affirm that the HCT/P was manufactured using, or otherwise contains, cattle material and must affirm that the HCT/P was manufactured in accordance with this section. If an HCT/P was manufactured using, or otherwise contains, cattle material, then the importer of record must, if requested, provide to FDA within 5 days records that are sufficient to demonstrate that the HCT/P is not manufactured using, and does not contain, prohibited cattle material.

(d) An HCT/P that is not in compliance with the requirements of paragraph (b) or (c) of this section is a violative HCT/P that is subject to retention, recall, destruction, and/or cessation of manufacturing under § 1271.440.

Dated: December 7, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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Federal Register

Friday,
January 12, 2007

Part III

Fish and Wildlife Service

50 CFR Parts 17

Endangered and Threatened Wildlife and Plants; Withdrawal of Proposed Rule To List Lepidium papilliferum (Slickspot Peppergrass); Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AU99

Endangered and Threatened Wildlife and Plants; Withdrawal of Proposed Rule To List Lepidium papilliferum (Slickspot Peppergrass)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; withdrawal.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), again withdraw our July 15, 2002, proposal (67 FR 46441) to list *Lepidium papilliferum* (slickspot peppergrass) as an endangered species under the Endangered Species Act of 1973, as amended (Act). The best available data for *L. papilliferum* indicates that, while its sagebrush-steppe matrix habitat is degraded, there is little evidence of negative impacts on the abundance of *L. papilliferum*, which inhabits slickspot microsites within this system. Annual abundance of the plant is strongly correlated with spring precipitation, therefore a high degree of variability in annual abundance is to be expected. Data on overall population trends are inconsistent; although recent declines that do not correlate with spring rainfall are noted in one portion of the species' range, range-wide data demonstrate increases in abundance that continue to track consistently with rainfall during those same years. The best available range-wide data indicate that abundance of the population range-wide is strongly correlated with precipitation and has increased in recent years in association with increased rainfall, as expected.

ADDRESSES: Supporting documentation for this action is available for public inspection, by appointment, during normal business hours at the Snake River Fish and Wildlife Office, 1387 S. Vinnell Way, Boise, ID 83709.

FOR FURTHER INFORMATION CONTACT: Jeffery Foss, Field Supervisor, Snake River Fish and Wildlife Office at the above address; by telephone at 208/378–5243; by facsimile at 208/378–5262; or by electronic mail at: *fw1srbocomment@fws.gov*.

SUPPLEMENTARY INFORMATION:

Species Information

Lepidium papilliferum was originally described as *L. montanum* var. *papilliferum* in 1900 by Louis Henderson. It was renamed *L. papilliferum* by Aven Nelson and J. Francis Macbride in 1913, based on its distinctive growth habit, short lifespan, and unusual pubescence (Nelson and Macbride 1913, p. 474). Hitchcock regarded *L. papilliferum* as *L. montanum* var. *papilliferum* (Hitchcock *et al.* 1964, p. 516; Hitchcock and Cronquist 1973). In a review of taxa in the mustard family (Brassicaceae), Rollins (1993) maintained the species based on differences in the physical features between *L. papilliferum* and *L. montanum*. More recently, a taxonomic review concluded that *L. papilliferum* warrants species recognition based on distinct morphological features (Lichvar 2002), and a contrasting life history when compared to *L. montanum* regarding seed dormancy and its seed bank (Meyer *et al.* 2005, p. 21). The preliminary results of recent genetic studies comparing *L. papilliferum* with *L. montanum* indicate that *L. papilliferum* forms a monophyletic group or subgroup that is genetically distinct from *L. montanum* (Larson *et al.* 2006, p. 13 and Figs. 4, 8; Smith 2006, pp. 5–7, Fig. 1). The currently accepted taxonomy recognizes *Lepidium papilliferum* (Henderson) A. Nels and J.F. Macbr as a full species (Taxonomic Serial No. 53383, Integrated Taxonomic Information System (ITIS), 2006).

Biology

Lepidium papilliferum is a taprooted, intricately branched plant. The plant flowers once and then dies (it is monocarpic), and displays two different life cycles, an annual and a biennial form. The plant averages 2 to 8 inches (in) (5 to 20 centimeters (cm)), but can reach up to 16 in (40 cm) in height. Leaves and stems are covered with fine, soft hairs, and the leaves are divided into linear segments. Flowers are numerous, 0.1 in (3 to 4 millimeter (mm)) diameter, white, and 4-petalled. Fruits (siliques) are 0.1 in (3 mm), round in outline, flattened, and 2-seeded (Moseley 1994, pp. 3 and 4; Holmgren *et al.* 2005, p. 260).

The annual form of the *Lepidium papilliferum* matures, reproduces by setting seed, and dies in one growing season. The biennial life form initiates growth in the first year as a rosette, but does not produce seed and die until the second year. Biennial rosettes must survive dry summers on the Snake River Plain and Owyhee Plateau, and consequently many of these rosettes die before flowering and producing seed. The proportion of annuals versus biennials in a population can vary greatly (Meyer *et al.* 2005, p. 15). Depending on individual plant vigor and the effectiveness of pollination, dozens, if not thousands, of seeds can be produced by a single *L. papilliferum* plant (Quinney 1998, pp. 15 and 17), with individual biennial plants producing a much greater number of seeds than annual plants (Meyer *et al.* 2005, p. 15). Average seed output for annual plants at the Orchard Training Area (OTA) (an Idaho Army National Guard training area on BLM land) in 1993, was 125 seeds per plant, and in 1994, was 46 seeds per plant. Biennial seed production in 1993 and 1994 averaged 787 and 105 seeds per plant, respectively (Meyer *et al.* 2005, p. 16).

Lepidium papilliferum seeds produced in a given year are dormant for at least a year before any germination takes place. Following this year of dormancy, approximately 6 percent of seeds produced in a given year germinate annually and approximately 3 percent die annually (Meyer *et al.* 2005, pp. 17, 18). After 12 years, all seeds in a given cohort will likely have either died or germinated (Meyer *et al.* 2005, p. 18). Seeds are released in late June or early July.

Like many short-lived plants growing in arid environments, above-ground numbers of *Lepidium papilliferum* individuals can fluctuate widely from one year to the next, depending on seasonal precipitation patterns (Mancuso and Moseley 1998, p. 1; Meyer *et al.* 2005, pp. 4, 12, 15; Palazzo *et al.* 2005, p. 9; Menke and Kaye 2006a, p. 8; Menke and Kaye 2006b, pp. 10, 11). In an analysis of monitoring data, minimum and maximum temperatures were not statistically correlated with *L. papilliferum* abundance (Menke and Kaye 2006b, p. 8). Above-ground plants represent only a portion of the population; the seed bank (a reserve of dormant seeds, generally found in the soil) contributes the other portion, and apparently in many years constitutes the majority of the population (Mancuso and Moseley 1998, p. 1). According to Meyer *et al.* (2005, p. 21), ''Without a persistent seedbank, *L. papilliferum* could probably not succeed as an annual in its stochastically varying habitat.'' Seed banks are adaptations for survival in a ''risky environment,'' because they buffer a species from stochastic impacts such as lack of soil moisture (Baskin and Baskin 2001, p. 160).

Lepidium papilliferum seeds have an extremely patchy distribution, making it difficult to estimate seed density without taking a large number of samples (Meyer and Allen 2005, pp. 5, 6). The vast majority of *L. papilliferum* seeds in slickspots (see Ecology and Habitat section) have been located near the soil surface, with lower numbers of seeds located in deeper soils (Meyer *et*

al. 2005, p. 19; Palazzo *et al.* 2005, p. 3). *L. papilliferum* seeds have been found in slickspots with no above-ground plants (Meyer *et al.* in press, p. 18; Palazzo *et al.* 2005, p. 10). Viable seeds have also been located outside of slickspots, indicating that some seed dispersal is occurring beyond slickspot habitat (Palazzo *et al.* 2005, p. 10). The primary seed dispersal mechanism for *L. papilliferum* has not been identified and is not known (Robertson and Ullappa 2004, p. 1708).

Lepidium papilliferum seeds located near the soil surface show higher rates of germination and viability (Meyer and Allen 2005, pp. 6 to 8; Palazzo *et al.* 2005, p. 10), and the greatest seedling emergence success rate (Meyer and Allen 2005, pp. 6 to 8). Seeds were more abundant, more viable, and had greater germination percentages and rates from the upper 2 in (5 cm) of soil (Palazzo *et al.* 2005, pp. 8, 10). In another study, the highest level (60 percent) of seedling emergence was observed at a seed depth of 0.1 in (approximately 2 mm), with a marked decrease in seedling emergence at 0.2 in (approximately 5 mm) (Meyer and Allen 2005, pp. 6, 7).

Deep burial of slickspot peppergrass seeds (average depths greater than 5.5 in (14 cm)) entombs seeds that are still viable and preserves them beyond the 12-year period previously assumed as the maximum period of viability for *Lepidium papilliferum* seeds (Meyer and Allen 2005, pp. 6, 9). While there may be processes such as badger (*Taxidea taxus*) burrow-digging that could return these buried viable seeds to the near-surface, the successful establishment of seedlings may be reduced due to modification of soil layers following previous disturbance events (Meyer and Allen 2005, pp. 6, 8). The effects of environmental threats such as wildfire on *L. papilliferum* seed dormancy and viability are currently unknown.

Lepidium papilliferum has low seed set in the absence of pollinators, and is primarily an outcrossing species requiring pollen from separate plants for more successful fruit production (Robertson 2003a, p. 5; Robertson and Klemash 2003, p. 339; Robertson and Ulappa 2004, p. 1707). In pollination experiments where researchers moved pollen from one plant to another, fruit production was observed to be higher with pollen from distant sources 246 to 330 feet (ft) (75 to 100 meters (m)) away within a plant patch, and 4 to 12.4 miles (mi) (6.5 to 20 kilometers (km)) away from another patch of plants (Robertson and Ulappa 2004, p. 1705). Genetic exchange can occur either thorough pollen or seed dispersal.

Lepidium papilliferum has been observed to be visited by at least 25 families of insects, although only some of these insects serve as effective pollinators (Robertson 2003b, pp. 10, 11; Robertson and Klemash 2003, p. 336). Scarcity of pollinators were not found to limit seed set at any site (Robertson *et al.* 2004, p. 14). Pollinators include insects from several families of bees and ants (Hymenoptera), including Apidae, Halictidae, Sphecidae, and Vespidae; beetles (Coleoptera), including Dermestidae, Meloidae, and Melyridae; flies (Diptera), including Bombyliidae, Syrphidae, and Tachinidae; and others (Robertson and Klemash 2003, p. 336). The pollen transfer efficiency for *L. papilliferum* varies among these insects. Pollinators of *L. papilliferum* with high pollen transfer efficiencies and visitation rates include sphecid and vespid wasps, bombyliid and tachnid flies, and honeybees, with lesser contributions from halictid bees.

The genetics of *Lepidium papilliferum* were studied using samples collected from areas across the entire range of the species, including both the Snake River Plain and a disjunct range on the Owyhee Plateau (Stillman *et al.* 2005, pp. 6, 8, 9). The largest amounts of genetic difference occurred between the Snake River Plain and the Owyhee Plateau populations. The Snake River Plain and the Owyhee Plateau populations are separated by 44 mi (70 km), which is considered beyond the distance that insect pollinators can travel or that seed dispersal can occur. Despite the distance that separates the Snake River Plain and the Owyhee Plateau populations, plants from these two areas share a 94-percent similarity in allelic diversity. This high degree of similarity suggests that they were either part of one continuous distribution or they originated from similar ancestral material (Stillman *et al.* 2005, pp. 6, 8, 9). Sites in the Snake River Plain with fewer numbers of plants had less genetic diversity than sites with larger numbers of plants. Interestingly, a correlation between population size and genetic diversity did not exist in the Owyhee Plateau region. The authors suggested that this may be because the Owyhee Plateau region is less fragmented than the Snake River Plain, but suggested further genetic research is needed. Larson (2006, p. 14 and Fig. 4) also found geographically well-defined populations of *Lepidium papilliferum* between the Snake River Plain and Owyhee Plateau based on genetics. In contrast to the Stillman *et al.* (2005) study, Larson's findings indicate the possibility of depressed genetic diversity in *L. papilliferum* based on significantly greater average similarity coefficients within collection sites of *L. papilliferum* compared to those of *L. montanum,* (Larson *et al.* 2006, p. 13).

Ecology and Habitat

The habitat of *Lepidium papilliferum* is found within semiarid sagebrush-steppe habitats in southern Idaho. This plant is known from the extensive volcanic plains of the Snake River Plain (and foothills) and the Owyhee Plateau, with most element occurrences (EOs) occurring on flat to gently sloping terrain (see Figure 1 below). Element occurrences are defined as ''an area of land in which a species is or was present'' (NatureServe 2002). *L. papilliferum* is associated with basalt ridges and plains, stable piedmont, and older alluvial floodplains and deposits (Fisher *et al.* 1996, pp. 14, 16).

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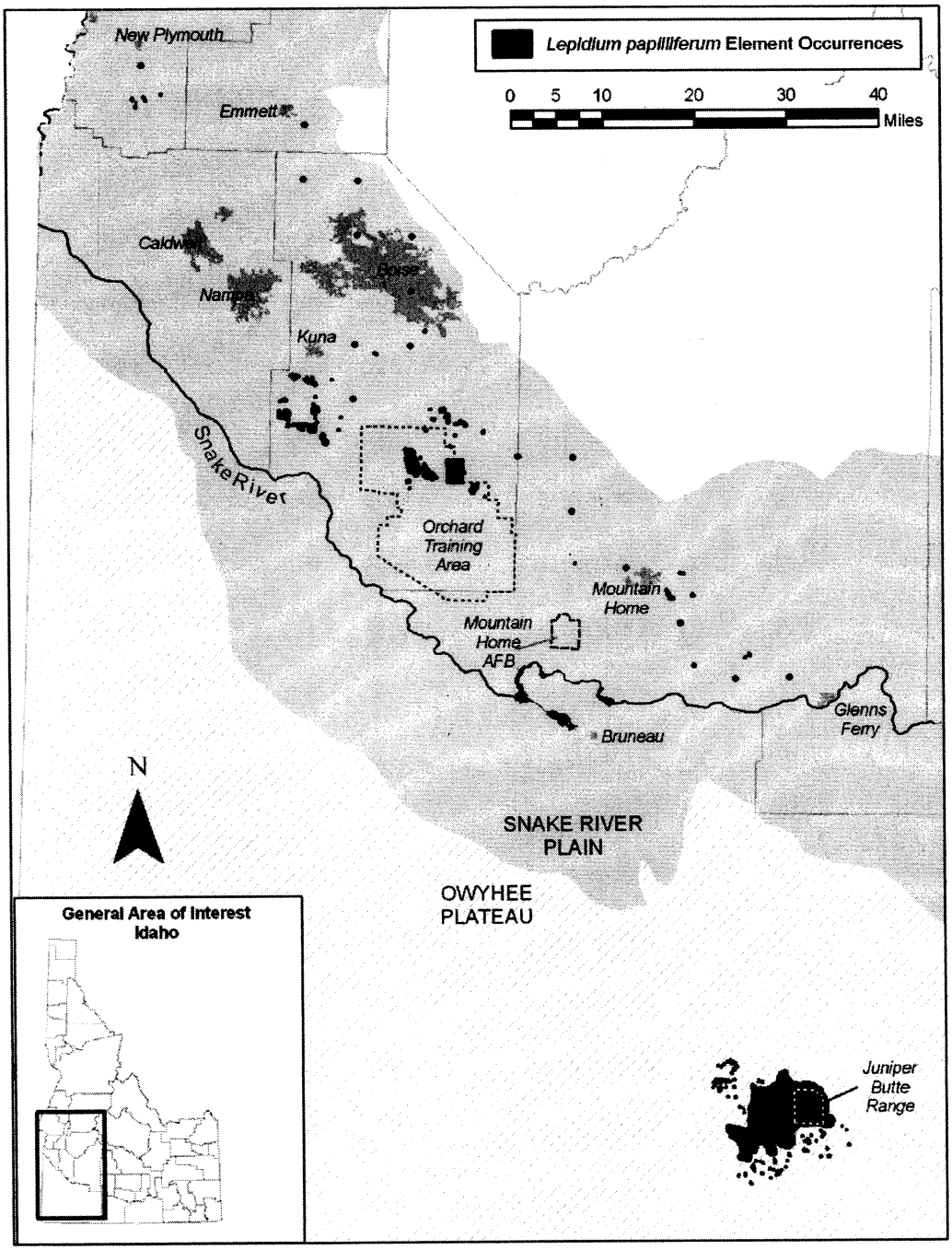

Figure 1. Range-wide Distribution for Lepidium papilliferum

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Range-wide, *Lepidium papilliferum* is associated with visually distinct microsites known as slickspots (mini-playas or natric sites) (Moseley 1994, p. 7). Slickspots are distinguished from the surrounding sagebrush matrix as having the following characteristics—microsites where water pools when rain falls (Fisher *et al.* 1996, pp. 2, 4); little vegetation; more distinct soil layers with a more columnar or prismatic structure; higher alkalinity and clay content and natric (higher sodium) properties (Fisher *et al.* 1996, pp. 15, 16; Meyer and Allen 2005, pp. 3 to 5, 8); and reduced levels of organic matter and nutrients due to lower biomass production (Meyer and Quinney 1993, pp. 3, 6; Fisher *et al.* 1996, p. 4). The slickspots range in size from less than 10 square feet (ft^2) (1 square meter (m^2)) to about 110 ft^2 (10 m^2) (Mancuso *et al.* 1998, p. 1), but most are between 10 ft^2 and 20 ft^2 (1 m^2 and 2 m^2).

Slickspots cover a relatively small cumulative area within the larger sagebrush-steppe matrix, and only a small percentage of slickspots are known to be occupied by *Lepidium papilliferum*. For example, a thorough field inventory within the Juniper Butte Range in 2002 found that of the 11,070

acres (ac) (4,480 hectares (ha)) surveyed, approximately 1 percent (109 ac (44 ha)) consisted of slickspot habitat, and only 4 percent of the slickspot habitat was occupied by above-ground *L. papilliferum* plants (U.S. Air Force 2002, p. 9). The total amount of occupied slickspot habitat (above-ground plants and known occurrences of seed in the soil) within this large occurrence was approximately 4 ac (1.6 ha) at the time it was surveyed (0.1 percent of the acreage).

Based on studies in 2004 on the Orchard Training Area (OTA), a training area of the Idaho Army Reserve National Guard (IARNG) on the Snake River Plain, slickspots have three primary layers: the surface silt layer, the restrictive layer, and the moist clay layer beneath. The top two layers (surface silt and restrictive) of slickspots are very thin; the surface silt layer varies in thickness from 0.1 to 1.2 in (a few mm to 3 cm) in slickspots known to support *Lepidium papilliferum*, and the restrictive layer varies in thickness from 0.4 to 1.2 in (1 to 3 cm) (Meyer and Allen 2005, p. 3). The moist clay basal layer, which continues down to bedrock, is consistently below the restrictive layer (Meyer and Allen 2005, p. 3). All slickspots have variations in surface silt thickness.

As part of the *Lepidium papilliferum* Habitat Integrity and Population (HIP) monitoring conducted range-wide in 2005, the depth of the surface silt layer was measured 3 times in every slickspot along 79 transects across the range of *L. papilliferum*; a total of 769 slickspots were sampled. Measurements were taken directly adjacent to live *L. papilliferum* plants; the range-wide mean surface silt layer depth was 0.31 in (0.78 cm) (Colket 2006a).

The surrounding sagebrush matrix soils are distinguished from slickspot soils by a deeper silt layer with a clay layer beneath, and usually the restrictive layer is lacking (Meyer and Allen 2005, pp. 3 to 5). Non-slickspot soils at the OTA had thick silt layers with a mean depth of 4.7 in (12 cm); the silt layer typically transitioned directly into the clay layer beneath, although some samples had restrictive layers which were abnormally thickened (over 3.9 in (10 cm)) (Meyer and Allen 2005, pp. 3 to 5, 8).

It is unknown how long slickspots take to form, but it is hypothesized to take several thousands of years (Nettleton and Petersen 1983, p. 193; Seronko 2006, p. 1). The conditions that allowed for the formation of slickspots in southwestern Idaho are thought to have occurred during a wetter Pleistocene climate. Holocene additions of wind-carried salts (often loess deposits) produced soils high in sodium (natric) (Nettleton and Petersen 1983, p. 191; Seronko 2006, p. 1). It may take several hundred years to alter or lose slickspots through natural climate change or severe natural erosion (Seronko 2006, p. 1). Some researchers hypothesize that, given current climatic conditions, new slickspots are no longer being created (Nettleton and Petersen 1983, pp. 166, 191, 206), but that some slickspots subjected to light disturbance in the past may re-form (Seronko 2006, p. 1). Slickspots may be destroyed and lost to disturbances that alter the physical properties of the soil layers.

The forces that hold clay particles together are greatly weakened when sodium-clay and water come into contact. In this condition, clay particles are easily detached or dispersed from larger aggregates, i.e., slickspot soils are especially susceptible to mechanical disturbances when wet (Rengasmy *et al.* 1984, p. 63; Seronko 2004, pp. 1, 2). Such disturbances disrupt the soil layers important to *Lepidium papilliferum's* seed germination and seedling growth. Meyer and Allen (2005, p. 9) suggest that if sufficient time passes following the disturbance of slickspot soil layers, it is possible that the slickspot soil layers may reform similar to their pre-disturbance configuration. Slickspots that no longer support *L. papilliferum*, but still retain the thin silt and restrictive layer structure, are the most likely sites to support reintroductions. Restoration and species reintroduction potential for *L. papilliferum* habitat have not been studied.

The highest monthly temperatures within the range of *Lepidium papilliferum* normally occur in July (approximately in the low 90 degrees Fahrenheit (approximately 33 degrees Celsius)), and lowest monthly temperatures occur in January (approximately in the low 20 degrees Fahrenheit (minus 7 degrees Celsius)). Average precipitation within the species' range is 11.7 in (29.7 cm) for Boise, 7.4 in (18.8 cm) for Bruneau, and 9.9 in (25.1 cm) for Mountain Home. Precipitation tends to fall as rain, primarily in winter and spring (November to May); the lowest rainfall occurs in July and August, and June, September, and October receive slightly more. Freeze-free days average about 120 days in Boise, 146 days in Bruneau, and 138 days in Mountain Home (WRCC 2006).

Spring precipitation has been correlated with above-ground numbers of *Lepidium papilliferum* in several analyses. Palazzo *et al.* (2005, p. 9) and Menke and Kaye (2006a, p. 8) utilized Habitat Integrity Index (HII) range-wide data collected from 1998 to 2001. Menke and Kaye (2006b, pp. 10, 11) utilized HII data collected from 1998 to 2002, as well as 2004 Habitat Integrity and Population (HIP) data. Meyer *et al.* (2005, p. 15) utilized demographic data from the OTA collected from 1993 to 1995. Palazzo *et al.* (2005, p. 9) found a positive relationship (p-value of less than 0.01) between above-ground plants and February to June precipitation. Menke and Kaye (2006a, p. 8) found March to May precipitation accounted for 99.4 percent (2006a, p. 8) and 89 percent (2006b, pp. 10, 11) of the variation in *L. papilliferum* numbers. Meyer *et al.* (2005, p. 15) found that an increase in February through May precipitation increased the number of *L. papilliferum* seedlings at the OTA. This correlation of abundance with spring rainfall is important, as it at least partially explains past fluctuations in population numbers, and suggests that perceived declines were largely a result of years with low precipitation levels. Menke and Kaye (2006b, p. 8) also found that minimum and maximum temperatures were not statistically correlated with *L. papilliferum* abundance.

The sparse native vegetation naturally present at slickspots suggests that *Lepidium papilliferum* is more tolerant than surrounding vegetation at surviving in alkaline soils and spring inundation. Plant ecology literature suggests that plants tolerant of stress (*e.g.*, alkaline soils) are poor competitors (Grime 1977, p. 1185).

Range and Distribution

Lepidium papilliferum is known only from the Snake River Plain and its adjacent northern foothills (an area 90 by 25 mi (145 by 40 km)) in southwest Idaho, and a disjunct population on the Owyhee Plateau in Idaho (see Figure 1 above). The plant occurs at elevations ranging from approximately 2,200 ft (670 m) to 5,400 ft (1,645 m) in Ada, Canyon, Gem, Elmore, Payette, and Owyhee Counties (Moseley 1994, pp. 3 to 9). The separation of population centers into two physiographic regions is important for the conservation of *L. papilliferum*. We regard the two physiographic regions as two distinct metapopulations, the Snake River Plain metapopulation and the Owyhee Plateau metapopulation. Metapopulation concepts are useful when considering fragmented habitats, such as those within *L. papilliferum's* range, because they include discussion of when extinction events exceed colonization events, which can cause

the species to not persist (Husband and Barrett 1996, pp. 461 to 462).

In 2003, a ''Candidate Conservation Agreement for Slickspot Peppergrass (*Lepidium papilliferum*)'' (CCA) was developed by several State, Federal, and private entities in Idaho (State of Idaho *et al.* 2003) (see Previous Federal Actions section). The CCA is based on two geographical management areas that include known EOs, one on the Snake River Plain and a second on the Owyhee Plateau, called ''consideration zones.'' Although somewhat arbitrary in nature, this designation is useful for management purposes. There are 1,595,205 ac (645,597 ha) within the Snake River Plain consideration zone, and 126,946 ac (51,373 ha) within the Owyhee Plateau consideration zone. Factors affecting the species vary between the two physiographic regions. For example, urban and rural development, agriculture, and infrastructure development of sagebrush-steppe habitat has been substantial within the Snake River Plain, but little development has occurred within the Owyhee Plateau portion of *L. papilliferum*'s range.

Element occurrences have been used to describe distribution of *Lepidium papilliferum* by assuming that slickspots within 1 kilometer (0.6 mi) of each other are capable of genetic exchange through pollination (Colket and Robertson, pers. comm. 2006). As of February 2006, there were 85 delineated EOs that occupied 13,359 ac (5,406 ha) (Colket *et al.* 2006). We estimate that the actual acreage occupied by *L. papilliferum* is only a fraction of a percent of this total acreage number because the majority of slickspots are not occupied by *L. papilliferum* and slickspots occupy a small percentage of the landscape (see U.S. Air Force 2002, p. 9, for an example). Of these EOs, 60 (11,025.3 ac (4,461.8 ha)) occur on the Snake River Plain, and 25 (2,333.8 ac (944.5 ha)) occur on the Owyhee Plateau (Colket *et al.* 2006, Table 14). Of the total EO acreage, 521 ac (211 ha) (3.9 percent) occur on private lands, 1,254 ac (507 ha) (9.4 percent) occur on lands managed by the State of Idaho, and 11,582 ac (4,687 ha) (86.7 percent) occur on Federal lands (USFWS 2006c). On the Snake River Plain, 85 percent of the EO acreage occurs on federally managed lands, 10.3 percent of the EO acreage occurs on State-managed lands, and 4.7 percent of the EO acreage occurs on private lands. On the Owyhee Plateau, 94.7 percent of the EO acreage occurs on Federally managed lands, with the remaining 5.3 percent occurring on State managed lands; no EOs on the Owyhee Plateau occur on private lands.

The approximate extant range of the plant was first described in 1994 (Moseley 1994, p. 6), and has not changed substantially since, although the amount of known occupied habitat, particularly on the Owyhee Plateau, has expanded in recent years. Since 2003, sixteen new occurrences, all within 3 mi (4.8 km) of previously existing occurrences, have been documented: 2 on the Snake River Plain with an area of 2.7 ac (1 ha) and approximately 2,500 individuals, and 14 on the Owyhee Plateau with an area of 46.6 ac (18 ha) and approximately 650 individuals (Colket *et al.* 2006, Tables and Appendix A). It should be noted that not all potential *L. papilliferum* habitat in southwest Idaho has been surveyed, and it is likely that additional occupied *L. papilliferum* sites will be found.

Estimating the number of individuals (abundance) of *Lepidium papilliferum* is confounded by its annual or biennial life cycle, because the number of individuals of each life form can fluctuate widely depending on precipitation. To assess abundance, we utilized four available data sets: range-wide EO records maintained by the Idaho Conservation Data Center (CDC), range-wide data associated with the HII/HIP monitoring, transect monitoring data collected on the OTA, and special use plot data from the OTA.

As of February 2006, the Idaho CDC had ranked 101 EO records for *Lepidium papilliferum* (Colket *et al.* 2006a, pp. 15 to 41); 9 are ranked as extirpated (lost) or probably extirpated, and 7 are considered historical (information for most is too vague for relocation). All 9 extirpations were verified locations from old herbarium collections, the most recent from 1955, where the habitat has been completely converted to urban or agricultural lands (Colket *et al.* 2006, Table 13). The remaining 85 records (as of February 2006) are for EOs considered extant (existing). In the review of EO specifications and ranks conducted in February 2006, observed abundance was categorized as being greater than 1,000 plants, 400 to 999 plants, 50 to 399 plants, less than 50 plants, 0 plants, or an unknown number of plants. This classification was based on the number of plants present at the last survey, regardless of year and associated precipitation patterns. Existing data provide an estimated abundance for extant EOs: 15 (18 percent) have over 1,000 plants, 11 (13 percent) have between 400 and 999 plants, 1 (1 percent) has about 400 plants, 18 (21 percent) have between 50 and 399 plants, 22 (26 percent) have fewer than 50 plants, 9 (11 percent) had no plants at the last visit, and 9 (11 percent) have an unknown number of individuals.

Two monitoring methods, HII and HIP, have been used range-wide for *Lepidium papilliferum*. Each included different methodologies, but are still useful for tracking abundance at transects across the two efforts. HII monitoring was developed to assess the overall habitat condition that includes attributes associated with the slickspots and the sagebrush-steppe habitat, occurred for 4 years (1998 to 2001), and is presented in various reports (Mancuso and Moseley 1998; Mancuso *et al.* 1998; Mancuso 2000, 2001, 2002; Menke and Kaye 2006a, b). HIP monitoring was developed to assess the overall habitat condition that includes those attributes associated with the slickspots and the sagebrush-steppe habitat, and also the effectiveness of the CCA. HIP monitoring was conducted in 2004 and 2005 (State of Idaho *et al.* 2006, p. 18), and is expected to continue. HIP monitoring results in 2004 are reported in Menke and Kaye 2006b, and results through 2005 are included in our report ''Best Available Biological Information for Slickspot Peppergrass (*Lepidium papilliferum*)'' (USFWS 2006f, Figures 8, 9). Although neither the HII nor HIP methodologies have been peer reviewed, they represent the best available survey and monitoring techniques for *L. papilliferum*.

Abundance data for *Lepidium papilliferum* have been collected range-wide since 1998, and collected at the OTA since the early 1990s. The range-wide HII and HIP transect data illustrate that plant abundance is positively correlated with spring precipitation, and specifically that rainfall in the months of March through May accounts for 89 percent of the variability in plant numbers (Menke and Kaye 2006b, p. 10). Plant abundance therefore fluctuates widely between years in association with precipitation. In the areas monitored by HII and HIP, Menke and Kaye (2006b, p. 10) report that *L. papilliferum* abundance decreased range-wide between 1998 and 1999, remained low through 2002, and began to increase again beginning in 2002. This pattern closely tracks that of rainfall during those same years. Abundance data from transects at the OTA illustrate declines in abundance first noted in 1996, with a declining trend in recent years that is not correlated with spring precipitation (Weaver 2006, pp. 1–6). Abundance data from the range-wide HII and HIP transects showed increasing trends in *L. papilliferum* between the years 2002 and 2005 (no data were collected in 2003) (USFWS 2006f, Figures 8, 9).

Thus range-wide abundance data from the HII and HIP transects continue to show a consistently positive correlation with spring precipitation. We consider this range-wide data to be the best available at this time.

We conducted a review of the abundance data and study methodology following the reopened comment period on the proposal to list *L. papilliferum* as endangered (October 23, 2006, to November 13, 2006; 71 FR 62078). A review of the special use plot counts at the OTA (USFWS 2006e, Figure 7) shows a decline in plant numbers during the drought years of 1992 (249 plants), 1997 (624 plants), and 2002 (270 plants) followed by a positive response in plant numbers as spring precipitation increased in subsequent years 1993 (6,369 plants), 1998 (3,330 plants), and 2003 (4,080 plants). Reviewing the special use plot data at OTA for 2004–2006 illustrates a relatively stable or declining number of plants despite increases in spring precipitation.

We reviewed the OTA population monitoring transect study and updated the description of the study methods from our BAI based upon clarification of new information provided by IARNG staff during the reopened comment period on the proposal to list *L. papilliferum* as endangered (October 23, 2006, to November 13, 2006; 71 FR 62078). The BAI cited study methods as described by IARNG staff and stated that the census effort occurred annually at the OTA and that observers cover 98 percent of the plants' habitat at OTA. New information obtained since the BAI was written suggests that 90 percent may be a more accurate estimate of the amount of habitat surveyed at OTA. Since 2003, additional plant inventories have increased the size of the known population of *L. papilliferum* at OTA, including the documentation of 365 new occupied slickspots in 2005 (URS Corporation 2005, pp. 6–7). The OTA population monitoring transects for 2005 reported 18,599 plants in the transect areas; the survey inventory by URS corporation reported 43,925 plants (365 new slickspots with *L. papilliferum*, 125 historic slickspots with *L. papilliferum*, 66 historic slickspots without *L. papilliferum*) in the areas surveyed at OTA (URS Corporation 2005, p. 7).

We reviewed the results of range-wide HII and HIP monitoring, including reported plant abundance since these studies were initiated in 1998, and new information available to us since the time we last issued a listing finding on this species. These data illustrate a general pattern of plant numbers correlating with spring precipitation (USFWS 2006f, Figures 8, 9). Data are incomplete for 2002 and 2003. Menke and Kaye (2006b, p. 19) report that ''populations generally decreased during 1998–2004 and these trends appear to be strongly influenced by spring precipitation.'' In contrast to the results reported from the OTA, range-wide abundance of *Lepidium papilliferum* as measured by the HII and HIP increased as spring precipitation increased in the years 2002 through 2005 (USFWS 2006f, Figures 8, 9). Comparing years 1998 and 2005, which are relatively comparable in terms of range-wide spring precipitation (6.6 inches and 6.3 inches, respectively), plant numbers are also similar (17,611 and 15,226 respectively), indicating little change in overall abundance of *L. papilliferum* range-wide over this time interval, despite the intervening fluctuations in yearly abundance that are to be expected for an ephemeral annual plant. In general, the HII and HIP data from 1998–2005 indicate that the abundance of *L. papilliferum* range-wide remained relatively stable over this time interval (USFWS 2006f, Figure 8). We consider this range-wide data to be the best available at this time.

Habitat Quality

Vegetation community data are collected as one component of *Lepidium papilliferum* HIP monitoring. One of the attributes documented in HIP monitoring is the fire history pattern. Observations are recorded to document if there is evidence of fires at four landscape scales; in the HIP transects, and in the surrounding habitat at 65 meters, 250 meters, and 500 meters from the transect. Given the mosaic pattern of wildfire burns, often the surrounding habitat may be burned while an individual HIP transect is unburned or predominately unburned. In 2004, vegetation communities were sampled at 71 HIP transects, and 41 (58 percent) of the transects were classified as unburned, with predominantly big sagebrush cover and less than 33 percent introduced annual cover; 7 (10 percent) were classified as unburned, with moderate big sagebrush cover and at least 33 percent introduced annual cover; 6 (8 percent) were classified as burned, with predominantly native vegetation, although introduced annual cover sometimes comprised up to 50 percent of the total plant cover; 2 (3 percent) were classified as burned, with predominantly introduced annual cover (*Salsola kali* (Russian thistle or tumbleweed) and *Ceratocephala testiculata* (bur buttercup, formerly *Ranunculus testiculatus*)), with low cheatgrass (*Bromus tectorum*) and some crested wheatgrass (*Agropyron cristatum*); 11 (14 percent) were classified as burned and dominated by cheatgrass; and 4 (6 percent) were classified as burned and seeded with crested wheatgrass (Colket 2005a, p. 8). In summary, over 42 percent of the HIP vegetation plots along HIP transects were in habitats with over 33 percent nonnative, invasive plant cover.

Menke and Kaye (2006b) evaluated the association between measures of habitat quality measured by HIP and abundance of *L. papilliferum*. For the one year for which data were available (2004), they report that *L. papilliferum* abundance was not significantly correlated with soil crust cover or weedy species cover in slickspots, and that the proportion of flowering plants had a positive correlation with soil crust cover, but was not significantly correlated with livestock print cover or weedy species cover (Menke and Kaye 2006b, p. 15). In their overall evaluation of habitat condition, they report that total vascular plant cover, species richness, and species diversity had declined between 1998 and 2004, and suggest that past fires have been a factor in degrading slickspot condition (Menke and Kaye 2006b, p. 19). Several features of slickspots, including soil crust cover and weedy species cover, were consistently more degraded in burned areas. Although slickspots in burned areas had more dense weedy annual species cover (Menke and Kaye 2006b, p. 19), Menke and Kaye state that ''Competition from weedy annual species (which may be promoted by fire), does not appear to influence abundance of *L. papilliferum* plants in a given year, but may influence reproductive output, other plant traits, and other life history stages' (Menke and Kaye 2006b, p. 17). Soil crust cover was significantly lower in 2004 transects with evidence of livestock grazing, but there was no direct relationship between abundance of *L. papilliferum* and total livestock print cover or cover of print penetrating to the slickspot clay layer (Menke and Kaye 2006b, p. 15).

Another measure of habitat quality within *Lepidium papilliferum*'s range is the EO ranking by the Idaho CDC. The first EO ranks for *L. papilliferum* were assigned in 1993 (Colket *et al.* 2006, Tables 1–13). In 2006, EO specifications and ranking were revised by the Idaho CDC (Colket *et al.* 2006, pp. 15 to 44). Due to the change in methodology, it is difficult to draw conclusions about changes in EO rankings over time. EO ranks are designed as an assessment of estimated viability or probability of persistence and help prioritize

conservation planning or actions (NatureServe 2002, p. 36). We consider EO rankings to be part of the best available data on the species at this time.

Table 1 summarizes the rankings for 85 EOs based on the 2006 revised methodology. A-ranked EOs have one or more of the following conditions that are summarized through a formula: (1) Over 1,000 detectable above-ground plants; (2) intact native plant communities with trace nonnative species cover; (3) slickspots with zero or trace nonnative cover or livestock disturbance; (4) zero or few minor anthropogenic disturbances; (5) a lack of burning; and (6) a surrounding landscape within 0.6 mi (1 km) that is not fragmented by agricultural lands, residential or commercial development, introduced annual grasslands, or drill seeding projects (Colket *et al.* 2006, p. 3). By contrast, D-ranked EOs exist in the most highly degraded habitats, with the fewest plants, and with the most degraded surrounding landscape (Colket *et al.* 2006, p. 3).

TABLE 1.—NUMBER OF ELEMENT OCCURRENCES IN 2006 BY CDC RANKING (PERCENT OF TOTAL)

[Colket *et al.* 2006, Tables 1 to 13 and Appendix C]

A	B	BC	C	pC [1]	D	pD [1]	E [2]	F	Total
0	15 (18)	1 (1)	26 (31)	4 (5)	19 (22)	1 (1)	10 (12)	9 (11)	85

[1] Probable ranks assigned when incomplete information available.
[2] Not enough habitat information available to make a ranking.

Of the 66 EOs with B through D rankings (13,123 ac (5,310 ha)), 51 occur on the Snake River Plain (10,804 ac (4,372 ha)), and 15 on the Owyhee Plateau (2,318 ac (938 ha)). Of these 66 middle-ranked EOs, 50 are ranked as a C or D (averaging fewer than 399 plants, partial to nonexistent native plant communities that are partially to predominately burned, and partially to predominantly fragmented landscapes). The 40 EOs on the Snake River Plain cover 3,170 ac (1,283 ha), and the 10 EOs on the Owyhee Plateau cover 73 ac (30 ha).

Habitat data (HII, HIP) have been collected annually for approximately one-half of the extant EOs since 1998. Given that monitoring methodologies and the specifications for determining EO rank changed in 2004/2005, and not every EO is monitored annually, it is not possible to draw definitive conclusions about the change in habitat quality over time. It is possible, however, to gain an understanding of the current condition of habitat quality from the available data. Based on the most recent EO ranks, at least 75 percent (n = 49) were ranked as C, D, or F, indicating that most EOs occurred in partially or predominantly fragmented landscapes with partial to nonexistent native plant communities. As discussed below we don't have any data that correlate *L. papilliferum* population numbers with effects to habitat.

Previous Federal Actions

For a description of Federal actions concerning *Lepidium papilliferum* that occurred prior to January 22, 2004, please refer to the document to withdraw our July 15, 2002, proposal published in the **Federal Register** on January 22, 2004 (69 FR 3094).

On January 22, 2004, we published a document withdrawing our proposed rule to list *Lepidium papilliferum* as endangered (69 FR 3094). That action was based on our conclusion that there was ''a lack of strong evidence of a negative population trend, and the formalized conservation plans (*e.g.*, the CCA and INRMPs) had sufficient certainty that they would be implemented and effective such that the risk to the species was reduced to a level below the statutory definition of endangered or threatened.''

On April 5, 2004, Western Watersheds Project filed a lawsuit challenging our decision to withdraw the proposed rule to list *Lepidium papilliferum* as threatened or endangered (*Western Watersheds Project* v. *Jeffery Foss, et al.*, Case No. CV 04–168–S–EJL). On August 19, 2005, the U.S. District Court for the District of Idaho reversed the decision to withdraw the proposed rule, with directions that the case be remanded to the Secretary of the Department of Interior for reconsideration of ''whether a proposed rule listing the slickspot peppergrass as either threatened or endangered should be adopted.''

After issuance of the District Court's remand order, we notified Federal, State and local agencies, county governments, elected officials, and other interested parties of the Court's decision in a letter dated October 13, 2005. We requested new scientific data and comments about *Lepidium papilliferum.* We also stated that scientific data received from the public would be included in an updated ''Draft Best Available Biological Information for Slickspot Peppergrass (*Lepidium papilliferum*)'' (BAI) document. In response to our request, we received a total of 13 comment letters. The updated BAI combined all existing and new information about the species and its habitat, and we utilized it in making this final listing determination.

On February 27, 2006, we opened a 30-day public comment and peer review period, through an electronic process referred to as VOCUS, for our comprehensive document entitled ''Draft Best Available Biological Information for Slickspot Peppergrass (*Lepidium papilliferum*)'' (USFWS 2006f). Following public and peer review, we used new data and technical corrections, along with existing data, for our analysis described below as the best available scientific and commercial data.

After an order by the district Court on October 4, 2006, which requires ''a final listing determination on the slickspot peppergrass by January 4, 2007,'' we opened a 22-day public comment period that closed on November 13, 2006 (71 FR 62078). A variety of documents were posted on the FWS Web site for public comment, including peer review comments on the draft BAI and results of the expert panel.

Summary of Comments and Responses

We received a total of 13 comment letters in response to our October 13, 2005, request for additional information to assist with the listing determination for *Lepidium papilliferum;* 17 public comment letters and 19 peer review responses on the Draft BAI released on February 27, 2006; and 20 public comment letters in response to our October 23, 2006, reopening of the public comment period. The majority of comments were specific to the draft BAI and associated data as well as issues surrounding the 2003 CCA developed to conserve *L. papilliferum.* Comments that were substantive or that provided new information were incorporated into the final determination where appropriate, or are addressed below. We consolidated the comments into categories by issue.

Issue 1: Several commenters provided new data and information regarding the biology, ecology, life history, genetics, and factors affecting *Lepidium papilliferum*, and requested that it be incorporated into the body of existing knowledge concerning the species and considered by us in making any future management determinations.

Our response: In making this final listing determination, we have considered scientific and commercial data contained in over 75 technical reports, published journal articles, and other general literature documents, including nearly 30 reports received since the January 23, 2004. The body of available information specific to this species has greatly expanded since 2004, with new information regarding species locations, known condition of its habitat, slickspot soil characteristics and disturbance, *Lepidium papilliferum's* pollinators, seed viability and germination, ongoing conservation efforts, genetics, and factors affecting the species. This information was contained in various State agency reports (Colket 2005a; Colket 2006; Colket *et al.* 2006; IDARNG 2005; State of Idaho *et al.* 2006) and other scientific reports and peer reviewed articles (Menke and Kaye 2006a, b; Meyer and Allen 2005; Meyer *et al.* 2005; Meyer *et al.* 2006; Palazzo *et al.* 2005; Robertson 2003a; Robertson and Klemesh 2003; Robertson and Ulappa 2004; Robertson *et al.* 2005; Stillman *et al.* 2005). Additionally, we reviewed and considered data from ongoing *L. papilliferum* conservation efforts (Binder 2006; Boise Airport 2003; Hoffman 2005; IDARNG 2005; State of Idaho *et al.* 2006; U.S. Air Force 2004). Further research and continued monitoring would provide a more thorough understanding of the species; however, we have a legal obligation to make a final listing determination based on the best available scientific and commercial data.

Issue 2: Some commenters stated that an urgent need to list *Lepidium papilliferum* exists due to ongoing and current threats. One commenter suggested that there is evidence for widespread and rapid population decline. Another commenter stated that the species is at such risk of extinction that it should be listed to ensure that the BLM and other Federal land management agencies implement management actions that result in substantive conservation. Other commenters stated that existing regulations are insufficient in providing for the long-term persistence of the species. Conversely, some commenters stated that existing regulatory mechanisms, primarily through the CCA and its associated conservation measures, are sufficient or more than sufficient to preclude the need to list *L. papilliferum* under the Act.

Our response: The Act requires us to make listing decisions based solely on the best scientific and commercial data available at the time the decision is made (section 4(b)(1)(A) of the Act). We thoroughly reviewed all available scientific and commercial data for *Lepidium papilliferum* in preparing this final determination. We reviewed historical and recent publications, and unpublished reports concerning *L. papilliferum* and the sagebrush-steppe habitat of southwestern Idaho. From this information, we produced the document ''Draft Best Available Biological Information for Slickspot Peppergrass (*Lepidium papilliferum*)'' (BAI); we solicited public comment and peer review on the BAI in February 2006. We also convened a panel of seven scientific experts to review the scientific information available to us pertaining to *L. papilliferum*. Additionally, we reopened the public comment period on the proposed rule in October 2006 (71 FR 62078) to solicit additional review and comment on new data that we have considered in this final determination.

We followed our Policy on Information Standards Under the Endangered Species Act, published in the **Federal Register** on July 1, 1994 (59 FR 34272), and our associated Information Quality Guidelines in preparing this final determination. Our evaluation of the significance of these numerous ongoing threats across the range of *Lepidium papilliferum* is presented in the Summary of Factors Affecting the Species section of this final determination. This analysis includes the adequacy of existing regulatory mechanisms, including public land management practices. During the listing process, we provided 6 public comment periods that were open for a total of 262 days, and held 2 public hearings. We received new information since the proposed rule specific to *L. papilliferum* that ranged from additional Idaho CDC survey data to slickspot soils information. While the body of available information specific to this species is limited, our legal obligation is to make a final listing determination based on the best available data.

Issue 3: Several comments regarded the effectiveness of the CCA (first approved in 2003 and subsequently revised in 2006) in conserving *Lepidium papilliferum.* Some commenters stated that the voluntary commitment of non-governmental cooperators developed during the CCA process is equal to or better for conservation of *L. papilliferum* than mandated actions that would be associated with listing the species. One commenter suggested that the commitment to better livestock grazing management by the *L. papilliferum* Conservation Committee and permittees continues, and is still strong after 2 years of implementation, and that the follow-through on implementing CCA conservation measures, such as responding to grazing triggers and off-highway vehicle (OHV) events during 2005, was good. The State of Idaho reported that, of the 203 conservation measures identified in the CCA, 193 were accomplished in either 2004 or 2005, and 7 measures were not implemented due to wildfire or ongoing litigation. One commenter stated that the inclusion of an adaptive management process within the CCA will ensure that the identified conservation measures, if initially ineffective, would become effective well before the probable extinction of *L. papilliferum* given existing threats. The U.S. Air Force provided comments on our October 23, 2006 draft description and analysis of conservation measures (71 FR 62078). The U.S. Air Force believed that several more conservation measures have been implemented and are effective in conserving *L. papilliferum* at the Juniper Butte Range than what we had determined.

Conversely, some comments suggested that there is little certainty that implementation of *Lepidium papilliferum* conservation measures identified in the CCA will occur. One commenter stated that the adaptive management approach used in the CCA provides no certainty of protection for *L. papilliferum.* Another commenter suggested that any cooperator can drop out of the CCA at any time without repercussion. Another comment asserted that the adaptive management approach as currently described in the CCA allows for a one-time disturbance event that could result in irreversible harm to L. *papilliferum habitat.* Comments indicated that the CCA provides vast opportunity for a one-time livestock penetrating trampling event to occur, and is therefore insufficient. Other comments suggested that the CCA does not protect *L. papilliferum* and its habitat from soil disturbance, and did not include active restoration measures for the vast majority of the species' habitats. Commenters stated that, due to the downward trend in *L. papilliferum* abundance, reintroduction of the species should be considered. One commenter stated that management

under an Instruction Memorandum (IM) is uncertain, and that because the IM is not a legal requirement, interpretation will be inconsistent among field staff.

Our response: We support utilizing a collaborative conservation approach to address factors affecting species being considered for listing under the Act. Prior to July 18, 2003, we worked with various agencies and individuals to assess the status of *Lepidium papilliferum,* and also to identify and implement conservation actions. Since February 2000, we have been an active technical advisor in an interagency group of biologists and stakeholders to share data and coordinate conservation actions for *L. papilliferum.*

Using our Policy for Evaluation of Conservation Efforts When Making Listing Decisions (PECE) (68 FR 15100), we reviewed the conservation measures in five plans, or conservation strategies, for *L. papilliferum:* (1) The Candidate Conservation Agreement for Slickspot Peppergrass (CCA), which was initially approved in 2003 and revised in 2006; (2) the Idaho Army National Guard Integrated Natural Resource Management Plan for Gowen Field/ Orchard Training Area; (3) the U.S. Air Force Integrated Natural Resource Management Plan for Mountain Home Air Force Base, which was modified in 2004 and contains more measures that promote the conservation of *L. papilliferum* than the 2000 version; (4) the Conservation Agreement (Hull's Gulch Agreement) by and between Boise City and the U.S. Fish and Wildlife Service for *Allium aasea* (Aase's onion), *Astragalus mulfordiae* (Mulford's milkvetch), and *Lepidium papilliferum* (slickspot peppergrass), which was in place until it expired on October 22, 2006, and (5) the Conservation Agreement for slickspot peppergrass (*Lepidium papilliferum*) at the Boise Airport, Ada County, Idaho. These five agreements and plans include a wide array of conservation measures to address the need to maintain and enhance slickspot peppergrass, and to potentially avoid or reduce adverse effects that might occur in relation to various types of activities. We recognize that many of the conservation efforts identified in the plans are having conservation benefits for the species, particularly as they relate to limiting the effects of wildfire and livestock use. We believe conservation efforts are important for this species because, while we do not have sufficient information to determine that potential threats are having a population level impact on the species, further research is necessary. To the extent that there are effects from activities, these conservation efforts should offset them.

We evaluated conservation efforts within each plan under PECE (60 FR 15100). PECE is relevant in situations where it is necessary to determine whether individual conservation efforts that have not been implemented, or that have been implemented but have not yet demonstrated whether they are effective, are sufficiently certain to be implemented and effective so as to have contributed to the elimination or adequate reduction of one or more threats to the species identified through our threats analysis conducted pursuant to section 4(a)(1) of the Act. In this case, the efforts that met the standard in PECE for sufficient certainty of implementation and effectiveness were not used as a basis for our conclusion, because our analysis did not show that the species met the definition of threatened or endangered. However, this does not mean that conservation efforts which have yet to be implemented, or which have yet to be demonstrated to be effective, are unimportant. In fact we strongly encourage continued implementation of all on-going and planned conservation efforts, as they can contribute to maintaining or improving the status of *L. papilliferum.*

Issue 4: There were several comments regarding the use of available monitoring and survey data in determining the historical and existing distribution, population size, and trend information for *Lepidium papilliferum.* One commenter suggested there have been no comprehensive systematic surveys for *L. papilliferum,* and therefore, we do not fully understand the distribution or status of the species. Numerous commenters stated that monitoring protocols and methods used to gather data regarding *L. papilliferum* trends and distribution were biased toward documenting declines, were insufficient, or were poorly timed, and therefore conclusions are poor. Several commenters stated that there is no clear relationship between *L. papilliferum* trends and threat factors affecting the species. Some commenters suggested that the data demonstrate a negative population trend for *L. papilliferum;* other commenters suggested the data are inconclusive, and no trend can be determined. One commenter thought the trend from 2004 to 2005 was positive or stable due to implementation of the CCA, a wet spring, and a minimal wildfire season. Another commenter identified that the number of extant EOs have increased from 45 in 1998 to 85 in 2006, and there has been only 1 EO that has been extirpated since 1955. Several commenters cited information relating *L. papilliferum* annual abundance to precipitation, while other commenters disputed the claim that annual abundance is related to precipitation. Several commenters stated that the number of element occurrences has increased from 1998 (45 extant EOs) to 2006 (85 extant EOs).

Several commenters thought that the soil type (slickspots) used by *Lepidium papilliferum* is a limited resource that is not reforming, because the processes that originally created it no longer occur. Slickspots being modified, altered, or developed are lost to the ecosystem forever.

Our response: In this determination, we have reviewed and considered scientific and commercial data contained in over 75 technical reports, published journal articles, and other documents, including nearly 30 reports received since January 22, 2004. We must base our listing determination for *Lepidium papilliferum* on the best available data regarding the plant's current known population status, the known condition of its habitat, and the current factors affecting the species, along with ongoing conservation efforts, as described in the Summary of Factors Affecting the Species section of this final determination. We also acknowledge that uncertainties exist.

While a systematic survey, utilizing similar techniques, has not been conducted for *Lepidium papilliferum* range-wide, at least 30 separate survey efforts for *L. papilliferum* have occurred (Baczkowski 2006; USFWS 2006d). Some of these surveys were within the known range of *L. papilliferum* habitat, and others were outside of the known distribution, for example, in the State of Oregon, in the Saylor Creek area between the Snake River Plain and the Owyhee Plateau, and the City of Hagerman. In 2003, for example, 2,350 acres were surveyed in the Saylor Creek area between the Snake River Plain metapopulations and the Owyhee Plateau metapopulations. During these surveys, 1,727 slickspots were documented, but no *L. papilliferum* individuals were found (U.S. Air Force 2003, p. 16). We agree that undiscovered sites occupied by *L. papilliferum* likely exist. Inventories for *L. papilliferum* have not been completed on the majority of private lands within its range due to restricted access. Recent discoveries of new occupied slickspot sites and new EOs since 1998 have not added substantially to our knowledge of where the species exists. For example, an inventory survey at the OTA in 2005 found 365 new slickspots with *L. papilliferum* all within the range of known habitat on the OTA (URS

Corporation 2005, p. 6). Since 2003, 16 new EOs on approximately 50 ac (28 ha) (0.4 percent of the total acreage) have been documented, all within 3 mi (4.8 km) of previously existing EOs (Colket *et al.* 2006, Tables 1 to 14). Although there has been only one documented extirpation since 1955, up to 9 small and isolated EOs had no plants detected during one or more recent monitoring surveys.

Numerous monitoring efforts have been conducted for *Lepidium papilliferum,* including population trend monitoring transects at the OTA (IDARNG 2005) completed since 1991, demographic monitoring at the OTA from 1993 to 1996 (Meyer *et al.* 2005), Habitat Integrity Index (HII) monitoring done by the Idaho CDC at *L. papilliferum* EOs range-wide conducted from 1998 to 2002 (Mancuso and Moseley 1998; Mancuso *et al.* 1998; Mancuso 2000; Mancuso 2001; Mancuso 2002), Habitat Integrity Population (HIP) monitoring built on HII monitoring at *L. papilliferum* EOs range-wide conducted by the Idaho CDC in 2004 and 2005 (Colket 2005a, Colket 2005b), and monitoring done at the Juniper Butte Range in 2003 and 2005 (U.S. Air Force 2003). HIP monitoring, the most extensive range-wide effort to date, was developed by the Idaho CDC in conjunction with the *L. papilliferum* Technical Team to statistically analyze and detect trends in *L. papilliferum* and its habitat (the technical team includes IDARNG, BLM, Air Force, the Service, Idaho Department of Agriculture, and other interested parties) (Colket 2005a, p. 3). Both the HII and HIP monitoring, because of the difficulties associated with tracking numbers of *L. papilliferum* individuals across years, utilize habitat information as a metric of *L. papilliferum* health (Mancuso *et al.* 1998, pp. 1 to 7).

Because of the fluctuations in *Lepidium papilliferum* numbers associated with precipitation (Meyer *et al.* 2005, pp. 4, 12, 15; Palazzo *et al.* 2005, p. 9; Menke and Kaye 2006b, p. 10), determining trends requires long-term monitoring data sets. Two long-term monitoring data sets in which we see a downward trend in recent years in numbers of individuals that do not mimic precipitation are the population trend monitoring transect data and special use plot data at the OTA. In contrast, an analysis by Palazzo *et al.* (2005, p. 9) for all 4 years of HII data found a relationship (p-value less than 0.01) between February to June precipitation and numbers of *L. papilliferum*. In their analysis of range-wide HII and HIP data collected from 1998–2002 and 2004 (no data was collected in 2003), Menke and Kaye (2006b, p. 10) further refined this relationship and found a strong positive relationship between precipitation from March through May and *L. papilliferum* abundance. In contrast to the monitoring data from OTA, the range-wide data shows that *L. papilliferum* continues to track consistently with precipitation throughout all years of the data set (Menke and Kaye 2006b, p. 10 and Figs. 1, 2). We consider this range-wide data to be the best available at this time.

The conditions that allowed for the formation of slickspots in southwestern Idaho are thought to have occurred during a wetter Pleistocene climate (Nettleton and Petersen 1983, p. 191; Seronko 2006). Under natural conditions, several hundred years may be necessary to alter or lose slickspots, generally through climate change or severe natural erosion (Seronko 2006). Meyer and Allen (2005, p. 9) suggest that if sufficient time passes following the disturbance of slickspot soil layers, it is possible that slickspots can reform similar to their pre-disturbance configuration.

Issue 5: Numerous commenters provided information or opinions regarding how various threats may or may not affect *Lepidium papilliferum*, its habitat, and its possible probability of extirpation. Threats specifically mentioned included residential, commercial, and agricultural development; military training; OHV use; nonnative, invasive plant species; wildfire; wildfire rehabilitation methods (including drill seeding and invasive, nonnative plant seedings); fragmentation; soil disturbance; herbicide spraying; wildlife grazing; herbivory; and agricultural pesticides (*e.g.*, insecticide for grasshoppers or Mormon crickets) affecting *L. papilliferum* pollinators. One commenter suggested that the decreased quality of sagebrush grassland (steppe) habitat is the primary problem with the apparent decline of *L. papilliferum*.

Our response: Our evaluation of the significance of the various threats across the range of *Lepidium papilliferum* is discussed in the Summary of Factors Affecting the Species section of this final determination. We analyzed the adequacy of existing regulatory mechanisms, including the effectiveness of ongoing, recently implemented, and proposed conservation efforts that attempt to conserve *L. papilliferum* in three conservation agreements, and two INRMPs from the IDARNG and the U.S. Air Force. The primary factors impacting *L. papilliferum* and its surrounding habitat include habitat degradation and modification of the sagebrush-steppe ecosystem from the current wildfire regime (i.e., increasing frequency, size, and duration of wildfires), invasion of nonnative weed species (*e.g.*, cheatgrass), effects of livestock use (*e.g.*, trampling and disruption of soils), and habitat loss due to agricultural and urban development. Less important factors that may affect the species include effects from rangeland revegetation projects, wildfire management practices, recreation, and military use. Herbivory is reported as sparse or at low levels, and is mainly by insects. Herbivory impacts to *L. papilliferum* from native ungulates such as elk, deer, and antelope have not been observed. However, pronghorn antelope tracks and droppings (U.S. Air Force 2003, p. 14), and elk tracks and droppings (State of Idaho *et al.* 2006, Appendix A) have been infrequently documented in slickspots that support *L. papilliferum*. Herbicide spraying was not considered by the Expert Panel to be an important threat to *L. papilliferum*, and is not discussed in this listing determination. While the decreased quality of sagebrush-steppe and the development and implementation of successful habitat restoration may impact the species, we have found no correlation to date between the existence of these threats and population numbers.

Issue 6: Several comments referred to the effects of livestock use on *Lepidium papilliferum* and its habitat. They suggested that livestock use (past, current, or future) adversely affects *L. papilliferum* by trampling and uprooting individual plants, transporting nonnative invasive seeds, disturbing slickspot habitat soil crusts, burying *L. papilliferum* seeds to a soil depth at which germination cannot occur, accelerating erosion of slickspots, compacting soils, and changing slickspot soil chemistry through the deposition of manure.

Conversely, several commenters suggested that livestock use has minimal effects and can even provide beneficial effects to *Lepidium papilliferum* and its habitat. One commenter suggested that only three documented examples exist in which livestock use has been implicated as the primary factor in either a reduction or elimination of *L. papilliferum* from a given area. In each case, the incident was isolated and occurred prior to implementation of the CCA. Several commenters suggested that *L. papilliferum* co-evolved with historical livestock use and wild ungulate grazing pressure; therefore the impact of existing livestock use is as likely to be

beneficial as it is to be adverse, although effects generally remain unknown. Commenters suggested that potential benefits to *L. papilliferum* from livestock use include reduced frequency, intensity, and magnitude of wildfire; reduced nonnative invasive annual grasses; and improved germination of *L. papilliferum* seeds as a result of abrasion and reduced physical resistance of the surface soil crust. One commenter suggested that without authorized livestock grazing permits on Federal lands, some conservation benefits would not occur, including weed control, wildfire suppression, habitat rehabilitation, and a ready source of information regarding the land upon which ranchers run their livestock. Other commenters suggested that insufficient information exists, so we cannot draw conclusions regarding the effects of livestock use on *L. papilliferum* and its habitat.

Our response: The most visible effect on *Lepidium papilliferum* and its slickspot habitat from livestock use is trampling impacts. Penetrating trampling is defined as livestock trampling of water-saturated slickspot soils that break through the restrictive soil layer (see Ecology and Habitat section above). Penetrating livestock trampling can affect the fragile soil layers of slickspots (Meyer *et al.* 2005, pp. 21, 22; Seronko 2004, pp. 1, 2), especially when it occurs during wet periods when slickspots are most vulnerable to disturbance. Penetrating trampling also potentially affects the seed bank for *L. papilliferum* by pushing the seeds below their ability to germinate (i.e., below 1.5 in (3 cm)) (Meyer *et al.* in press, pp. 3, 24, 25). Livestock use at an appropriate level, and during dry conditions, may reduce the spread of nonnative annual grasses at some *L. papilliferum* sites. However, using livestock to control nonnative annual grasses would need to occur during early spring when the grasses are growing strongly, and spring is when slickspots are most likely to be wet and most susceptible to damage. Responsive management, involving quickly removing livestock during rain events and moving them regularly to prevent soil disturbance, would be difficult over large areas.

Livestock use has been documented (Colket *et al.* 2006, Appendix C) within 62 of the 75 *Lepidium papilliferum* EOs for which habitat information has been collected (49 of 60 on the Snake River Plain and 13 of 15 on the Owyhee Plateau). Penetrating hoof prints have been documented within 21 EOs on the Snake River Plain, and 9 on the Owyhee Plateau (Colket *et al.* 2006, Appendix C).

Data limitations have made it difficult to establish impact (or effect) thresholds from livestock management activities for *Lepidium papilliferum*. Based on a single year of HIP data (2004), there was no correlation between *L. papilliferum* abundance in the short-term and total livestock print cover or cover of prints penetrating to the slickspot clay layer (Menke and Kaye 2006b, p. 15). The HIP data are observational in nature; controlled experiments are needed to more accurately assess the effects of livestock on *L. papilliferum* and its habitat. At this time we have no data that long-term declines in abundance will arise from livestock grazing. Adaptive management techniques for areas occupied by *L. papilliferum* and affected by livestock use could result in new information from ongoing and proposed livestock use studies and monitoring conservation efforts for the species. We anticipate that additional information regarding *L. papilliferum* and livestock use, from research currently underway by the U.S. Air Force and University of Idaho will be available for use in species conservation.

A more complete discussion on the effects of livestock use on *Lepidium papilliferum* and its habitat is found in the Summary of Factors Affecting the Species section.

Issue 7: One commenter suggested that wildfire historically (prior to European influence) occurred on a 60- to 100-year frequency and resulted in small burned areas where wind erosion could scour slickspots, maintaining the thin silt layer on the slickspot and the mini-playa as a depression. Wind scour likely occurred, since the only species growing on the slickspot was *Lepidium papilliferum*. With exotic species currently occupying slickspots, wind erosion may not be effectively scouring them, and in fact, deposition may be occurring. One commenter suggested that historical wildfire intervals in Wyoming big sagebrush communities were much longer, and some areas rarely, if ever, burned.

Conversely, one commenter stated that while an abundance of information exists regarding wildfire in *Lepidium papilliferum* habitat, no long-term monitoring data confirmed the significance of its effect on *L. papilliferum*.

Our response: As previously stated in the July 15, 2002, proposed rule (67 FR 46441) and January 22, 2004, document to withdraw the proposed rule (69 FR 3094), wildfire affects *Lepidium papilliferum* EOs throughout the species' range. Where habitat information is known, 42 of 60 EOs on the Snake River Plain and 6 of 15 on the Owyhee Plateau have been at least partially burned; 57 EOs on the Snake River Plain and 12 on the Owyhee Plateau have adjacent landscapes that are at least partially burned (Colket *et al.* 2006, Appendix C).

Current research indicates wildfire frequency in the sagebrush-steppe ecosystem throughout the range of *Lepidium papilliferum* has increased, from a historical average of once every 60 to 110 years to once every 5 years at many sites, due to the invasion of nonnative annuals such as cheatgrass that became common on the Snake River Plain rangelands in the 1950's (Wright and Bailey 1982, p. 158; Billings 1990, pp. 307 to 308; Whisenant 1990, p. 4; USGS 1999, pp. 1 to 9; West and Young 2000, p. 262). Wildfires in cheatgrass tend to be larger, burn more uniformly, and leave fewer patches of unburned vegetation, all of which influence the post-fire recovery of native sagebrush-steppe vegetation (Whisenant 1990, p. 4). The result of this altered wildfire regime has been the conversion of vast areas of the former sagebrush-steppe ecosystem into nonnative annual grasslands (USGS 1999, pp. 1 to 9). Frequent wildfires can also promote soil erosion and sedimentation (Bunting *et al.* 2003, p. 82) in arid environments such as the sagebrush-steppe ecosystem. Increased sedimentation can result in a silt layer that is too thick for optimal *L. papilliferum* seed germination (Meyer and Allen 2005, pp. 6 to 7), and that allows weedy species to invade slickspots. See the Summary of Factors Affecting the Species section for a more complete discussion.

Following wildfire events, the use of nonnative forage grass species (such as crested wheatgrass and Russian wildrye (*Elymus junceus*)) for rehabilitation can result in successful establishment of perennial plants, ultimately reducing and diminishing the impacts of cheatgrass and its accelerated wildfire frequency. The use of nonnative species that closely mimic the biology and ecological function of species native to the area may be a necessary first step in restoring a site following wildfire if native seed cannot be used due to limited availability or prohibitive cost.

Of the known *Lepidium papilliferum* occurrences, 14 (19 percent) are located within areas where wildfire rehabilitation projects and crested wheatgrass seedings have occurred (Colket *et al.* 2006, Appendix C). Although *L. papilliferum* still occurs in these areas, most support lower numbers of plants (Mancuso and

Moseley 1998). See ''Factor A'' in the Summary of Factors Affecting the Species section below for a more detailed discussion.

In a review of available information, the Expert Panel considered the current wildfire regime the most important factor affecting *Lepidium papilliferum* and its remaining habitat.

Issue 8: One commenter expressed concerns regarding the U.S. Air Force's development of the Juniper Butte Range (beginning in 1998) on the Owyhee Plateau where *Lepidium papilliferum* and its habitat occur. Development and use of this training range, along with resulting road construction, human presence, and proposed use of aerial flares/white phosphorus munitions during training exercises, has increased the risk of wildfire within a substantial portion of *L. papilliferum*'s range.

Our response: Currently, the impact of military training activities does not represent a principal threat to *Lepidium papilliferum*. Both the IDARNG and U.S. Air Force are implementing conservation efforts that potentially avoid or reduce adverse effects of military training on the species and its habitat. Threats from military activities are localized and have little significance across the range of the species.

Military activities within the range of *Lepidium papilliferum* include ordnance use, facility development, and transportation, all of which create an increased risk of wildfire and nonnative plant invasions. Military training occurs on the Snake River Plain at the OTA, on all or portions of seven EOs, and on the Owyhee Plateau at the Juniper Butte Range on a portion of one EO (sub EO 704). The U.S. Air Force intends to use 300 ac (121 ha) of the 11,070-acre Juniper Butte Range as the actual bombing impact area (U.S. Air Force 2000). It anticipates that a small amount of ordnance will be dropped outside the bombing impact area, but the potential impact to *L. papilliferum* would likely be minimal.

The Integrated Natural Resource Management Plan (INRMP) developed for the Juniper Butte Range provides management directions that ameliorate many of the threats from military training exercises. Range-wide, the most intact *Lepidium papilliferum* habitat occurs at the OTA, where similar conservation efforts have been implemented for 14 years (Colket *et al.* 2006, pp. 22 to 23; Meyer 2005, p. 1). The IDARNG has implemented a variety of actions to meet the conservation needs of *L. papilliferum*, while still providing for military training activities. These actions include wildfire suppression efforts, and restricting ground-operated military training to areas where the plants are not found.

Issue 9: Some commenters asserted the taxonomic status of *Lepidium papilliferum* is problematic and warrants further evaluation. For example, one commenter suggested that our failure to complete a genetic study of *Lepidium montanum* seriously flaws any discussion assessing *L. papilliferum* as a species on its own. A few commenters suggested that if *L. papilliferum* is a subspecies or variety it is not eligible for protection under the Act.

Our response: Lepidium papilliferum was originally described as *L. montanum* var. *papilliferum* in 1900 by Louis Henderson. It was renamed *L. papilliferum* by Aven Nelson and J. Francis Macbride in 1913 based on its distinctive growth habit, short lifespan, and unusual pubescence (Nelson and Macbride 1913, p. 474). Hitchcock regarded *L. papilliferum* as *L. montanum* var. *papilliferum*, influencing several publications including *Flora of Idaho* and *Flora of the Pacific Northwest* (Hitchcock *et al.* 1964, p. 516; Hitchcock and Cronquist 1973, p. 170; Steele 1981, p. 55; Moseley 1994, p. 2). In a review of taxa in the mustard family (Brassicaceae), Rollins (1993) maintained the species based on differences in the physical features between *L. papilliferum* and *L. montanum* such as: (1) *L. papilliferum* has trichomes (hair-like structures) occurring on the filaments of stamens (part of flower that produces pollen), and *L. montanum* does not; (2) all the leaves on *L. papilliferum* are pinnately divided, and *L. montanum* has some leaves that are not divided; (3) the shape of the silicle [silique] (seed capsule) of *L. papilliferum* is different from that of *L. montanum*; and (4) the silicle of *L. papilliferum* has no wings, or even vestiges of wings, at its apex (end of the capsule), unlike that of *L. montanum* (Rollins 1993, p. 578; Moseley 1994, p. 2).

A review of the taxonomic status by Lichvar (2002), using classic morphological features and study of herbarium specimens, concluded that *L. papilliferum* has distinct morphological features that warrant species recognition. Meyer *et al.* (2005, p. 17) described a life history contrast when compared to *L. montanum* regarding seed dormancy and the seed bank. *L. papilliferum* seeds can remain dormant (and viable) and persist in the seed bank for about 12 years, whereas *L. montanum* has largely non-dormant seeds (Meyer *et al.* 2005, p. 17). Most recently, *L. papilliferum* has been accepted as a distinct species by Intermountain Flora, a recognized regional text (Holmgren *et al.* 2005, p. 259); the U.S. Department of Agriculture's ''PLANTS Database'' (USDANRCS 2006); and the Biota of North America Project, the recognized taxonomic reference for the United States (ITIS 2006).

The preliminary results of two studies on the genetics of *Lepidium papilliferum* recently became available. The first, based on a relatively small sample size and more limited methodology, found that *L. papilliferum* forms a distinct monophyletic group that is most closely related to *L. fremontii* (Smith 2006, pp. 5 to 7 and Fig. 1). The second, utilizing larger sample sizes and additionally applying the methodology of AFLP (amplified fragment length polymorphisms, recognized for greater resolution or discriminatory power in detecting genetic differentiation) (Mueller and Wolfenbarger 1999, pp. 389 to 393; Savelkoul *et al.* 1999, p. 3085)), found that *L. papilliferum* forms a distinct monophyletic group or subgroup, and indicates that it is most closely related to *L. montanum* var. montanum (Larson *et al.* 2006, p. 13, 15, and Fig. 4). These genetic studies are consistent with the interpretation that *L. papilliferum* is either a variety or subspecies of *L. montanum*, or that it is a full and distinct species that has recently diverged from *L. montanum*. Plant species and subspecies (or varieties) are eligible for protection under the Act.

Issue 10: One commenter stated that very little scientific research has been conducted on *Lepidium papilliferum*, and subsequently very little peer-reviewed literature is available for the species. Most of the information we have is based on technical reports and personal communications.

Our response: The Act requires us to make listing decisions based on the best scientific and commercial data available at the time the decision is made (section 4(b)(1)(A) of the Act). Following the August 19, 2005, Federal Court decision regarding our January 22, 2004, document to withdraw the proposed rule to list *Lepidium papilliferum* as endangered, we sought and received new scientific and commercial data pertaining to the species. We incorporated all relevant new information into the ''Draft Best Available Information (BAI) for Slickspot peppergrass (*Lepidium papilliferum*)'' document, which was updated from the 2003 version. We solicited public comment and peer review on the draft BAI document and requested additional scientific data pertaining to the species. We followed

our Information Quality Guidelines in preparing this final determination (see Information Quality Act discussion below). We also convened a panel of seven scientific experts (see Expert Panel discussion below) to review the available data pertaining to *L. papilliferum* prior to making this final determination.

Information Quality Act

In our review of the status of *Lepidium papilliferum*, we assembled information that addressed the current biological and ecological condition of the plant and its habitats. This information included reports from private industry, public universities, State and Federal resource agencies, published texts on a variety of biological topics, and peer-reviewed literature from the primary scientific journals. Additionally, we included unpublished scientific and commercial data , documents written and included in literature, and personal communications. Personal communications were used when they represented information that was pertinent and not available through other sources such as technical reports or published texts.

We carefully evaluated each piece of data for its usefulness in the review process, and used those that contributed important information to the review. State and Federal government documents are generally considered to be of high utility, objectivity, and integrity. These documents are often subject to public review and comment, and State and Federal agencies generally employ the current standards in resource survey, monitoring, and analysis methodologies. The peer-reviewed scientific literature and scientific textbooks are rigorously reviewed and edited at several levels before publication, and represent the highest degree of utility, objectivity, and integrity.

In compiling this document, we tried to present the information in an accurate, clear, complete, and unbiased manner. Given that the data available on this species covered a wide spectrum from peer-reviewed literature to personal communications, we developed this document with the goal of providing a high degree of transparency regarding the source of data.

We followed our Information Quality Act Guidelines in developing this document. These guidelines provide direction for ensuring and maximizing the quality of information disseminated to the public. The guidelines define quality as an encompassing term that includes utility, objectivity, and integrity. Utility refers to the usefulness of the information to its intended users, including the public. Objectivity includes disseminating information in an accurate, clear, complete, and unbiased manner and ensuring accurate, reliable, and unbiased information. If data and analytic results have been subjected to formal, independent peer review, we generally presume that the information is of acceptable objectivity. Integrity refers to the security of information, i.e., protection of the information from unauthorized access or revision to ensure that the information is not compromised through corruption or falsification.

One of our goals in obtaining public comment and peer review of the draft BAI was to ensure that we were considering the best available data while accurately representing the source of the information. Background information on the taxonomy, distribution, abundance, life history, conservation actions, and needs of *Lepidium papilliferum,* and threats affecting the species, were derived from previous petition findings, previous **Federal Register** notices, Idaho's Conservation Data Center EO records, and other pertinent references from 1897 (when the species was first collected) through 2006.

The supporting information, administrative finding, and other relevant materials can be reviewed in person at the address listed in the **ADDRESSES** section, or copies of information can be made available to you (see References Cited at the end of this rule).

Summary of Factors Affecting the Species

Section 4 of the Act and its implementing regulations (50 CFR part 424) set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act. The five listing factors are: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; and (E) other natural or manmade factors affecting its continued existence.

A. The Present or Threatened Destruction, Modification, or Curtailment of its Habitat or Range

Current Wildfire Regime

The invasion of nonnative plant species, particularly annual grasses such as cheatgrass and medusahead (*Taeniatherum caput-medusae*), beginning in the early 1900's has increased the amount and continuity of fine fuels across the landscape. As cheatgrass became more dominant on the rangelands of the Snake River Plain in the 1950's, wildfire frequency intervals began to shorten from the historic average of between 60 to 110 years to the current frequency intervals of less than 5 years in many areas on the Snake River Plain where *Lepidium papilliferum* resides (Whisenant 1990, p. 4) and within the sagebrush-steppe ecosystem as a whole (Wright and Bailey 1982, p. 158; Billings 1990, pp. 307 to 308; USGS 1999, pp. 1 to 9, West and Young 2000, p. 262). Wildfires tend to be larger and burn more uniformly when annual grasses are present, resulting in fewer patches of unburned vegetation, which can affect the post-fire recovery of native sagebrush-steppe vegetation (Whisenant 1990, p. 4). This altered wildfire regime has contributed to the conversion of vast areas of sagebrush-steppe ecosystem into nonnative annual grasslands (USGS 1999, pp. 1 to 9). More frequent wildfires also promote soil erosion and sedimentation (Bunting *et al.* 2003, p. 82) in arid environments such as the sagebrush-steppe ecosystem. Increased sedimentation can result in a silt layer that is too thick for optimal *L. papilliferum* germination (Meyer and Allen 2005, pp. 6 to 7).

Of the 75 EOs for which habitat information is known, 48 (42 of 60 on the Snake River Plain and 6 of 15 on the Owyhee Plateau) have been at least partially burned, and 69 (57 on the Snake River Plain and 12 on the Owyhee Plateau) have adjacent landscapes that are at least partially burned (Colket *et al.* 2006, Appendix C). Within the Snake River Plain, approximately 448,917 acres (181,670 ha) (28 percent) were burned between 1970 and 2003 (calculated from USBLM 2004). Within the Owyhee Plateau 60,467 acres (24,470 ha) (47 percent) have burned between 1970 and 2003 (calculated from BLM 2004).

Table 3 shows the evidence of wildfire documented through HIP range-wide transect monitoring in 2005. Wildfire evidence can remain on the landscape for up to 20 years, and evidence documented in Table 3 includes both recent and historical fires.

TABLE 3.—EVIDENCE OF WILDFIRE DOCUMENTED AT HIP TRANSECTS IN 2005 (COLKET 2005A, TABLES 1 AND 2)

	Number of transects at least partially burned	Number of transects not burned	Total transects	Adjacent landscapes within 0.31 mi (500 m) of EOs burned or partially burned
Snake River Plain	26	31	57	45
Owyhee Plateau	12	10	22	21
Total	38	41	79	66

In a statistical analysis of HII data between 1998 and 2001, burned areas at the beginning of the study had depleted shrub and soil crust cover that persisted throughout the monitoring period (Menke and Kaye 2006a, p. iii). In addition, burned areas had less native plant cover, greater nonnative plant cover, increased slickspot perimeter compromise, and increased organic debris accumulation (Menke and Kaye 2006a, p. iii). Similarly, in a statistical analysis of HII and HIP data between 1998 and 2004, burned areas had less soil crust cover and higher nonnative plant cover (Menke and Kaye 2006b, p. 3). Although the proportion of flowering plants was positively correlated with soil crust cover, there was no relationship between *L. papilliferum* plant abundance and soil crust cover or weedy species cover in slickspots based on the 2004 HIP data (Menke and Kaye 2006b, p. 15). In their analysis, Menke and Kaye (2006b, p. 17) concluded that competition from weedy annual species does not appear to influence abundance of *L. papilliferum* plants in a given year, although it may influence reproductive output or other traits, and that past fire disturbance does not appear to significantly alter longer-term trends in plant abundance. Past fires have apparently degraded slickspot condition, as evidenced by lower soil crust cover and greater exotic species cover (Menke and Kaye 2006b, p. 19), however *Lepidium papilliferum* abundance was statistically similar between burned and unburned transects from 1998 to 2004 (Menke and Kaye 2006b, p. 10), and the proportion of *L. papilliferum* in flower was similar between burned and unburned transects in 2004 (Menke and Kaye 2006b, p. 15).

Past fires appear to have had a lasting negative impact on the plant community surrounding slickspots, including increased exotic species cover and decreased soil crust cover (Menke and Kaye 2006b, p. 19). Menke and Kaye (2006b, p. 17) note that the HII and HIP data are observational only, and controlled experiments are needed to more accurately assess the impacts of factors such as fire and grazing on *L. papilliferum* (Menke and Kaye 2006b, p. 17). At this point, given the equivocal nature of the habitat integrity and population monitoring data, the effects of an altered sagebrush steppe wildfire regime on *L. papilliferum* need further study. We have no data at this point that indicates that fire has a long-term impact on the species abundance; the available data show no correlation between fire and *L. papilliferum* population numbers.

Existing conservation measures designed to reduce the adverse effects of wildfire apply to approximately 96 percent of *Lepidium papilliferum*'s occupied range. For example, the IDARNG, U.S. Air Force, and BLM will continue their rapid response or mutual support agreement for wildfire control. BLM has established wildfire suppression goals for management areas in the CCA (State of Idaho *et al.* 2006, Table 5).

The military is implementing a number of efforts that address wildfire suppression that have been shown to be effective in certain respects at controlling this threat. However, we are not relying on the implementation of conservation measures to make this finding. Implemented and effective conservation measures will, however, help to counter habitat degradation generally and may help conserve the species. Since the late 1980s, the policies of the IDARNG included immediate wildfire suppression during military activities to prevent damage to intact sagebrush-steppe and *Lepidium papilliferum* sites within the OTA (IDARNG 2004, pp. 65 to 67). Seven occurrences of *L. papilliferum* occur within this area (Colket *et al.* 2006, pp. 8 to 9). Since 2002, the U.S. Air Force has instituted a high-level rapid response for wildfire suppression on the Juniper Butte Range (U.S. Air Force 2004, pp. 6–45 to 6–47). The U.S. Air Force addresses wildfire prevention through reducing standing fuels and weeds, planting fire-resistant vegetation in areas with a higher potential for ignition sources (*e.g.*, along roads), and using wildfire indices to determine wildfire hazard ratings and restricting activities when the rating is extreme (U.S. Air Force 2004, pp. 6–45 through 6–47). The BLM and IDARNG are continuing their mutual support agreement for wildfire suppression in the Snake River Birds of Prey National Conservation Area (IDARNG 2004, p. 83).

On the OTA, the reduction in wildfires within EOs has demonstrated that management efforts to suppress wildfire can be effective. The 7 EOs on the OTA represent nearly 40 percent of the total area occupied by *Lepidium papilliferum* (see Figure 1 above), and aggressive wildfire suppression has occurred for over 12 years. The feasibility of implementing rapid response wildfire suppression techniques elsewhere is complicated by the fact that many of the remaining *L. papilliferum* EOs are in remote areas away from wildfire control facilities. The current wildfire regime is interrelated with several other factors that may affect *L. papilliferum,* including the replacement of large areas of native vegetation with more flammable nonnative grasses, increased sedimentation of slickspots, and habitat fragmentation. While these effects may be occurring, the existing data do not correlate them with declines in abundance of *L. papilliferum*.

Invasive Nonnative Species

The most common nonnative annual grasses known to occur in *Lepidium papilliferum's* habitat include cheatgrass and medusahead. Annual forbs most commonly associated with slickspots include clasping pepperweed (*Lepidium perfoliatum*), tumbleweed (also known as Russian thistle), tumble mustard (*Sisymbrium altissimum*) (also known as tall tumble mustard), and bur buttercup (Colket 2005a, p. 6). Nonnative plants may become established in *L. papilliferum* habitats by spreading through natural dispersal (unseeded) or may be intentionally planted through re-vegetation projects (seeded). Invasive nonnative plants can alter attributes of ecosystems, including geomorphology, wildfire regime, hydrology, microclimate, nutrient cycle, and productivity (Dukes and Mooney 2003, pp. 1 to 35). They can also negatively affect native plants through

competitive exclusion, niche displacement, hybridization, and competition for pollinators; examples are widespread among taxa and ecosystems (D'Antonio and Vitousek 1992, pp. 63 to 87; Olson 1999, p. 5; Mooney and Cleland 2001, p. 1). All 75 EOs for which habitat information is available have nonnative, unseeded plants present (Colket *et al.* 2006a, Appendix C).

The results from 2004 HIP monitoring revealed that all 71 HIP transects monitored within EOs (49 on the Snake River Plain and 22 on the Owyhee Plateau) had nonnative, unseeded plant cover. For example, within the Snake River Plain (49 transects), 1 had nonnative plant cover occurring over 50 percent of the transect, 7 transects had nonnative plant cover between 25 and 50 percent of the transect, and 10 transects had nonnative plant cover between 10 and 25 percent. Two transects on the Owyhee Plateau had nonnative plant cover between 10 and 25 percent (Colket 2005a, pp. 46 to 47).

In their analysis of *Lepidium papilliferum* population trends in association with plant community trends and habitat quality based on HII and HIP monitoring data from 1998–2002 and 2004, Menke and Kaye (2006b, p. 12) report that species diversity and species richness of the plant community had declined, but that exotic species cover and shrub cover had remained the same. Total exotic species cover and exotic grass cover was high in burned transects in all years (Menke and Kaye 2006b, p. 15). Weedy species cover was higher in burned slickspots, but there was no significant correlation between weedy species cover and either abundance of *L. papilliferum* or proportion of *L. papilliferum* in flower (Menke and Kaye 2006b, p. 15). The authors note that although competition from weedy annuals does not appear to influence the short-term abundance of *L. papilliferum,* it may be influencing other plant traits or life history stages not assessed in this study (Menke and Kaye 2006b, p. 17). However, we have no data to corroborate that this threat will result in future declines in abundance.

Existing conservation measures designed to reduce the potential adverse effects of nonnative, unseeded species apply to approximately 96 percent of *Lepidium papilliferum*'s occupied range (CCA, U.S. Air Force INRMP, IDARNG INRMP). Conservation measures identified within the CCA include protecting remnant blocks of native vegetation, prioritized weed control measures at *L. papilliferum* EOs, protective weed control techniques, revegetation requirements in disturbed areas, education on nonnative species and their spread, vehicle wash points and stations, and research support and funding for nonnative species control (State of Idaho *et al.* 2006, pp. 131 to 132).

The military has a number of ongoing efforts to suppress non-native species. The IDARNG requires all military vehicles entering the OTA from a distance greater than 50 mi (80.4 km) to be washed at a high-pressure wash rack facility to prevent weed seed introduction. Noxious weeds at small sites are hand-pulled when they are found by IDARNG staff, and noxious weed sites on the OTA are reported annually to BLM for treatment (IDARNG 2004, p. 67). The U.S. Air Force reduces the spread of exotic annual species by reseeding disturbed areas with native vegetation to the maximum extent practicable, eradicating noxious weeds prior to spread, and requiring cleaning of U.S. Air Force vehicles and equipment on a wash rack upon return to base. They avoid the use of pesticides within 25 feet of slickspots and use pesticides only if wind conditions are favorable (away from the slickspot) to prevent the loss of *Lepidium papilliferum* (U.S. Air Force 2004, pp. R–4, R–5).

The OTA has demonstrated that management efforts to suppress wildfire, rehabilitating areas with native species, and using wildfire rehabilitation activities with minimal ground disturbance can be effective in reducing the wildfire threat and reducing rates of spread of nonnative unseeded species. Nonnative, unseeded species are increasing at the OTA, although not as rapidly as at other areas where these conservation efforts are not being implemented or have only been implemented for a short period.

We have no evidence that correlates invasive species presence with declines of *L. papilliferum* or the proportion of *L. papilliferum* in flower (Menke and Kaye 2006b, p. 15).

Livestock Use

Trampling of *Lepidium papilliferum* and slickspots can result from livestock use. Table 4 documents the extent of livestock use at HIP transects. Livestock trampling can affect the soil layers of slickspots (Colket 2005a, p. 34; Meyer *et al.* 2005, pp. 21 and 22; Seronko 2004, pp. 1 and 2). Trampling when slickspots are dry can lead to mechanical damage to the slickspot soil crust, potentially resulting in invasion of nonnative plants into the slickspots and altering the hydrologic function of slickspots. Livestock trampling of water-saturated slickspot soils that breaks through the restrictive layer, which is referred to as penetrating trampling (State of Idaho *et al.* 2006, p. 9), has the potential to alter the soil structure and the functionality of slickspots (Rengasamy *et al.* 1984, p. 63; Seronko 2004, pp. 1 and 2). Penetrating trampling, which occurs when slickspots are wet, also has the potential to affect the seed bank for *L. papilliferum.* Meyer and Allen (2005, pp. 6 and 7); seed emergence success decreased with increasing depth from a mean of 54 percent at the shallowest plant depth of 2 mm to a mean of 5 percent at 30 mm depth.

TABLE 4.—LIVESTOCK USE DOCUMENTED AT ELEMENT OCCURRENCES AND HIP TRANSECTS IN 2004 (COLKET *et al.* 2006, APPENDIX C).

[Evidence of livestock use does not infer effects throughout a transect or EO]

	Evidence of penetrating trampling (EO)	Evidence of penetrating trampling (HIP Transects)
Snake River Plain	21/60	19/49
Owyhee Plateau	9/15	20/22
Total	30/75	33/71

In a statistical analysis of HII data from 1998 to 2001, it was found that recent livestock use had neutral effects on *Lepidium papilliferum*, slickspot attributes, and plant community attributes (Menke and Kaye 2006a, p. iii). Recent livestock use estimated by HIP monitoring in the year 2004 resulted in decreased soil crust cover in slickspots, decreased vascular plant cover, and decreased plant litter cover in the surrounding plant community (Menke and Kaye 2006b, p. 3). There was no significant correlation between total livestock print cover or cover of prints penetrating to the slickspot clay layer and abundance of *L. papilliferum*, and both the abundance of *L. papilliferum* per slickspot and proportion of flowering plants was similar between grazed and ungrazed transects for the single year of data reported in 2004 (Menke and Kaye 2006b, p. 15). In the surrounding plant community, grazed and ungrazed transects had similar species richness, diversity, and soil crust cover, but total vascular plant cover and plant litter cover were significantly lower in grazed transects (Menke and Kaye 2006b, pp. 15 and 16).

Livestock trampling events that are most likely to adversely affect *Lepidium papilliferum* usually occur when large numbers of livestock are concentrated on or around slickspots that are saturated with water (Hoffman 2005; Meyer *et al.* 2005, pp. 21 to 22). Saturated conditions typically exist for short periods each year and may never occur in some (drought) years (Hoffman 2005). Predicting when soils will be wet in a climate with few and inconsistent precipitation events is difficult. Consequently, managing livestock to avoid penetrating tramping events is difficult. Supplemental salt and watering sites can alter livestock distribution, and depending on location, can increase or decrease trampling of slickspots.

At least two penetrating trampling events have been suggested as the cause of substantial losses in *Lepidium papilliferum* numbers. In 1996, when other sites at the OTA had a reasonably high numbers of *L. papilliferum* individuals, a study site referred to as the ''States site'' experienced substantial declines. In 1993, this site had thousands of plants. In the spring of 1996, a trampling event disrupted or buried the in-situ seed bank (Meyer *et al.* 2005, pp. 21 and 22). Since this trampling event, fewer than 10 plants have been observed at the site despite yearly visits (Meyer *et al.* 2005, pp. 21 and 22). In another study area, four of five sites experienced increases in plant numbers; the fifth site, Glenn's Ferry, was the only one that incurred a trampling event, and the only one with a dramatic reduction in *L. papilliferum* numbers (Robertson 2003b, p. 8). Research designed to specifically examine the relationship between livestock use trampling effects and *L. papilliferum* is currently being conducted by University of Idaho and the State of Idaho in cooperation with us (State of Idaho *et al.* 2006, p. 119). However, at this point we have nothing but this anecdotal evidence to indicate a threat. Information we do have does not suggest that habitat threats are correlated with declines in species population levels.

There are also indirect effects from livestock use that have impacted the sagebrush-steppe ecosystem. The spread of both native and nonnative plant species has been attributed to livestock use (Frost and Launchbaugh 2003, pp. 43 to 45). The spread of cheatgrass on the Snake River Plain has been attributed to several causes, including the past practice of heavy livestock use in the late 1800s (Mack 1981, pp. 145 to 165). Today, nonnative, annual plants such as cheatgrass are so widespread that they have been documented spreading into areas that have not been disturbed (Piemeisal 1951, p. 71; Tisdale *et al.* 1965, pp. 349 and 351; Stohlgren *et al.* 1999, p. 45); therefore, the absence of livestock use does not protect the landscape from invasive, nonnative weeds (Frost and Launchbaugh 2003, p. 44). With careful management, livestock grazing may be used as a tool to select for certain native species or even to control cheatgrass (Frost and Launchbaugh 2003, p. 43).

There was no significant difference in cover of exotic plant species in slickspots between grazed and ungrazed areas in the 2004 HIP dataset, although soil crust cover was significantly lower in grazed transects (Menke and Kaye 2006b, p. 19). Analysis of HII data from 1999 through 2001 found no effect of livestock grazing on slickspot perimeter integrity, weedy species density, perennial forb or grass establishment, or organic debris accumulation in slickspots (Menke and Kaye 2006a, p. 10). Cumulative livestock sign had a significant negative correlation with exotic grass dominance around slickspots (Menke and Kaye 2006a, p. 11) and with the frequency of slickspots with dense weedy annuals in 2001 (Menke and Kaye 2006a, p. 10). The analysis of grazing effects was limited since the HII data were observational only (no controlled experiments were performed), all areas were likely grazed at some point in the past, and grazing effects could only be observed in habitats that had been burned in the past (Menke and Kaye 2006a, p. 18).

The conservation plans (CCA, U.S. Air Force INRMP, IDARNG INRMP) contain numerous measures to avoid, mitigate, and monitor effects of livestock use on the species. Livestock grazing conservation measures implemented through the CCA and the U.S. Air Force INRMP apply to all Federal and State-managed lands (96 percent of the acreage) within the occupied range of *Lepidium papilliferum*. Conservation measures prescribed by the CCA include minimum distances for placement of salt and water troughs away from occurrences of the species, and several troughs and salt blocks have been moved as a result of these measures (State of Idaho *et al.* 2006, p. 133; State of Idaho *et al.* 2005). The CCA also includes measures to reduce trampling during wet periods, including trailing (moving cattle to, or between, allotments repeatedly on the same path) restrictions (State of Idaho *et al.* 2006, pp. 132 to 134). High priority EOs, as identified in the CCA, tend to have more restrictive conservation measures, such as no early spring grazing, fencing to exclude livestock, and delaying turnout of livestock when soils are saturated (State of Idaho *et al.* 2006, pp. 133 to 134). High priority EOs were designated based on existing habitat quality, geographic location relative to other existing EOs, minimal land use activities, the absence or presence of resources to address threats, and the need to preserve enough EOs throughout the species' range to prevent extinction in case of a catastrophic event. In high priority EOs, greater emphasis is placed on protection and restoration of habitat. BLM has changed the season of grazing use from spring to fall, and implemented a deferred rotation management system on some allotments to protect flowering annuals from grazing (State of Idaho *et al.* 2006, pp. 133 to 134).

Under the revised Juniper Butte Range INRMP, the U.S. Air Force will continue to use livestock throughout the majority of the Juniper Butte Range to reduce the amount of standing grass biomass to reduce wildfire risk (U.S. Air Force 2004, pp. 6–37 to 6–39). The grazing component plan for the INRMP states that livestock use will occur annually for up to 60 days while the bombing range is shut down for clean-up and target maintenance. The shutdown period lasts a maximum of 60 days within a 90-day period, from April 1 through June 30 (U.S. Air Force 2000, pp. B–18 to B–21). The INRMP

emphasizes avoiding grazing when slickspots are wet in order to reduce trampling of slickspot habitats. It also provides guidance for annual monitoring of slickspot soil moisture to determine livestock turnout dates for Juniper Butte Range (U.S. Air Force 2000, pp. B–18 to B–21). The U.S. Air Force established three fenced areas of 173 ac (70.0 ha), 8 ac (3.2), and 30 ac (12.1 ha), respectively, in 2002, with the intent of promoting *Lepidium papilliferum* research and seed collection (Binder 2006), when compatible with the Air Force mission.

There was no significant correlation between total livestock print cover or cover of prints penetrating to the slickspot clay layer and abundance of *L. papilliferum*, and both the abundance of *L. papilliferum* per slickspot and proportion of flowering plants was similar between grazed and ungrazed transects for the single year of data reported in 2004 (Menke and Kaye 2006b, p. 15) and no other data were available that indicated otherwise. Therefore, we do not believe that livestock impacts are a threat to the species.

Residential and Agricultural Development

Past residential and agricultural development has been responsible for five documented local extirpations and four probable local extirpations of *Lepidium papilliferum* (Colket *et al.* 2006, p. 4). The long-term viability of *L. papilliferum* occurrences on private land on the Snake River Plain has the potential to be compromised due to the continuation of residential and urban development in and around Boise (Moseley 1994, p. 20). Today, all or portions of 18 *L. papilliferum* EOs covering 457 acres (3.5 percent) (not including EOs managed by cities or counties) occur on private land. However, half of these 18 EOs are smaller than one acre, and most are classified as having fair to poor habitat quality (Colket *et al.* 2006, pp. 39 to 41). Residential and agricultural development can affect *L. papilliferum* and slickspot habitat through habitat conversion, increased nonnative plant invasions, increased off-highway vehicle use, increased wildfire, changes to insect populations, and increased fragmentation. Future residential and agricultural development on private land occupied by the species is a potential threat that is limited to 3.5 percent of the total known element occurrence acreage, therefore such development is not a significant threat.

Gravel or cinder mining may affect *Lepidium papilliferum* on State and Federal lands (Mancuso 2000, p. 13). One site was impacted by illegal mining activity in 1999 on BLM and private lands (DeBolt 1999). No other impacts from gravel or cinder mining have been documented, therefore gravel or cinder mining does not constitute a significant threat to the species.

Power, gas, and other lines, and related roads, affect and fragment *Lepidium papilliferum* EOs. Utility lines and accompanying roads have been documented running through at least four EOs, gas lines run through two EOs, and roads run through at least six EOs (Colket *et al.* 2006, Appendix C). In addition to direct habitat destruction, these corridors allow off-road vehicle access and increase the chance of nonnative plant invasions and human-ignited wildfires. Transportation corridors associated with development also increase the probability of human-ignited wildfires and the spread of nonnative, invasive plants. Future developments associated with power, gas, other lines, and related roads through habitat occupied by the species may be a potential threat depending upon design and mitigation measures associated with the developments. But at this time we have no data that such development constitutes a significant threat to the species.

Of the *Lepidium papilliferum* EOs for which habitat information has been collected, 14 of 75 (13 of 60 on the Snake River Plain and 1 of 15 on the Owyhee Plateau) have development (*e.g.*, utility lines, mining, agricultural development, and residential development) within them, and 28, all on the Snake River Plain, have development adjacent to them within 0.31 mi (500 m) (Colket *et al.* 2006, Appendix C). On the Owyhee Plateau, one EO has development occurring within it, and no EOs have development within 0.31 mi (500 m) (Colket *et al.* 2006, Appendix C).

Within the Snake River Plain, an estimated 327,549 ac (132,554 ha) (20 percent) has been converted to agriculture (IDWR 1999), and 94,974 ac (38,435 ha) (6 percent) has been converted to urban areas (University of Idaho 2001).

Development was not a parameter that was measured in 2004 through the HIP transect monitoring program (Colket 2005a). In 2005, 79 HIP transects were monitored (57 on the Snake River Plain and 22 on the Owyhee Plateau); of these transects only one transect on the Snake River Plain had development occurring at the transect (in this case residential/commercial). Monitoring in 2005 on the Snake River Plain also documented residential and commercial development occurring within 0.31 mi (500 m) of 17 transects, and agricultural development was documented adjacent to 10 transects (Colket 2005b, Table 2).

Currently, the effects from development to *Lepidium papilliferum* are confined geographically to the Snake River Plain, however these threats are not significant. Development does not appear to be a threat at all for *L. papilliferum* EOs on the Owyhee Plateau.

Nonnative Seeded Species

A decline in habitat quality for *Lepidium papilliferum* since 1998 in terms of decreased vascular plant cover, species richness, and species diversity was noted by Menke and Kaye (2006b, p. 19), although they found no change in the cover of exotic grasses or forbs in the plant community between 1998 and 2004, and no relationship between short-term abundance of *L. papilliferum* and weedy species cover in slickspots (Menke and Kaye 2006b, p. 15). At this time, we have no data supporting a conclusion that longer-term abundance will be negatively affected by the presence of exotic grasses.

Rangeland revegetation priorities on public lands in southeast Idaho have included providing forage for livestock, erosion control, wildfire prevention, reducing nonnative annual grass density, and watershed rehabilitation. Some nonnative perennials can out-compete native species and decrease biodiversity (summarized by Harrison *et al.* 1996, 62 pp.). For example, crested wheatgrass, a forage species that was once commonly planted within the range of *Lepidium papilliferum*, is a competitor and its seedlings are better than some native species at acquiring moisture at low temperatures (Lesica and DeLuca 1998, p. 1; Pyke and Archer 1991, p. 4; Bunting *et al.* 2003, p. 82). The results from surveys conducted on the Owyhee Plateau by (Popovich 2002, p. 16) indicated that the number of *L. papilliferum* plants per site was lower in habitat with crested wheatgrass seedings, compared to native sagebrush-steppe habitat areas or burned areas that had not been seeded (Popovich 2002, p. 16). Forage kochia (*Bassia prostrata*, formerly *Kochia prostrata*) is another nonnative species that has been used for rangeland habitat restoration. Thousands of forage kochia plants have been observed in relatively small slickspots, and it is documented as a direct competitor with *L. papilliferum* in slickspots (DeBolt 2002; Quinney 2005). In one study area within the Poen fire rehabilitation project, post-wildfire monitoring over a 6-year period following aerial seeding with forage

kochia showed eventual loss of *L. papilliferum* along the monitoring transect, and a dramatic increase in forage kochia (DeBolt 2002). Four other slickspots, containing a total of 31 individual *L. papilliferum* plants and numerous forage kochia plants in 2000, were void of *L. papilliferum* and dominated by forage kochia in 2005 (Quinney 2005). Blue flax (*Linum lewisii*) is another nonnative seeded plant that was found within HIP transects (Colket 2005a, p. 6). It is not clear why these *L. papilliferum* plants were absent.

Nonnative seeded species exist in 23 of the 75 EOs with documented habitat information (17 of 60 on the Snake River Plain and 6 of 15 on the Owyhee Plateau), and 18 (14 on the Snake River Plain and 4 on the Owyhee Plateau) have non-native seeded species adjacent to the EO within 0.31 mi (500 m).

The effects of invasive, nonnative seeded plants are monitored as parts of HIP range-wide transect monitoring for *Lepidium papilliferum*. In 2004, 71 *L. papilliferum* HIP transects (49 on the Snake River Plain and 22 on the Owyhee Plateau) were measured (Colket 2005a, pp. 46 to 47). Results indicate that 11 transects within the Snake River Plain and 13 transects within the Owyhee Plateau had introduced perennial plant cover (nonnative, seeded species) (Colket 2005a, pp. 46 to 47). In general, the documented high percentage of plant cover in the 2004 HIP transect monitoring is attributable to crested wheatgrass, except at the site with the highest percent cover. This site in the Snake River Plain contained 26.8 percent cover in forage kochia (Colket 2005a, pp. 17, 32). Approximately 80 percent (9,163 ac (3,708 ha)) of the Juniper Butte Range is dominated by nonnative perennial plant communities as a result of wildfire rehabilitation efforts (U.S. Air Force 1998, pp. 31–120 to 3–121).

Although the use of native plant species for wildfire rehabilitation is preferable, previously there have been problems with the availability and high cost of native seed (Jirik 1999, p. 110; Brooks and Pyke 2001, p. 9). In recent years, with an increase in research and agencies (*e.g.*, BLM) investing heavily in projects such as the Great Basin Native Plant Selection and Increase Project and the Great Basin Restoration Initiative, native seeds and plants are more available to use in restoration of sagebrush-steppe habitat. However, restoration of sagebrush-steppe habitat, and *Lepidium papilliferum* habitat in particular, is still considered a difficult and expensive task.

Under current policies, BLM no longer uses forage kochia as a wildfire rehabilitation species in *Lepidium papilliferum* habitat (USBLM 2002). BLM emphasizes the use of native plants, including forbs, in seed mixes and avoids the use of invasive, nonnative species (State of Idaho *et al.* 2006, p. 26). In January 2004, BLM issued an Instruction Memorandum to employees on compliance with CCA requirements for emergency stabilization and wildfire rehabilitation activities (State of Idaho *et al.* 2006, p. 71).

The military has a number of ongoing efforts to address invasive nonnative, seeded plants. These efforts are implemented and effective in reducing this threat. The U.S. Air Force uses only non-invasive plant materials and will not use forage kochia, intermediate wheatgrass (*Thinopyrum intermedium*, formerly *Agropyron intermedium*), or salt-tolerant species such as four-wing saltbush (*Atriplex canescens*) in revegetation efforts, with native plants being used to the maximum extent practicable and in concert with the military mission for rehabilitation efforts (U.S. Air Force 2004, p. R–4). The IDARNG INRMP for the OTA includes the objectives for maintenance; where possible, improvement of *Lepidium papilliferum* habitat; and restoration of areas damaged by wildfire, through native species and broadcast seeding, collecting, and planting small amounts of native seed not commercially available, and monitoring the success of seeding efforts (IDARNG 2004, p. 72 to 73). Since 1991, the IDARNG has examined historical records and has seeded areas back to the native vegetation that was present prior to past wildfires. Care is taken to ensure that restoration does not damage *L. papilliferum* or its habitat, or introduce species into the habitat that were not present in presettlement times (IDARNG 2004, p. 73).

The IDARNG has demonstrated that diligent efforts to suppress wildfire, the use of native species, and minimal ground-disturbing wildfire rehabilitation activities can be effective in reducing the wildfire threat and rates at which nonnative species spread. Because of limited rainfall and harsh conditions, restoration is a difficult task and often requires repeated seedings on the OTA (IDARNG 2004, p.73). Methods currently used by the IDARNG may not be economically feasible for revegetation of large areas of damaged habitat found in other parts of the range of the species.

Menke and Kaye (2006b, p. 19) evaluated rangewide data from 1998–2004 and found a decline in the quality of habitat surrounding slickspots occupied with *Lepidium papilliferum* in terms of decreased vascular plant cover, species richness, and species diversity. They found no change in the cover of exotic grasses or forbs in the plant community between 1998 and 2004, and no relationship between short-term abundance of *L. papilliferum* and weedy species cover in slickspots (Menke and Kaye 2006b, p. 15). Because abundance cannot be correlated with habitat changes, we find that a decline in habitat quality is not threatening the species.

Wildfire Management and Post-Wildfire Rehabilitation

Activities associated with wildfire management include fuel management projects (*e.g.*, greenstrips, prescribed fire), wildfire suppression activities, and post-wildfire rehabilitation. These activities can potentially impact existing *Lepidium papilliferum* occurrences and damage slickspot habitat (ILPG 1999) by the establishment of nonnatives or by mechanical disturbances.

Drill seeding is a rehabilitation technique that is used after wildfire. Drill seeding uses a rangeland drill that plants and covers seed simultaneously in furrows. It is designed to give the seeds moisture and temperature advantages that will enhance their competitive fitness and, consequently, their success rate (Scholten and Bunting 2001, p. 3). Drill seeding has been used on wildfire rehabilitation projects on BLM lands where *Lepidium papilliferum* occurs. It impacts slickspots through mechanical disturbance and introduces other, often nonnative, plant materials. Historically, slickspots were not understood to have any special ecological value, and so no attempt was made to avoid them during rehabilitation activities. We have no data on the extent that drill seeding may still be affecting *L. papilliferum* habitat, although some habitat areas have buffers established to protect them.

Disk or drill seeding has occurred on 14 of 60 EOs on the Snake River Plain and 10 of 15 EOs on the Owyhee Plateau (Colket *et al.* 2006, Appendix C). Drill seeding may have less severe impacts on slickspot habitat than disking the soil, but the success of restoring slickspots and *Lepidium papilliferum* plants varies considerably. The benefits of post-fire revegetation, and subsequent recovery of soil surfaces conducive to germination and establishment of native perennial grass and shrub communities, may outweigh the initial short-term disturbance associated with drill

seeding (Young and Allen 1996, pp. 533 to 534; Bunting *et al.* 2003, pp. 82 to 85).

Ground disturbance associated with wildfire control, such as establishment of fire lines (areas with vegetation removed to break fuel continuity), fire camps, and staging areas, and the use of wildfire suppression vehicles, can also impact existing *Lepidium papilliferum* occurrences and damage slickspot habitat (ILPG 1999). Similarly, construction of fuel breaks, while beneficial in slowing the movement of wildfire, may also impact *L. papilliferum* through ground disturbance or the use of invasive, nonnative, seeded species. Only two EOs, both on the Snake River Plain, are documented as having wildfire lines within them, although neither has documented wildfire lines within slickspots (Colket *et al.* 2006, Appendix C). Herbicides used to pretreat rehabilitation areas prior to seeding may also impact *L. papilliferum*. These activities may injure or kill individual plants or the seed bank through mechanical disturbance or direct exposure to herbicides. Indirect effects associated with mechanical disturbance of slickspot soils include increased probability of establishment of invasive, nonnative plants, burying of the seed bank to a depth where seedlings cannot emerge from the soil, and mixing of slickspot soil layers, which affects the suitability of a microsite for the species.

The effect of drill seeding is monitored as part of the HIP range-wide transect monitoring. In 2004, of the 71 *Lepidium papilliferum* transects monitored, 3 transects on the Snake River Plain and 5 transects on the Owyhee Plateau had evidence of old drill seedings within slickspots; no transects had evidence of firefighting disturbances within slickspots (Colket 2005a, pp. 44 to 45).

Through the CCA, BLM has implemented a number of conservation measures to avoid or minimize impacts to the species from wildfire prevention, wildfire suppression, and post-wildfire emergency rehabilitation activities. These measures are effective to reduce this threat at least partially. BLM and fire cooperators distribute maps and inform crew members of the location of *Lepidium papilliferum* to maximize wildfire protection in those areas, and to minimize potential impacts from suppression related activities (State of Idaho *et al.* 2006, p. 26). Per conservation measure .08 of the CCA, BLM uses seeding techniques that minimize soil disturbance, such as no-till drills and rangeland drills equipped with depth bands, when rehabilitation and restoration projects have the potential to impact occupied or suitable habitat (State of Idaho *et al.* 2006, p. 26). Rehabilitation and restoration standard operating procedures for *L. papilliferum* were issued in an Instruction Memorandum in January 2004 (State of Idaho *et al.* 2005, p. 33). BLM avoids spraying herbicides within or near known occupied habitat, and conducts pretreatment surveys of at least 5 percent of previously unsurveyed habitat prior to herbicide or ground disturbing treatments associated with emergency wildfire rehabilitation activities (State of Idaho *et al.* 2006, p. 27).

The military has a number of ongoing, effective efforts to address wildfire management activities. The potential for wildfire ignition and spread are decreased by the placement of appropriate restrictions on activities, and the use of wildfire indices to restrict activities when the wildfire rating hazard is extreme (U.S. Air Force 2004, p. R–3). The U.S. Air Force uses drill seeders equipped with depth bands to avoid unnecessary disturbance to soils, avoids slickspots to the maximum extent practicable in drill seeding efforts, and uses broadcast seeding to the maximum extent practicable consistent with reseeding goals (U.S. Air Force 2004, p. R–4). The IDARNG restores wildfire-damaged areas using native species and broadcast seeding. Similarly, the IDARNG provides their fire crews with maps of all known occupied habitat, and actively suppresses all wildfires on the OTA. Blading is not permitted in *Lepidium papilliferum* habitat areas on the OTA. Existing roadways serve as fuel breaks within the OTA, and allow for quick access for wildfire management (IDARNG 2004, p. 73). Since 1987, the IDARNG has demonstrated that efforts to suppress wildfire and the use of native species with minimal ground-disturbing fire rehabilitation activities can be effective in reducing the wildfire threat and reducing establishment rates of nonnative, unseeded species associated with wildfire management activities (IDARNG 2004, p. 73).

Wildfire management has positive consequences (i.e., the control of wildfires) and potentially negative consequences (i.e., destruction of slickspots through habitat restoration and wildfire control practices), depending on how the activity is implemented. The Expert Panel considered wildfire management to be less of an impact than the first four factors discussed above. After our review of the available data, we have determined that wildfire management can potentially impact *Lepidium papilliferum*, although this activity is not threatening the species.

Recreation

Recreational activities that may affect *Lepidium papilliferum* include hiking, horseback riding, and off-highway vehicles. Juniper Butte Range and areas of the OTA are protected from recreational activities because of military restrictions.

Off-highway vehicle use has been documented in 16 of the 75 EOs (16 of 60 on the Snake River Plain, none on the Owyhee Plateau) for which habitat information has been collected (Colket *et al.* 2006, Appendix C).

Effects from recreational activities are monitored as part of the HIP range-wide transect monitoring for *Lepidium papilliferum*. In 2004, 3 of 49 transects on the Snake River Plain showed off-highway vehicle tracks within the EO area, and 1 transect had off-highway vehicle tracks directly through it (Colket 2005b, Table 1). In 2005, two EOs on the Snake River Plan had tracks in the general occurrence area, and one had tractor tracks running through the transect (Colket 2005b, Table 1). New tracks are documented each year, so monitoring reports are not cumulative. Off-highway vehicle use was also monitored within the Owyhee Plateau *L. papilliferum* EOs in 2004 and 2005, but no off-highway use was documented. An analysis of HII transects between 1998 and 2001 indicated that only a few transects had OHV use in each year, that impacts appeared to be minimal, and that OHV use regionally does not appear to be a major agent of habitat degradation, while noting that concentrated OHV use in localized areas could potentially be more problematic (Menke and Kaye 2006a, p. 18). Therefore, we have determined from the available data that any potential impact to *Lepidium papilliferum* from recreation appears to be localized. Additionally, we have no data indicating that recreation is a major agent of habitat degradation and therefore is not threatening the species.

Military Training

Military activities within the range of *Lepidium papilliferum* include ordnance impact areas, training activities, military development, and an increased risk of wildfire and nonnative plant invasions. Military training occurs on the Snake River Plain at the OTA (seven EOs) and on the Owyhee Plateau at the Juniper Butte Range (a portion of one EO). INRMPs developed for both the Juniper Butte Range and the OTA provide management direction reducing or eliminating many of these threats

from military training exercises. The OTA, where 14 years of INRMP conservation efforts have been implemented, is considered the most intact, native *L. papilliferum* habitat range-wide (Colket *et al.* 2006, pp. 22 to 23; Meyer 2005, p. 1).

The IDARNG and the U.S. Air Force are implementing various conservation efforts to avoid or reduce adverse effects of military training on the species and its habitat, and the IDARNG has had measures in place that promote the conservation of *Lepidium papilliferum* prior to revisions to the IDARNG INRMP made in 2004. The threat of military training is localized in area, and minimal in significance across the range of the species.

Summary of Factor A

There is little disagreement that the quality and composition of the sage-brush steppe ecosystems that surrounds the slickspot microsites inhabited by *Lepidium papilliferum* has become degraded over time. Increased fire frequencies largely caused by the invasion of exotic annual grasses are of particular concern, as are potentially destructive penetrating trampling events of slickspots by livestock. What is not clear is the relationship between these factors and the long-term persistence or viability of *L. papilliferum*. What little data we have at this time does not indicate any direct relationship between the abundance of *L. papilliferum* and factors such as livestock use and weedy species cover. Burning appears to have a negative impact on slickspot conditions, such as increasing exotic species cover and decreasing soil crust cover, but these factors were not significantly correlated with *L. papilliferum* abundance. Accordingly we find that *L. papilliferum* is not threatened by habitat changes to the extent that protection under the Act is needed.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

We have no data indicating that overutilization for commercial, recreational, scientific, or educational purposes is a threat to *Lepidium papilliferum*.

C. Disease or Predation

Herbivory of *Lepidium papilliferum* is reported as sparse. Herbivory by rodents and insects has been occasionally observed on *L. papilliferum* plants. In one instance, grasshoppers (possibly Acrididae) were observed consuming *L. papilliferum* flower petals (Geertson 2004, p. 3). We are unaware of any specific studies documenting foraging on *L. papilliferum* by Mormon crickets (*Anabrus simplex*). Insect herbivores have been studied as part of pollinator and reproductive biology studies (Robertson *et al.* 2004). Flower petal herbivory of *L. papilliferum* by chrysomelid beetles (*Phyllotreta* spp.) was shown to be detrimental to seed production because of decreased pollinator visitation; pollinators did not visit flowers with missing flower petals. Other insect herbivores include plutellid moth larvae, which eat all portions of the plant; harvester ants which eat entire fruits or leaves from plants; mirid bugs, which probably suck phloem; grasshoppers (Acrididae); and leafhoppers (Cicadellidae), which probably suck phloem (Robertson *et al.* 2004, p. 12). At three different sites (one at Kuna Butte and two at the Orchard Training Area), 35 percent, 37 percent, and 23 percent of plants showed evidence of insect herbivore damage (Robertson *et al.* 2004).

Herbivory impacts to *L. papilliferum* from large, native ungulates, such as elk, deer and antelope, have not been observed. However, pronghorn antelope tracks and droppings (U.S. Air Force 2003, p. 14) and elk tracks and droppings (State of Idaho *et al.* 2006, Appendix A) have been infrequently documented in slickspots that support *L. papilliferum*. Domestic sheep have been observed pulling the plants from the ground and spitting them out (Quinney and Weaver 1998). Herbivory by cattle has not been observed.

We have no data to support the conclusion that disease or predation are a significant threat to *Lepidium papilliferum*.

D. Inadequacy of Existing Regulatory Mechanisms

Lepidium papilliferum is considered a sensitive species by BLM (BLM 2003, p. 2–1). BLM has regulations that address the need to protect sensitive, candidate, and federally listed species, and BLM has initiated monitoring of *L. papilliferum* on Federal lands. Monitoring can be used to identify threats, which can result in management actions necessary for controlling *L. papilliferum* habitat degradation.

As a signatory of the CCA (State of Idaho *et al.* 2003, 2006), BLM is the primary land management agency implementing conservation efforts for this species. The majority of implemented conservation efforts associated with the CCA occur on BLM lands. In recent years, BLM has initiated efforts to conserve the species, and the CCA represents a major commitment by BLM for management of lands that account for a majority of the range of the species (87 percent of the total area and portions of 71 of the 85 extant EOs). Conservation efforts are not a basis for our finding here, but ongoing conservation efforts will be helpful in offsetting any effects that do occur from potential threats, and further voluntary conservation efforts are encouraged. Therefore, available data does not suggest that existing regulatory mechanisms are inadequate.

E. Other Natural or Manmade Factors Affecting Its Continued Existence

The Expert Panel identified unpredictable rain events and drought as climate factors affecting *Lepidium papilliferum,* but did not consider them to be significant threats to the species. We have no data that climatic patterns of rainfall will significantly change over time. Therefore, we do not consider drought or lack of rainfall to pose an extinction risk, although it can cause a short-term decline in population numbers. No other threats to *L. papilliferum* were identified under Factor E.

Summary of Factors Affecting the Species—Conclusion

The primary factors affecting *Lepidium papilliferum* are habitat based. We examined other potential threats and determined that the available data does not suggest that the other factors are threatening the species. We examined data available for effects of wildfire frequency, invasive nonnative plants (especially annual grasses), livestock impacts, and residential and agricultural development. While disturbances to *L. papilliferum* can result from wildfire, commercial and residential development, livestock use, and ground-disturbing wildfire management practices or recreation activities the available data did not support a finding that the species is threatened by one or more of these potential threats. Our analysis of the factors affecting the species indicates that there is cause for concern regarding the decline in quality of the sagebrush-steppe ecosystem and the slickspot microhabits within. We examined the increased frequency of fires, fueled largely by invasive exotic annual grasses, and how it is altering the diversity and composition of the native plant community. We found that there was no evidence that habitat degradation is a threat to the species such that listing is warranted at this time. However, the concerns generated by our analysis emphasize the need for further research and support for ongoing efforts to restore and manage the

sagebrush steppe ecosystem. This also underscores the necessity for close monitoring of *L. papilliferum* and other components of the sagebrush community to better determine the response of these species to the alteration of their environment. The best available data do not demonstrate any relationship between altered habitat conditions and the status of *L. papilliferum.* The limited data available do not demonstrate any significant relationship between the abundance of *L. papilliferum* and factors such as livestock use or weedy species cover. The two available datasets of abundance monitoring present conflicting results regarding the trend of the population over time. The population of *L. papilliferum* is positively correlated with spring precipitation. *L. papilliferum* evolved in an arid environment and has adapted to fluctuations in precipitation. We have no data demonstrating that precipitation levels are varying significantly from historical patterns. Accordingly, we do not find that fluctuation in precipitation is a threat to the species.

Status Review Process

Section 4(b)(1)(A) of the Act requires us to consider the best scientific and commercial data available, as well as efforts being made by States or other entities to protect a species, when making a listing decision. To meet this standard, we systematically collected information on *Lepidium papilliferum,* its habitats, and environmental factors affecting the species from a wide array of sources. In addition, we received a substantial amount of unpublished information from other Federal agencies, States, private industry, and individuals. We solicited information on all Federal, State, or local conservation efforts currently in operation or planned for either *L. papilliferum* or its habitat.

In addition, we convened an Expert Panel of seven independent scientists who assisted in evaluating the available data and discussed threats to *L. papilliferum.* Expert Panels are not a required component of our analysis, but are used occasionally by the Service to help inform decision makers when there is uncertainty. Scientific information on *Lepidium papilliferum* and associated habitat is limited; data gaps and uncertainty exist in the scientific community's knowledge of threats that may affect *L. papilliferum* populations across its geographical range of sagebrush-steppe habitat. For these reasons, we requested input from scientific experts to help us assess the status of *L. papilliferum.* The Expert Panel consisted of experts in the fields of small populations/fragmentation, annual desert plants, sagebrush community ecology, wildfire/nonnative species, soils and livestock use, and *L. papilliferum.* The discussion of the Expert Panel, and other available data, was then considered by our Manager Panel in order to develop the decision reported in this finding.

We conducted three phases of information synthesis and evaluation. First, the information on individual planned conservation efforts was evaluated to determine which of the efforts that have not yet been implemented, or have been implemented but have not yet demonstrated whether they are effective, met the standard for sufficient certainty of implementation and effectiveness in the Policy for Evaluating Conservation Efforts (68 FR 15115, March 28, 2003). Second, we employed the assistance of an Expert Panel that evaluated all factors possibly affecting the species' current status. Subsequent to the work done by the expert panel new information became available. Our Manager Panel evaluated all the information, including the new information, on status, trends, ongoing conservation efforts, and potential risk to determine whether the species should be listed as threatened, listed as endangered, or not warranted for listing. We structured these three phases by differentiating two distinct stages of the analysis: (1) A risk analysis phase that included compiling biological information and estimating the risk to the species; and (2) a risk management phase where our Manager Panel evaluated whether the potential threats identified as part of our section 4(a)(1) analysis, and summarized in this finding, qualify *Lepidium papilliferum* as a threatened or endangered species under the Act.

Policy for Evaluation of Conservation Efforts

PECE provides a framework and criteria for evaluating conservation efforts that have not been implemented or have not demonstrated whether they are effective at the time of a listing decision. Recognizing that the certainty of implementation and effectiveness of various planned efforts within a conservation plan, strategy, or agreement may vary, PECE requires that we evaluate each individual conservation effort that has not been implemented or for which effectiveness has not been demonstrated, and the policy provides criteria to direct our analysis. PECE specifies that to consider that a conservation effort(s) contributes to forming a basis for not listing a species or listing a species as threatened rather than endangered, we must find that the conservation effort is sufficiently certain to be implemented and effective so as to have contributed to the elimination or adequate reduction of one or more threats to the species identified through the section 4(a)(1) analysis. (68 FR 15115, March 28, 2003). Thus, PECE is relevant in situations where a threats analysis, conducted without consideration of conservation efforts that meet the standard in PECE, indicates that listing is warranted. In such situations, we then consider the effect of conservation efforts that meet the ''sufficient certainty'' standard in PECE to determine whether such efforts have contributed to the elimination or adequate reduction of threats, leading to a determination that the species does not meet the definition of threatened or endangered and therefore does not warrant listing, or that that listing as threatened, rather than endangered, is appropriate.

Because of the time needed to evaluate large numbers of individual conservation efforts under PECE, it sometimes is necessary to proceed with the evaluation process prior to completing the threats analysis pursuant to section 4(a)(1) of the Act, i.e., before we have determined whether efforts that meet the standard in PECE will actually play a role in our determination. That was the case in this situation.

For the PECE analysis, we reviewed activities identified in five plans or conservation strategies. The five plans were: (1) The Candidate Conservation Agreement for Slickspot Peppergrass; (2) the Idaho Army National Guard Integrated Natural Resource Management Plan for Gowen Field/Orchard Training Area; (3) the U.S. Air Force Integrated Natural Resource Management Plan for Mountain Home Air Force Base; (4) the Conservation Agreement by and between Boise City and the U.S. Fish and Wildlife Service for *Allium aasea* (Aase's onion), *Astragalus mulfordiae* (Mulford's milkvetch), and *Lepidium papilliferum* (slickspot peppergrass); and (5) the Conservation Agreement for Slickspot Peppergrass (*Lepidium papilliferum*) at the Boise Airport, Ada County, Idaho.

We reviewed each conservation effort contained in the five conservation plans to determine which had been implemented and demonstrated effectiveness in reducing one or more threats. We relied on available documentation to determine if the effort was implemented by the time of our analysis. As explained above, conservation efforts that have been

implemented and demonstrated effectiveness are not subject to evaluation under PECE, and are considered as part of the section 4(a)(1) threats analysis (below). We also used the criteria in PECE to evaluate efforts that had not been implemented, and efforts that had been implemented but had not yet demonstrated whether they were effective. We did not rely on those efforts that met the PECE standard in our determination. We made our determination on the basis of the threats analysis and information about population status and trends (see below). However, we consider the conservation plans and the continued commitment of stakeholders to implement the conservation efforts important to the long-term sustainability of *Lepidium papilliferum*.

Expert Panel

In May 2006, we convened a panel composed of seven experts to provide assistance in understanding the ecology and biology of *Lepidium papilliferum,* to assess the threats and extinction risk to the species, and to identify areas of scientific uncertainty. The panelists brought a variety of expertise to the discussion, including knowledge and experience with wildfire, nonnative species, range and grazing issues, soils, small populations and fragmentation, annual desert plants, and sagebrush community ecology, and included a *L. papilliferum* species expert.

The top two potential threats identified by the Expert Panel were the invasion of cheatgrass and the subsequent changes to the fire regime in the sagebrush-steppe ecosystem. Several members of the panel agreed that the expansion of cheatgrass will likely create annual grasslands that will dominate the Snake River Plain within the next 50 years, and would impact *Lepidium papilliferum* and its habitat. The invasion of exotic annual grasses in turn increases the frequency of fire, leading to further alterations of the native plant community.

Following the May 2006 Expert Panel, the Service received additional information including new analysis of *Lepidium papiliferum* population and habitat monitoring data (*e.g.*, Menke and Kaye 2006b). This information was not available to the expert panel and did not factor into their extinction risk estimates. The Service considers the extinction risk estimates by the expert panel to be informative in that they provide a context in which we were able to assess the new information. However, the estimates have limited applicability to our determination in light of this new information. In particular, the new information limits the Service's confidence in extrapolation of *L. papilliferum* population trends at the OTA to population trends in the remaining Snake River Plain metapopulation and the range-wide population.

Manager Panel

Our Manager Panel reviewed background materials, interacted with the Expert Panel during their exercises, and participated in discussions about the application of the Act and specific terms contained in the Act. The managers based their assessments on the data in the record, including comments previously received; the data presented by the individual members of the Expert Panel, as well as data received subsequent to the Expert Panel process; known information gaps and uncertainty; the number and severity of the threats affecting the species; and mitigating circumstances that might ameliorate one or more of the threats. The Manager Panel convened on three occasions. This rule is based on the record of these discussions and all relevant and available information pertaining to the threats to and status of the species.

Determination

We examined the data regarding *L. papilliferum* populations and occurrence as well as the specific habitat needs of the species. We included an examination of habitat degradation and modification to the sagebrush-steppe ecosystem and the slickspot microhabitats from the current wildfire regime (i.e., increasing frequency, size, and duration), invasion of non-native weed species (*e.g.*, cheatgrass), effects of livestock use (*e.g.*, penetrating trampling, disruption of soil crust covers), and residential and agricultural development to determine whether there were any resulting effects on *L. papilliferum*.While the sagebrush steppe-ecosystem has experienced decreased native shrub cover and increased exotic grass cover, we have no data demonstrating that these factors affect *L. papilliferum* populations. Data at this point are limited and based on observational measures rather than controlled experiments, but indicate no significant relationship between the abundance of *L. papilliferum* and factors such as livestock use or weedy species cover in slickspots. The data limitations point to the value of the conservation activities and collection of data and to improve our understanding of the species, as well as preventive actions. However, we do not have evidence that the factors evaluated here have led to a negative population trend range-wide in *L. papilliferum.*

Determining range-wide abundance and population trends of *Lepidium papilliferum* is complicated by its annual and biennial life histories and its correlation to spring precipitation, which can vary widely from year to year. Spring rainfall patterns also vary at the local scale, which can influence abundance of the plant from one population to another in the same local area. Abundance estimates are confounded because seeds can remain dormant (and viable) in the seed bank for at least 12 years. All of these factors lead to great natural variability in the abundance of *L. papilliferum* from year to year, which confounds our assessment of population trends.

Currently we have two relatively long-term datasets of abundance monitoring for *Lepidium papilliferum* on which to base our evaluation of population trends for this species, the data from the OTA and the data from range-wide HII and HIP monitoring (which includes several transects on the OTA). The dataset from the OTA indicates recent declines in the abundance of the species that do not correlate as expected with patterns of spring precipitation, beginning in 2003 (Weaver 2006, pp. 1–6). Data from the range-wide HII and HIP transects demonstrate that although the population declined following one of its highest recorded peaks in abundance in 1998 (the first year for which HII data was available), the range-wide population then stabilized and began increasing after 2003 (Menke and Kaye 2006b, Figure 3; USFWS 2006f, Figures 8, 9). The range-wide data show increases in populations since 2003, and populations have continued to show a positive relationship to spring precipitation. The available data are not consistent with regard to an overall population trend for *L. papilliferum.* The data from OTA indicate that plant abundance declined after 1995 and was generally correlating with spring precipitation until 2003 through present when plant abundance did not increase with higher levels of spring precipitation. Range-wide data indicate that *L. papilliferum* abundance has correlated with spring precipitation and abundance of the plant range-wide has increased since 2004 to levels comparable to 1998 range-wide data. We consider this range-wide data to be the best available at this time.

Identification of data gaps and uncertainties helps explain the limits of our understanding of future risk to *Lepidium papilliferum.* We are required to make a determination whether the species qualifies as threatened or

endangered under the Act based solely on the best available scientific and commercial data. To ensure that we considered this data in the proper context, the Manager Panel (see Status Review Process) participated in a structured analysis that included an evaluation of the Act's statutory requirements, in particular the Act's definitions of threatened and endangered, and a review of the data from the risk analysis and all other compiled biological information. They considered the data about risks to *L. papilliferum,* including explicit measures of uncertainty, and the data supporting the existence of those risks, in the context of the requirements of the Act. The definitions in the Act include: an endangered species is in danger of extinction throughout all or a significant portion of its range, and a threatened species is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. 1532(6), (20)).

The Manager Panel convened on three occasions: once during the science panel and shortly after the science panel in May 2006, and again in November 2006.

When the Manager Panel convened in November 2006, focal points of discussion included results of the Menke and Kaye 2006 report that was not available at the time of the science panel and new insights gained from public comment and review of monitoring results. Of particular note were the results that spring precipitation (March–May) explained 89 percent of the variation in plant abundance for the years 1998–2001, 2002, and 2004 sampled by range-wide HII and HIP transects (Menke and Kaye 2006b, p. 10). In addition, this report demonstrated a consistent correlation between the abundance of *Lepidium papilliferum* and spring rainfall throughout all years and reported population increases range-wide since 2003, which contradicted trends reported based on data from the OTA.

Upon reviewing the studies and plant abundance data, the Manager Panel concluded that indications of declines in plant abundance at OTA cannot be reasonably extrapolated to the range-wide population of *Lepidium papilliferum,* and that the conflicting data indicating range-wide population increases in recent years from the HII and HIP transects add additional uncertainty to our ability to assess the nature of any population trend for *L. papilliferum.* The high variability in plant numbers from year to year, expected for an ephemeral annual plant with a dormant seed bank that is highly dependent on seasonal rainfall, increases the difficulty of discerning any trend in abundance data over time. Although the quality of the sagebrush-steppe slickspot habitat of *L. papilliferum* has become degraded due to a variety of threats, the existing data do not support a determination that those threats are affecting *L. papilliferum* across all or a significant portion of its range sufficient to require the protections of the Act at this time. The managers decided that the data before them did not support a determination that *L. papilliferum* is exhibiting a population decline. The available data do not lead us to conclude that the species is declining range-wide, thus we are unable to establish that there is a point in time when the species is likely to be in danger of extinction throughout all or a significant part of its range. The district court decision found that our previous analysis of foreseeable future was unsupported in the record. In particular, the court noted that the expert panel concluded that there was a 64–80 percent chance that *L. papilliferum* would become extinct in the next 100 years. Thus, the court thought that our ultimate conclusion that the species was not likely to become in danger of extinction in the foreseeable future depended upon a preliminary conclusion that the foreseeable future was in this case a period of time considerably less than 100 years. Because the court found that we had not adequately explained why the Service selected the timeperiod it did for foreseeable future, the court held that our determination was arbitrary and capricious. In contrast, given the new information, the question of how much of the future is foreseeable is no longer relevant. We conclude that apparent abundance of the plant can fluctuate widely from one year to the next, and abundance is strongly correlated with spring precipitation. We have no data demonstrating that precipitation levels are varying significantly from historical patterns. *L. papilliferum* evolved in an arid environment and has adapted to fluctuations in precipitation by a strategy of relatively long-term seed viability and by increased seed production during favorable conditions. Thus, there is no current evidence that threats are working to threaten the species with endangerment and we cannot predict extinction at any point in time in the foreseeable future, regardless of whether the foreseeable future is defined as less than 100 years, 100 years, or more than 100 years.

In summary, the Act requires us to make a decision based on the best available data at the time of the listing determination. The best available data for *Lepidium papilliferum* indicate that, while the broad scale habitat in which the species exists is degraded, we have no data that correlates this with species abundance. We know that annual abundance is strongly correlated with spring precipitation (March–May) and a high degree of variability in annual abundance is therefore to be expected. The best available range-wide data indicate that abundance of the population range-wide is strongly correlated with precipitation and has increased in recent years in association with increased rainfall, as expected.

Accordingly based solely on the best available data, we find that *Lepidium papilliferum* is not presently in danger of extinction throughout all or a significant portion of its range nor is it likely to become an endangered species throughout all or a significant portion of its range in the foreseeable future.

References Cited

A complete list of all references cited herein, as well as others, is available upon request from our Snake River Basin Office (see **ADDRESSES** section).

Author(s)

The primary authors of this final rule are staff of the U.S. Fish and Wildlife Service.

Authority: 16 U.S.C. 1531 *et seq.*

Dated January 4, 2007.

H. Dale Hall,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 07–60 Filed 1–11–07; 8:45 am]

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Federal Register

Friday,
January 12, 2007

Part IV

Department of Labor

Office of the Secretary

The Department of Labor's Employee Occupational Safety and Health, Workers' Compensation, Drug Free Workplace, Employee Assistance, Voluntary Employee Health Services Fitness, and Drug Free Workplace Programs; Notice

DEPARTMENT OF LABOR

Office of the Secretary

[Secretary's Order 1–2007]

The Department of Labor's Employee Occupational Safety and Health, Workers' Compensation, Drug Free Workplace, Employee Assistance, Voluntary Employee Health Services Fitness, and Drug Free Workplace Programs

1. Purpose

To reaffirm policies and assign responsibilities for internal programs that promote the safety, well-being and productivity of the Department's employees, while conserving its financial resources. This Order addresses implementation and management of the occupational employee safety, health, workers' compensation, and return-to-work efforts, voluntary employee health services, employee assistance, fitness, and Drug Free Workplace programs.

2. Authorities and Directives Affected

A. Authorities. This Order is issued pursuant to section 19 of the Occupational Safety and Health Act of 1970 (Pub. L. 51–596); Executive Order 12196 (45 FR 12769), as amended by Executive Order 12223 (45 FR 45235); 29 CFR Part 1960; 5 U.S.C. 7901, et seq.; Executive Order 12564 (51 FR 32889); Mandatory Guidelines for Federal Workplace Drug Testing Programs, Alcohol, Drug Abuse, and Mental Health Administration, Department of Health and Human Services (April 11, 1988); the Federal Employee Substance Abuse Education and Treatment Act of 1986 (Pub. L. 99–570); the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (Pub. L. 93–282), and as amended by Pub. L. 96–180; the Drug Abuse Prevention, Treatment, and Rehabilitation Act of 1979 (Pub L. 96–181); the Privacy Act of 1974 (5 U.S.C. 552a), as amended; Health Insurance and Portability and Accountability Act of 1996 (''HIPAA'') (Pub. L. 104–191); Executive Order 10450 (18 FR 2489); Section 503 of the Supplemental Appropriations Act of 1987 (Pub. L. 100–71) (5 U.S.C. 7301 note); Mandatory Guidelines for Federal Workplace Drug Testing Programs, Substance Abuse and Mental Health Services Administration, Department of Health and Human Services (HHS) guidelines, as amended (53 FR 11970), April 11, 1988, and as revised in 1994; the Civil Service Reform Act of 1978 (5 U.S.C. 2301); the Department of Labor Drug-Free Workplace Plan, July 2004.

B. *Directives Affected.* This order supersedes and cancels Secretary's Order 5–95.

3. Background

Various public laws and federal regulations require Federal agencies to establish and operate comprehensive occupational safety and health, workers' compensation, employee assistance, and drug-free workplace programs. Other public laws and federal regulations authorize Federal agencies to establish and operate voluntary employee health services and fitness programs. Accordingly, this Order prescribes the policies and procedures to which DOL managers and employees are expected to adhere and assigns responsibility for their development and implementation.

4. Scope

This Order is applicable to all DOL employees, work activities, facilities, motor vehicles, and equipment.[k3]

5. Policy

It is the policy of the Department of Labor:

- To provide its employees places and conditions of employment that are free from recognized hazards that are likely to cause death or serious physical harm;
- To comply with applicable federal occupational safety and health standards, requirements, and procedures;
- To ensure prompt abatement of unsafe or unhealthful working conditions;
- To ensure that no employee is subject to restraint, interference, coercion, discrimination, or reprisal for filing reports of unsafe or unhealthful working conditions or otherwise appropriately participating in the Department's occupational safety and health program;
- To inspect, at least annually, all of its workplaces;
- To provide appropriate occupational safety and health-related education for managers, supervisors, employees, and those persons assigned safety and occupational health responsibilities;
- To support employees in staying fit, healthy, drug-free and productive on the job;
- To assist them when workers' compensation services are sought; and
- To provide meaningful return-to-work opportunities for employees injured or made ill on the job.

The Department's staff shall use their best and continuous efforts to maintain a safe and healthful work environment in accordance with best work practices and legislative requirements. All staff shall strive to eliminate hazards that might result in personal injuries, fires, security losses or damage to property by providing the necessary training, encouragement, resources and accountability. Occupational illness prevention shall be accomplished through appropriate industrial hygiene and occupational medical programs, including engineering controls, employee monitoring, health testing and education.

6. Responsibilities

A. *The Assistant Secretary for Administration and Management* is the Designated Agency Safety and Health Official (DASHO) pursuant to section 1–201 (c) of Executive Order 12196, and is responsible for establishing, administering, managing, and conducting internal self-evaluation of the Department's occupational safety and health program. In addition to safety and occupational health responsibilities as DASHO, the Assistant Secretary for Administration and Management is also responsible for establishing, administering, and managing the Department's programs relating to voluntary employee health services, fitness, employee assistance, drug-free workplace, workers' compensation, and return-to-work efforts. The Department of Labor Manual Series (DLMS) provides information on the conduct of some of these programs. In addition, the ASAM is responsible for:

(1) Securing the services of professional staff qualified to provide technical support and management assistance to DOL agencies on occupational safety and health, workers' compensation, return-to-work, drug-free workplace, and employee assistance programs.

(2) Providing voluntary health, wellness, and fitness programs for DOL employees, as appropriate.

B. *The Office of Worker Safety and Health* established in the Office of the Assistant Secretary for Administration and Management is an integral part of the Department's internal safety management program. OWSH shall assist management in implementing and monitoring this order to accomplish its objectives and ensure that the programs under OWSH's purview function as directed. Performance will be continuously measured and periodically evaluated by OWSH to determine areas requiring improvement. In addition, the OWSH is responsible for providing guidance and advice to management,

and employees regarding safety and health matters, developing hazard control designs, methods, procedures and programs, measuring and evaluating the effectiveness of hazard controls, compiling, analyzing and reporting performance data, and developing pertinent education and training information. Further, OWSH provides program direction to the Regional Administrators/OASAM and Regional safety and health managers. Finally, OWSH is responsible for centralized management of the Department's Workers' Compensation Program, from initiation of claims through claim management and return-to-work coordination.

C. *The Office of WorkLife and Benefits Programs (OWLBP)* established in the Office of the Assistant Secretary for Administration and Management is responsible for providing programs to improve the health and well-being of employees.

These programs include but are not limited to voluntary employee health services, including provision of health clinics where practical, provision of health and wellness guidance, provision of an employee assistance program, and drug free workplace program. The OWLBP provides policy and guidance for the Department in these program areas. The OWLBP shall assist management in implementing and monitoring this order to accomplish its objectives and ensure that the programs under the Office's purview function as directed.

D. The DOL Agency Heads are responsible for:

(1) Giving full management support to the Department's safety and occupational health, workers' compensation, return-to-work ,voluntary employee health services, fitness, employee assistance, and drug-free workplace programs, as provided in this Order.

(2) Implementing and maintaining occupational safety and health programs in their national and field offices in accordance with Departmental policy, applicable statutory, regulatory, administrative, and contractual requirements.

(3) Appointing and having trained a sufficient number of staff throughout their organizations to perform collateral or full-time support for the following programs: Occupational safety and health, workers' compensation coordination, return-to-work program drug-free workplace, voluntary employee health services, fitness, employee assistance, and to support safety and health committees; and to assist managers, supervisors, and employees in the implementation of their responsibilities outlined in this Order.

(4) Providing leadership that supports attainment of the Department's safety, health and return-to-employment goals developed to reduce employee accidents, injuries, and illnesses, and contain workers' compensation costs.

(5) Holding managers, supervisors and employees accountable for their adherence to established occupational safety and health, workers' compensation policies employee assistance, and drug free workplace, rules, regulations, and procedures.

(6) Ensuring that agency managers, supervisors, and employees participate in educational and training experiences necessary to carry out their assigned duties in a safe and healthful manner.

(7) Ensuring that employee representatives have the opportunity to participate in the DOL safety and occupational health program, including the opportunity to participate in educational and training experiences necessary to carry out their safety and occupational health responsibilities.

E. *Regional Administrators—OASAM (RA/OASAM)* are responsible for securing the services of professional staff to provide leadership, guidance, training, coordination, oversight, evaluation, cost containment initiatives, and technical assistance services to agency officials, managers, supervisors, employees, employee representatives, and safety and health committee members.

F. *DOL Managers and Supervisors* are responsible for:

(1) Ensuring that employees adhere to Departmental occupational safety, health, drug-free workplace and workers' compensation rules, regulations and standards, and integrating safety and health considerations into the planning of every job or task.

(2) Taking prompt action to have identified occupational safety and health hazards in their work environment abated, and providing instructions to employees on safe and proper work practices and procedures.

(3) Promptly and accurately reporting all accidents, injuries and occupational illnesses occurring on official duty by employees or contractors under their supervision electronically through the Safety and Health Information Management System (SHIMS), and participating on Accident Review Boards (ARBs).

(4) Conferring with the human resources office when the manager or supervisor believes that the employee's medical condition may be adversely affecting performance or conduct, to determine the manager's obligations under the Rehabilitation Act of 1973, including but not limited to, notifying the employee of the agency's Employee Assistance Program (EAP).

(5) Taking necessary steps to ensure the integrity of the Department's Workers' Compensation program, particularly the continuation of pay and return-to-work elements.

G. *DOL employees* are responsible for;

(1) Maintaining a high degree of safety awareness;

(2) Performing their duties in a safe manner and encouraging other employees to do likewise;

(3) Wearing and/or using personal protective equipment when necessary;

(4) Properly using tools and equipment provided;

(5) Immediately reporting safety and health-related hazards, accidents/injuries/occupational illnesses, unsafe or unhealthful acts or workplace conditions to their supervisors or occupational safety and health personnel; and

(6) Participating in appropriate occupational safety and health education and training.

H. *Safety and Health Committees* will be formed under the auspices of OWSH and in keeping with negotiated labor/management contracts, forming communication links between employees and the various levels of management, advising management on occupational safety and occupational health issues, and assisting with implementing occupational safety and occupational health awareness activities.

I. *The Solicitor* is responsible for providing legal advice and assistance to all Department of Labor officials relating to the implementation and administration of all aspects of this Order.

7. Effective Date

This Order is effective immediately.

Dated: January 5, 2007.

Elaine L. Chao,

Secretary of Labor.

[FR Doc. E7–264 Filed 1–11–07; 8:45 am]

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Federal Register

Friday,
January 12, 2007

Part V

Department of Labor

Employment and Training Administration

20 CFR Part 655

Labor Condition Application Requirements for Employers Seeking To Use Nonimmigrants on E–3 Visas in Specialty Occupations; Filing Procedures; Proposed Rule

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 655

RIN 1205–AB43

Labor Condition Application Requirements for Employers Seeking To Use Nonimmigrants on E–3 Visas in Specialty Occupations; Filing Procedures

AGENCY: Employment and Training Administration and Wage and Hour Division, Employment Standards Administration, Department of Labor.

ACTION: Notice of proposed rulemaking; request for comments.

SUMMARY: The Department of Labor (the Department or DOL) is proposing to amend its regulations regarding the temporary employment of nonimmigrant foreign professionals to implement procedural requirements applicable to the new E–3 visa category. This new visa classification was established by title V of the REAL ID Act of 2005 (Division B) in the Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Tsunami Relief, 2005, and applies to certain Australian nationals coming to the United States solely to perform services in specialty occupations. This Notice of Proposed Rulemaking (NPRM or proposed rule) clarifies the procedures that employers must follow in obtaining a DOL-certified labor condition application before seeking an E–3 visa for a foreign worker.

DATES: Interested persons are invited to submit written comments on this proposed rule on or before February 12, 2007.

ADDRESSES: You may submit comments, identified by RIN number 1205–AB43, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *E-mail: E3.comments@dol.gov*. Include RIN number 1205–AB43 in the subject line of the message.
- *Mail:* U.S. Department of Labor, Employment and Training Administration, 200 Constitution Avenue, NW., Room N–5641, Washington, DC 20210.
- *Hand Delivery/Courier:* 200 Constitution Avenue, NW., Room N–5641.

Please note that due to security concerns, postal mail delivery in Washington, DC may be delayed. Therefore, the Department encourages the public to submit comments via e-mail or Internet as indicated above.

Please also note that all comments received will be posted on the *www.regulations.gov* Web site. The *www.regulations.gov* Web site is the federal eRulemaking portal and all comments received will be available and accessible to the public. Therefore, the Department recommends that commenters safeguard their personal information such as social security numbers, personal addresses, telephone numbers, and e-mail addresses included in their comments as such may become easily available to the public via the *www.regulations.gov* Web site. If a comment is e-mailed directly to the Department's address without going through *www.regulations.gov*, the comment will have the sender's e-mail address attached to it and therefore, the email address and information contained therein may be posted online. It is the responsibility of the commenter to safeguard their information.

Instructions: All submissions must include the agency name and Regulatory Information Number (RIN 1205–AB43) for this rulemaking and must be received on or before the last day of the comment period. The Department will not open, read, or consider any comments received after that date. Also, the Department will not acknowledge receipt of any comments received.

All comments received will be posted on *www.regulations.gov* and may be posted without information redacted. The *www.regulations.gov* Web Site is a federal eRulemaking portal which is accessible to the public. Therefore, the Department is informing the public that personal information included in comments such as social security numbers, and personal addresses, phone numbers, and email address may be easily available to the public online. Also, if commenter's e-mail a comment directly to the Department's address without going through *www.regulations.gov,* the comment will have the sender's e-mail address attached to it and it may be posted.

Docket: All comments will be available for public inspection without change, including any personal information provided, between 8:30 a.m. and 5 p.m., at the Department of Labor, Employment and Training Administration, Office of Foreign Labor Certification, 200 Constitution Avenue, NW., Room C–4312, Washington, DC 20210. Copies of the rule are available in alternative formats of large print and electronic file on computer disk, which may be obtained at the above-stated address. The rule is available on the Internet at the Web address *http://www.doleta.gov*.

FOR FURTHER INFORMATION CONTACT: William L. Carlson, Administrator, Office of Foreign Labor Certification, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Room C–4312, Washington, DC 20210; Telephone: (202) 693–3010 (this is not a toll-free number).

For information regarding the E–3 enforcement process in 20 CFR part 655, subpart I, contact Diane Koplewski, Immigration Team Leader, Office of Enforcement Policy, Wage and Hour Division, Employment Standards Administration (ESA), U.S. Department of Labor, 200 Constitution Avenue, NW., Room S–3516, Washington, DC 20210; Telephone: (202) 693–0071 (this is not a toll-free number).

Individuals with hearing or speech impairments may access the telephone numbers above via TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

On May 11, 2005, title V of the REAL ID Act of 2005 (Division B) in the Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Tsunami Relief, 2005 (Pub. L. 109–13, § 501, 119 Stat. 231, 278 (2005)), amended section 101(a)(15)(E) of the Immigration and Nationality Act (Act or INA) (8 U.S.C. 1184 *et seq.*) to add a new nonimmigrant classification for aliens who enter the United States under a treaty with a foreign country of which the alien is a national. 8 U.S.C. 1101(a)(15)(E). Section 501 of title V of the REAL ID Act established reciprocal visas, known as the E–3 visa category, for Australian nationals who enter solely to perform services in specialty occupations in the United States. The definition of a specialty occupation for the E–3 visa program is the same as it is for the H–1B visa program. 8 U.S.C. 1184(i)(1); 20 CFR 655.715.

The E–3 visa classification applies only to nationals of the Commonwealth of Australia and is limited to 10,500 initial visas annually. 8 U.S.C. 1184(g)(11)(A)–1184(g)(11)(B). Spouses and children do not count against the numerical limitation nor are they required to possess the nationality of the principal. 8 U.S.C. 1184(g)(11)(C). The sponsoring employer must present a labor condition application (LCA) attesting to the wages and working conditions certified by the Department

of Labor (Department or DOL) to the Department of State (DOS) Consular Officer at the time of visa application. 8 U.S.C. 1101(a)(15)(E)(iii), 1182(t)(1); *see also* 22 CFR 41.51.

An employer seeking to employ aliens on an E–3 visa to work in a specialty occupation in the United States must file a labor attestation under section 212(t) of the Immigration and Nationality Act, 8 U.S.C. 1182(t), with the Employment and Training Administration (ETA) of DOL. This requirement is the same requirement applicable to employers seeking to employ Chilean or Singaporean nationals on nonimmigrant H–1B1 worker visas as professionals in specialty occupations under 8 U.S.C. 1182(t). The labor attestation requirements in INA section 212(t) for H–1B1, and now E–3, parallel the labor condition application requirements in section 212(n) of the INA, 8 U.S.C. 1182(n), for nonimmigrant H–1B visas that permit employers to hire foreign professionals in specialty occupations.

Since most of the requirements in section 212(n) and section 212(t) are similar, the Department extended its H–1B regulations—with certain exceptions as required by the H–1B1 statute—to the H–1B1 program through an Interim Final Rule published on November 23, 2004, at 69 FR 68222. The H–1B1 Interim Final Rule was adopted with one change in a Final Rule published in the **Federal Register** on June 30, 2006 at 71 FR 37802. In this NPRM, the Department seeks to extend the H–1B regulations to the E–3 program.

II. Statutory Requirements

An employer who wishes to employ a professional who is a national of the Commonwealth of Australia in the United States under the E–3 visa program must submit a labor condition application to DOL that includes elements required of an employer under the existing H–1B and H–1B1 visa programs. INA section 212(t)(1), 212(n)(1); 8 U.S.C. 1182(t)(1), 1182(n)(1). As required under the H–1B and H–1B1 programs, the E–3 employer must attest that:

- It is offering the nonimmigrant, and will pay during the period of authorized employment, wages that are at least the actual wage level paid to other employees with similar experience and qualifications for the specific employment in question, or the prevailing wage level for the occupational classification in the area of intended employment, whichever is greater;
- It will provide working conditions for the nonimmigrant that will not adversely affect working conditions for similarly employed workers;
- There is no strike or lockout in the course of a labor dispute in the occupational classification at the worksite; and
- It has provided notice of its filing of a labor attestation to its employees' bargaining representative for the occupational classification affected or, if there is no bargaining representative, has provided notice to its employees in the affected occupational classification by physical posting or other means.

As required in the H–1B and H–1B1 programs, the Department may review E–3 labor attestations only for completeness and obvious inaccuracies. Unless a filing is incomplete or obviously inaccurate, the Secretary of Labor must certify the E–3 filing within seven days of filing. INA section 212(t)(2)(C); 8 U.S.C. 1182(t)(2)(C). The maximum period for which an E–3 labor attestation will be certified is two years from the employment start date as indicated on the LCA. This certification period is consistent with the Department of Homeland Security's (DHS) regulation for admission of treaty traders and investors for a maximum period of two years and Department of State's practice. *See* 8 CFR § 214.2(e)(19)–(20); *see also* U.S. Dep't of State, 2005 Foreign Affairs Manual 9 (Issued at 9 FAM 41.51, N16.9, ''Validity of Issued Visa''). An employer must file a new E–3 labor condition application to renew an attestation beyond the initial two-year period.

After the DOL attestation process is completed, DHS' United States Citizenship and Immigration Services and DOS are responsible for processing the individual E–3 visa requests. DOS issued a Final Rule for the E–3 program at 22 CFR 41.51(c) on September 2, 2005. 70 FR 52292. Under that process, a petition to DHS is not necessary for initial E–3 visa requests. Instead, a foreign worker who is seeking an E–3 visa and is not currently in the United States must present the necessary evidence for classification directly to the Consular Officer at the time of visa application. 22 CFR 41.51(c).

As with labor condition applications for H–1B and H–1B1 nonimmigrants, the Secretary of Labor must compile a list by employer and occupational classification of all labor attestations filed regarding E–3 nonimmigrants. The list identifies the wage rate, number of alien professionals sought, period of intended employment, and date of need for each attestation. INA section 212(t)(2)(B); 8 U.S.C. 1182(t)(2)(B). The Department must make the list available for public inspection in Washington, DC.

Enforcement provisions for E–3 labor condition applications are based on the requirements of the H–1B1 visa program. *See* INA section 212(t)(3); 8 U.S.C. 1182(t)(3). The Department will receive, investigate, and make determinations on complaints filed by any aggrieved person or organization regarding the failure of an employer to meet the terms of its attestations. DOL is also authorized to conduct random investigations for a period of up to five years of any employer found by DOL to have committed a willful failure to meet a required attestation or to have made a willful misrepresentation of a material fact in an attestation. 8 U.S.C. 1182(t)(3)(E). Penalties for failure to meet conditions of the E–3 labor attestations are the same as those under the H–1B1 program. Enforcement of E–3 labor attestations is handled by the Wage and Hour Division, Employment Standards Administration (ESA), of DOL.

III. Overview of Regulatory Changes

As summarized in section II above, the Act requires the Department to align the E–3 visa program with the requirements of the H–1B and H–1B1 program. Therefore, this proposed rule will amend the H–1B and H–1B1 regulations in 20 CFR part 655, subparts H and I, and extend those subparts' procedures, with limited exceptions based upon statutory requirements, to temporary entry and employment under E–3 visas as follows.

The Department is proposing in § 655.0(d) to include the new E–3 visa category in the scope and purpose of the regulation. This paragraph would be expanded to state that the labor condition application process applies to three categories of nonimmigrants in the United States.

The Department also proposes to add § 655.700(c)(3) to address the process for filing labor condition applications under the E–3 visa category. DOL's statutory responsibilities regarding the E–3 program took effect on the enactment date of the Emergency Supplemental Appropriations Act on May 11, 2005. Pub.L. 109–13, Div. B, § 103(d), 119 Stat. 231, 308 (May 11, 2005). Subsequently, on July 19, 2005, the Department published E–3 application procedures as a Notice in the **Federal Register** at 70 FR 41430. Therefore, E–3 attestations filed on or after July 19, 2005, but prior to this proposed rule's effective date, will be handled according to the statutory terms and the processing procedures that the Department has established.

Existing § 655.700(c)(4) outlines the Department's protocol for accepting and certifying H–1B1 visa LCAs between the effective date of the legislation (January 1, 2004) and the date the Department published the Interim Final Rule (November 23, 2004). Those LCAs filed on or after January 1, 2004, but before November 23, 2004, were processed under the H–1B1 statutory provisions and the processing procedures previously published on the Department's Web site. Any LCAs received on or after November 23, 2004, were processed according to the requirements of the Interim Final Rule.

The Department proposes to amend § 655.700 paragraphs (d)(1) and (d)(2) to include the E–3 visa category.

The Department proposes to amend § 655.700(d)(3) to require employers seeking to employ nonimmigrant professionals temporarily under E–3 visas to file labor attestations with the Department, which has been amended to include ETA Form 9035E (electronic).

The Department proposes to amend § 655.700(d)(4) to extend the employer responsibilities under the H–1B1 program to E–3. In addition, § 655.700(d)(1), which lists certain H–1B regulations that are not applicable to the H–1B1 program, is proposed to be amended to also exclude E–3. Among the exclusions listed in paragraph (d)(1) are the special attestations related to ''H–1B-dependent employers'' and ''willful violators'' of the H–1B rules. Currently, these provisions only apply to H–1B nonimmigrant program and do not apply to the H–1B1 program. The Department proposes to amend § 655.700 to also exclude the E–3 nonimmigrant program from the listed H–1B provisions. These changes are consistent with the statutory requirement to align the E–3 program with the H–1B1 program.

The Department proposes amending §§ 655.705, 655.715, 655.730 and 655.740 to include references to the new E–3 visa category.

In § 655.750(a), the reference to entering multiple periods of intended employment on Forms 9035 and 9035E is proposed to be removed. Although the language has appeared in the regulations, the forms, including the new Internet version, historically have not included opportunities for submitting such information. In addition, it has not been the practice of employers filing LCAs to include multiple periods of intended employment on the written forms.

Section 655.750(a) is proposed to be amended to specify the maximum validity period for approved E–3 LCAs. The Department addressed the validity period in 1994 when it adopted the current H–1B regulations. At that time, the Department decided to adopt a three-year period for H–1B visa holders because it was consistent with the Immigration and Naturalization Services' admission period for such workers. 59 FR 65646, 65648–65649 (December 20, 1994). The same rationale applies to the maximum validity period for approved E–3 LCAs, which we have set at two years to correspond to the U.S. Citizenship and Immigration Service's admission period.

The proposed rule also addresses the maximum validity period for a nonimmigrant who begins employment before the LCA is certified, as is authorized by the portability provision at section 214(n) of the INA, 8 U.S.C. 1184(n). Under the proposed rule, the maximum validity period for the E–3 LCA is two years, which begins on the employment date listed on the approved LCA. The E–3 LCA validity period is unaffected by an employee's change in employers. Therefore, the portability of a nonimmigrant has no impact on the E–3 LCA maximum validity period.

In § 655.750(b)(2), a process for withdrawing E–3 labor condition applications has also been proposed consistent with statutory requirements.

Subpart I of this Part is proposed to be revised to include the new E–3 visa category in the heading.

As specified above, this NPRM also includes technical and clarifying amendments to subparts H and I of 20 CFR Part 655, primarily to include the new E–3 visa category. Therefore, consistent with the labor condition application process under the H–1B and H–1B1 programs, employers filing under the E–3 program may file applications electronically at *http://www.foreignlaborcert.doleta.gov*. Under appropriate circumstances, employers may mail applications to: Manager, Temporary Programs, U.S. Department of Labor, ETA/OFLC, 200 Constitution Avenue, NW., Room C–4312, Washington, DC 20210.

IV. Administrative Information

Executive Order 12866—Regulatory Planning and Review: We have determined that this rule is not an ''economically significant regulatory action'' within the meaning of Executive Order 12866. The procedures for filing a labor attestation under the new E–3 visa category on behalf of nonimmigrant professionals from Australia will not have an economic impact of $100 million or more. Employers seeking to employ E–3 nonimmigrant professionals will continue to use the same procedures and forms presently required for the H–1B and H–1B1 nonimmigrant programs. E–3 visas will be subject to annual numerical limits. Although this NPRM is not economically significant as defined by Executive Order 12866, it is a significant rule and has therefore been reviewed by the Office of Management and Budget (OMB). This NPRM is considered otherwise significant because it implements a new program and must be closely coordinated with other Federal agencies that are also responsible for implementing the E–3 program, such as the Departments of State and of Homeland Security.

Regulatory Flexibility Analysis: We have notified the Chief Counsel for Advocacy, Small Business Administration, and made the certification under the Regulatory Flexibility Act (RFA) at 5 U.S.C. 605(b), that this NPRM would not have a significant economic impact on a substantial number of small entities.

This rule would implement statutory provisions enacted by Congress that narrowly extend the scope of DOL's existing H–1B and H–1B1 programs to include similar labor attestation filing requirements for the temporary entry of nonimmigrant Australian professionals under the new E–3 visa classification. Employers seeking to hire these E–3 nonimmigrant professionals will use the same procedures and forms presently required for H–1B and H–1B1 nonimmigrant professionals. In addition, E–3 visas will be subject to an annual numerical limit of 10,500 per fiscal year.

Based on E–3 filing data for fiscal year 2005 (FY 2005), the Department estimates that in the upcoming year employers will file approximately 833 attestations with the Department under the E–3 program. According to the definition of ''small business'' under the Small Business Administration Act, the majority of employers filing in FY 2005 are not categorized as small businesses. Under the Small Business Administration Act, a small business is one that is ''independently owned and operated and which is not dominant in its field of operation.'' Further, the definition varies from industry to industry to the extent necessary to properly reflect industry size differences.

The Department determined its size standard analysis based on 13 CFR Part 121 that describes the size standards. In terms of the size standards, although some employers will file multiple attestations with the Department in a year the Department does not anticipate a significant expansion in filings in this

program because the E–3 visa category is subject to annual numerical limits. The Department further relied on the FY 2005 data of the major industries that applied for E–3 temporary visas with the Department to form its analysis.

The Department determined that the following industries predominate in the E–3 program: (1) Healthcare and Social Assistance industry (attestations filed for Medical Residents, Chiropractors, Physical Therapists, Acupuncturists, Dentists, Physicians, Veterinarians, Psychiatrists, Mental Health Counselors, and Medical Lab Technicians); (2) Educational industry (attestations filed for Teachers, Professors, and Tutors); (3) Finance and Insurance industry (attestations filed for Accountants, Business Analysts, Financial Analysts and Investor Analysts); and (4) Professional, Scientific and Technological Industry (attestations filed for Computer Programmers, Technicians, Information and Support Specialists, Software Engineers, and Systems and Program Analysts). The Department has reviewed the data from each of these industries as described below to determine that there is no significant impact on small businesses.

In the United States, there are 708,000 Professional, Scientific and Technological small businesses. In FY 2005, 68 attestations were filed with the Department for positions in the Professional, Scientific and Technological industry. Using this data, we estimate the number of different (or non-duplicated) employers who will file the expected 68 applications with the Department, represents approximately 0.010% of all Professional, Scientific and Technological small businesses.

In the United States, there are 65,933 Educational small businesses. In FY 2005, 43 attestations were filed with the Department for positions in the Education industry. Using this data, we estimate the number of different (or non-duplicated) employers who will file the expected 43 applications with the Department, represents approximately 0.065% of all Educational small businesses.

In the United States, there are 560,083 Healthcare and Social Assistance small businesses. In FY 2005, 33 attestations were filed with the Department for positions in the Healthcare and Social Assistance industry. Using this data, we estimate the number of different (or non-duplicated) employers who will file the expected 33 applications with the Department, represents approximately 0.006% of all Healthcare and Social Assistance small businesses.

In the United States, there are 259,846 Finance and Insurance small businesses. In FY 2005, 26 attestations were filed with the Department for positions in the Finance and Insurance industry. Using this data, we estimate the number of different (or non-duplicated) employers who will file the expected 26 applications with the Department, represents approximately 0.010% of all Finance and Insurance small businesses. For the reasons stated above, DOL does not believe this proposed rule will impact a substantial number of small entities.

Moreover, the Department of Labor does not believe this proposed rule would have a significant economic impact on small businesses. First, the Department does not require employers to submit a filing fee for the H–1B1 program, which is consistent with past practice. Therefore, under this NPRM, an employer would submit an E–3 visa application to the Department at no cost. Second, the Department estimates that it takes less than thirty minutes to complete Form ETA 9035E or Form ETA 9035. Given that the Department did not add fields to the OMB approved forms, no additional time is required to prepare and submit the forms. Therefore, under this NPRM, an employer would spend the same amount of time preparing and submitting Form ETA 9035E or Form ETA 9035 for the H–1B1 program as the employer would for application under the H–1B program. In sum, the attestation and filing activities under this NPRM are no different from those required under the existing H–1B program and this NPRM establishes no additional economic burden on small entities.

Unfunded Mandates Reform Act of 1995: This NPRM would not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996: This NPRM is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996 (SBREFA). The standards for determining whether a rule is a major rule as defined by section 804 of SBREFA are similar to those used to determine whether a rule is an ''economically significant regulatory action'' within the meaning of Executive Order 12866. Further, because the Department certified that this rule is not an economically significant rule under Executive Order 12866, we certify also that it is not a major rule under SBREFA. Therefore, this NPRM would not result in an annual effect on the economy of $100 million or more; cause a major increase in costs or prices; or have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Executive Order 13132—Federalism: This proposed rule 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 as described by Executive Order 13132. Therefore, the Department has determined that this proposed rule will not have a sufficient federalism implication to warrant the preparation of a summary impact statement.

Assessment of Federal Regulations and Policies on Families: This NPRM does not affect family well-being.

Paperwork Reduction Act: Forms and information collection requirements related to the Department's E–3, H–1B, and H–1B1 programs under 20 CFR part 655, subpart H, are approved currently under OMB control number 1205–0310 (expiration date November 30, 2008). This NPRM does not include a substantive or material modification of that collection of information. Existing H–1B/H–1B1 paperwork forms and filing procedures will be used by potential employers of an additional category of foreign temporary workers—nationals from Australia. Because E–3 visas will be subject to annual numerical limits, the Department does not anticipate a substantial increase in filings under 20 CFR part 655, subpart H.

Catalog of Federal Domestic Assistance Number: This program is listed in the *Catalog of Federal Domestic Assistance* at Number 17.252, ''Attestations by Employers Using Non-Immigrant Aliens in Specialty Occupations.''

List of Subjects in 20 CFR Part 655

Administrative practice and procedure, Agriculture, Aliens, Australia, Chile, Employment, Forest and forest products, Health professions, Immigration, Labor, Longshore work, Migrant labor, Penalties, Reporting requirements, Singapore, Students, Wages.

Accordingly, we propose that 20 CFR part 655, Code of Federal Regulations, be amended as follows:

PART 655—TEMPORARY EMPLOYMENT OF ALIENS IN THE UNITED STATES

1. The authority citation for part 655 is revised to read as follows:

Authority: Section 655.0 issued under 8 U.S.C. 1101(a)(15)(H)(i) and (ii), 1182(m), (n), and (t), 1184, 1188, and 1288(c) and (d); 29 U.S.C. 49 *et seq.*; sec. 3(c)(1), Pub. L. 101–238, 103 Stat. 2099, 2102 (8 U.S.C. 1182 note); sec. 221(a), Pub. L. 101–649, 104 Stat. 4978, 5027 (8 U.S.C. 1184 note); sec. 323, Pub. L. 103–206, 107 Stat. 2149; Title IV, Pub. L. 105–277, 112 Stat. 2681; Pub. L. 106–95, 113 Stat. 1312 (8 U.S.C. 1182 note); and 8 CFR 213.2(h)(4)(i).

Section 655.00 issued under 8 U.S.C. 1101(a)(15)(H)(ii), 1184, and 1188; 29 U.S.C. 49 *et seq.*; and 8 CFR 214.2(h)(4)(i).

Subparts A and C Issued Under 8 U.S.C. 1101(a)(15)(H)(ii)(b) and 1184; 29 U.S.C. 49 *et seq.*; and 8 CFR 214.2(h)(4)(i).

Subpart B Issued Under 8 U.S.C. 1101(a)(15)(H)(ii)(a), 1184, and 1188; and 29 U.S.C. 49 *et seq.*

Subparts D and E Issued Under 8 U.S.C. 1101(a)(15)(H)(i)(a), 1182(m), and 1184; 29 U.S.C. 49 *et seq.*; and sec. 3(c)(1), Pub. L. 101–238, 103 Stat. 2099, 2103 (8 U.S.C. 1182 note).

Subparts F and G Issued Under 8 U.S.C. 1184 and 1288(c); and 29 U.S.C. 49 *et seq.*

Subparts H and I Issued Under 8 U.S.C. 8 U.S.C. 1101(a)(15)(E)(iii), 1101(a)(15)(H)(i)(b) and (b1), 1182(n), 1182(t), and 1184; 29 U.S.C. 49 *et seq.*; sec. 303(a)(8), Pub. L. 102–232, 105 Stat. 1733, 1748 (8 U.S.C. 1182 note); and Title IV, Pub. L. 105–277, 112 Stat. 2681.

Subparts J and K Issued Under 29 U.S.C. 49 *et seq.*; and sec. 221(a), Pub. L. 101–649, 104 Stat. 4978, 5027 (8 U.S.C. 1184 Note).

Subparts L and M Issued Under 8 U.S.C. 1101(a)(15)(H)(i)(c), 1182(m), and 1184; and 29 U.S.C. 49 *et seq.*

2. Revise § 655.0(d) to read as follows:

§ 655.0 Scope and purpose of Part.

* * * * *

(d) *Subparts H and I of this Part.* Subpart H of this part sets forth the process by which employers can file labor condition applications (LCAs) with, and the requirements for obtaining approval from, the Department of Labor to temporarily employ the following three categories of nonimmigrants in the United States: H–1B visas for temporary employment in specialty occupations or as fashion models of distinguished merit and ability; H–1B1 visas for temporary employment in specialty occupations of nonimmigrant professionals from countries with which the United States has entered into certain agreements identified in section 214(g)(8)(A) of the INA; and E–3 visas for nationals of the Commonwealth of Australia for temporary employment in a specialty occupation. Subpart I of this part establishes the enforcement provisions that apply to the H–1B, H–1B1 and E–3 visa programs.

* * * * *

3. Revise the heading of subpart H to read as follows:

Subpart H—Labor Condition Applications and Requirements for Employers Seeking To Employ Nonimmigrants on H–1B Visas in Specialty Occupations and as Fashion Models, and Requirements for Employers Seeking To Employ Nonimmigrants on H–1B1 and E–3 Visas in Specialty Occupations

4. Amend § 655.700 by revising the section heading and introductory text, paragraphs (c)(3), (d)(1), (d)(2), (d)(3), (d)(4)(i) and (d)(4)(ii), and adding new paragraph (c)(4) to read as follows:

§ 655.700 What statutory provisions govern the employment of H–1B, H–1B1, and E–3 nonimmigrants and how do employers apply for H–1B, H–1B1, and E–3 visas?

Under the E–3 visa program, the Immigration and Nationality Act (INA), as amended, permits certain nonimmigrant treaty aliens to be admitted to the United States solely to perform services in a specialty occupation (INA section 101(a)(15)(E)(iii)). Under the H–1B1 visa program, the INA permits nonimmigrant professionals in specialty occupations from countries with which the United States has entered into certain agreements that are identified in section 214(g)(8)(A) of the INA to temporarily enter the United States for employment in a specialty occupation. Employers seeking to employ nonimmigrant workers in specialty occupations under H–1B, H–1B1 or E–3 visas must file a labor condition application with the Department of Labor as described in § 655.730(c) and (d). Certain procedures described in this subpart H for obtaining a visa and entering the U.S. after the Department of Labor attestation process, including procedures in § 655.705, apply only to H–1B nonimmigrants. The procedures for receiving an E–3 or H–1B1 visa and entering the U.S. on an E–3 or H–1B1 visa after the attestation process is certified by the Department of Labor, are identified in the regulations and procedures of the Department of State and the United States Citizenship and Immigration Services (USCIS) of the Department of Homeland Security. Consult the Department of State (*http://www.state.gov/*) and USCIS (*http://uscis.gov/*) Web sites and regulations for specific instructions regarding the E–3 and H–1B1 visas.

* * * * *

(c) * * *

(3) *E–3 visas:* Subject to paragraph (d) of this section, this subpart H and subpart I of this part apply to all employers seeking to employ foreign workers under the E–3 visa classification in specialty occupations under INA section 101(a)(15)(E)(iii) (8 U.S.C. 1101(a)(15)(E)(iii)). This paragraph (c)(3) applies to labor condition applications filed on or after (*this will be the date of publication of the final rule in the* ***Federal Register***). E–3 labor condition applications filed prior to that date but on or after May 11, 2005 (i.e., the effective date of the statute), will be processed according to the E–3 statutory terms and the E–3 processing procedures published on July 19, 2005 in the **Federal Register** at 74 FR 41434.

(4) *H–1B1 visas:* Subject to paragraph (d) of this section, subparts H and I of this part apply to all employers seeking to employ foreign workers under the H–1B1 visa classification in specialty occupations described in INA section 101(a)(15)(H)(i)(b1) (8 U.S.C. 1101(a)(15)(H)(i)(b1)), under the U.S.-Chile and U.S.-Singapore Free Trade Agreements as long as the Agreements are in effect. (INA section 214(g)(8)(A) (8 U.S.C. 1184(g)(8)(A)). This paragraph (c)(4) applies to H–1B1 labor condition applications filed on or after November 23, 2004. Further, H–1B1 labor condition applications filed prior to that date but on or after January 1, 2004, the effective date of the H–1B1 program, will be handled according to the H–1B1 statutory terms and the H–1B1 processing procedures as described in paragraph (d)(3) of this section.

(d) *Nonimmigrant on E–3 or H–1B1 visas*—(1) *Exclusions.* The following sections in this subpart and in subpart I of this part do not apply to E–3 and H–1B1 nonimmigrants, but apply only to H–1B nonimmigrants: §§ 655.700(a), (b), (c)(1) and (2); 655.705(b) and (c); 655.710(b); 655.730(d)(5) and (e)(3); 655.736; 655.737; 655.738; 655.739; 655.760(a)(8), (9) and (10); and 655.805(a)(7), (8) and (9). Further, any of the following references in subparts H or I of this part, whether in the excluded sections listed above or elsewhere, do not apply to E–3 and H–1B1 nonimmigrants, but apply only to H–1B nonimmigrants: references to fashion models of distinguished merit and ability (H–1B, but not H–1B1 and E–3 visas, are available to such fashion models); references to a petition process before the DHS (the petition process applies only to H–1B, but not to initial H–1B1 and E–3 visas); references to additional attestation obligations of H–1B-dependent employers and employers

found to have willfully violated the H–1B program requirements (these provisions do not apply to the H–1B1 and E–3 programs); and references in § 655.750(a) or elsewhere in this part to the provision in INA section 214(n) (formerly INA section 214(m)) regarding increased portability of H–1B status (by the statutory terms, the portability provision is inapplicable to H–1B1 and E–3 nonimmigrants).

(2) *Terminology.* For purposes of subparts H and I of this part, except in those sections identified in paragraph (d)(1) of this section as inapplicable to E–3 and H–1B1 nonimmigrants and as otherwise excluded:

(i) The term ''H–1B'' includes ''E–3'' and ''H–1B1'' (INA section 101(a)(15)(E)(iii) and (a)(15)(H)(i)(b1)); and

(ii) The term ''labor condition application'' or ''LCA'' includes a labor attestation made under section 212(t)(1) of the INA for an E–3 or H–1B1 nonimmigrant professional classified under INA section 101(a)(15)(E)(iii) and (a)(15)(H)(i)(b1).

(3) *Filing procedures for E–3 and H–1B1 labor attestations.* Employers seeking to employ an E–3 or H–1B1 nonimmigrant must submit a completed ETA Form 9035 or ETA Form 9035E (electronic) to DOL in the manner prescribed in §§ 655.720 and 655.730. Employers must indicate on the form whether the labor condition application is for an ''E–3 Australia,'' ''H–1B1 Chile'' or ''H–1B1 Singapore'' nonimmigrant. Any changes in the procedures and instructions for submitting labor condition applications will be provided in a notice published in the **Federal Register** and posted on the ETA Web site at *http://www.foreignlaborcert.doleta.gov*.

(4) *Employer's responsibilities regarding E–3 and H–1B1 labor attestation.* Each employer seeking an E–3 or H–1B1 nonimmigrant in a specialty occupation has several responsibilities, as described more fully in subparts H and I of this part, including the following:

(i) By submitting a signed and completed LCA, the employer makes certain representations and agrees to several attestations regarding the employer's responsibilities, including the wages, working conditions, and benefits to be provided to the E–3 or H–1B1 nonimmigrant. These attestations are specifically identified and incorporated in the LCA, and are fully described on Form ETA 9035CP (cover pages).

(ii) The employer reaffirms its acceptance of all of the attestation obligations by transmitting the certified labor attestation to the nonimmigrant, the Department of State, and/or the USCIS according to the procedures of those agencies.

* * * * *

5. Amend § 655.705 as follows:

a. Revise the section heading to read as set forth below.

b. Amend paragraph (c), by removing the phrase ''employer responsibilities under the H–1B1 program'' and adding in lieu thereof the phrase ''employer's responsibilities under the H–1B1 and E–3 programs''.

§ 655.705 What Federal agencies are involved in the H–1B, H–1B1, and E–3 programs, and what are the responsibilities of those agencies and of employers?

* * * * *

6. Amend § 655.715 as follows:

a. Amend paragraph (1) in definition of *Specialty Occupation* by removing the phrase ''For purposes of the H–1B (not including H–1B1) program'' and adding in lieu therof the phrase ''For purposes of the E–3 and H–1B programs (but not the H–1B1 program)''.

b. Revise the definition of *Employer* to read as follows:

§ 655.715 Definitions.

* * * * *

Employer means a person, firm, corporation, contractor, or other association or organization in the United States that has an employment relationship with H–1B, H–1B1 or E–3 nonimmigrants and/or U.S. worker(s). In the case of an H–1B nonimmigrant (not including E–3 and H–1B1 nonimmigrants), the person, firm, contractor, or other association or organization in the United States that files a petition with the United States Citizenship and Immigration Services (USCIS) of the Department of Homeland Security (DHS) on behalf of the nonimmigrant is deemed to be the employer of that nonimmigrant. In the case of an E–3 and H–1B1 nonimmigrant, the person, firm, contractor, or other association or organization in the United States that files an LCA with the Department of Labor on behalf of the nonimmigrant is deemed to be the employer of that nonimmigrant.

* * * * *

7. Amend § 655.720(a) by removing the phrase ''regarding H–1B and H–1B1 nonimmigrants'' and by adding in lieu thereof the phrase ''regarding H–1B, H–1B1 and E–3 nonimmigrants''.

8. Amend § 655.730 as follows:

a. Revise the introductory text to read as set forth below.

b. In paragraph (c)(4)(vii), remove the parenthetical phrase ''(and not applications regarding H–1B1 nonimmigrants) and add in lieu thereof the parenthetical phrase ''(and not application regarding H–1B1 and E–3 nonimmigrants)''.

c. In paragraph (c)(5), remove the sentence ''Separate LCAs must be filed for H–1B and H–1B1 nonimmigrants.'' and add in lieu thereof the sentence ''Separate LCAs must be filed for H–1B, H–1B1, and E–3 nonimmigrants.''

d. In paragraph (d)(5), remove the parenthetical phrase ''(and not regarding H–1B1 nonimmigrants)'' and add in lieu thereof the parenthetical phrase ''(and not applications regarding H–1B1 or E–3 nonimmigrants).

§ 655.730 What is the process for filing a labor condition application?

This section applies to the filing of labor condition applications for H–1B, H–1B1, and E–3 nonimmigrants.

* * * * *

9. Amend § 655.740(a)(2)(ii) by removing the phrase ''disqualified from employing H–1B nonimmigrants under section 212(n)(2) of the INA or from employing H–1B1 nonimmigrants under 212(t)(3) of the INA'' and adding in lieu thereof the phrase ''disqualified from employing H–1B nonimmigrants under section 212(n)(2) of the INA or from employing H–1B1 or E–3 nonimmigrants under section 212(t)(3) of the INA.''

10. In § 655.750, paragraphs (a) and (b)(2) are revised to read as follows:

§ 655.750 What is the validity period of the labor condition application?

(a) *Validity of certified labor condition applications.* A labor condition application (LCA) certified under § 655.740 is valid for the period of employment indicated by the authorized DOL official on Form ETA 9035E or ETA 9035. The validity period of a labor condition application will not begin before the application is certified and the period of authorized employment begins. If the approved application is the initial LCA issued for the nonimmigrant, the period of authorized employment must not exceed 3 years for a labor condition application issued on behalf of an H–1B or H–1B1 nonimmigrant and must not exceed 2 years for a labor condition application issued on behalf of an E–3 nonimmigrant. If a nonimmigrant is employed before the LCA is certified, the period of authorized employment in the aggregate is based on the first date of employment and ends:

(1) In the case of an H–1B or H–1B1 LCA, on the latest date indicated or three years after the employment start

date under the LCA, whichever comes first; or

(2) In the case of an E–3 LCA, on the latest date indicated or two years after the employment start date under the LCA, whichever comes first.

(b) * * *

(2) Requests for withdrawals must be in writing and must be sent to ETA, Office of Foreign Labor Certification. ETA will publish the mailing address, and any future mailing address changes, in the **Federal Register**, and will also post the address on the DOL Web site at *http://www.foreignlaborcert.doleta.gov.*

* * * * *

11. Amend § 655.760(b) by removing the phrase ''H–1B1 nonimmigrants'' and adding in lieu thereof the phrase ''regarding H–1B1 and E–3 nonimmigrants.''

12. Revise the heading of subpart I to read as follows:

Subpart I—Enforcement of H–1B Labor Condition Applications and H–1B1 and E–3 Labor Attestations

Signed in Washington, DC, this 3rd day of January, 2007.

Emily Stover DeRocco,

Assistant Secretary, Employment and Training Administration, Labor.

Paul DeCamp,

Administrator, Wage and Hour Division, Employment Standards Administration, Labor.

[FR Doc. 07–44 Filed 1–11–07; 8:45 am]

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H.R. 6345/P.L. 109–473

To make a conforming amendment to the Federal Deposit Insurance Act with respect to examinations of certain insured depository institutions, and for other purposes. (Jan. 11, 2007; 120 Stat. 3561)

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